

NON-INTERVENTIONAL (NI)/LOW-INTERVENTIONAL STUDY TYPE 1 (LIS1)

STUDY REPORT

Study Information

Title	INO-TRANSIT: – INO tuzumab T reatment R etrospective A nalysis for N avigating tran S ITION to CD19 CAR- T . Real-world (RWD) treatment patterns and clinical outcomes in patients with relapsed/refractory (R/R) B-cell acute lymphoblastic leukaemia (ALL) treated with inotuzumab-ozogamicin (InO) as bridge to chimeric antigen receptor T-cell (CAR-T) therapy in Spain, the United Kingdom (UK) and the United States (US).
Protocol number	B1931044
Version identifier of the study report	1.0
Date	23 April 2026
EU Post Authorization Study (PAS) register number	EUPAS1000000118
Active substance	Inotuzumab ozogamicin (InO)
Medicinal product	Inotuzumab ozogamicin [Besponsa®]
Research question and objectives	What are the demographics, clinical characteristics, treatment patterns and outcomes of R/R ALL patients treated with InO as a bridging therapy to CD19-directed CAR-T therapy in the RWD? This research question will be addressed through the following research objectives: • (Primary objective) To describe the demographics and clinical characteristics of R/R ALL patients treated with InO as a bridging therapy to CAR-T • (Secondary objective) To describe relevant treatment effectiveness outcomes for the study population, including response to treatment, time-to-next salvage treatment and

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	survival (Secondary objective) To describe InO treatment patterns in the study population, including the use of InO in combination or monotherapy, timing of treatment and dosage information
Country(-ies) of study	United Kingdom (UK) United States of America (US) Spain
Author	Redacted Adelphi Group Limited t/a Adelphi Real World, Adelphi Mill, 5th Floor, Grimshaw Lane, Bollington, Cheshire, SK10 5JB Redacted

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Appendix 3.1. List of Investigators by Country

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1. ABSTRACT (STAND-ALONE DOCUMENT)

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2. LIST OF ABBREVIATIONS

Abbreviation	Definition
ALL	Acute Lymphoblastic Leukaemia (Note: Not limited to B-cell ALL)
AEMPS	Agencia Española de Medicamentos y Productos Sanitarios
B-ALL	B-cell Acute Lymphoblastic Leukaemia
BMI	Body Mass Index
CAR-T	Chimeric Antigen Receptor T-Cell
95% CI	95% Confidence Intervals
CIBMTR	Centre for International Blood and Marrow Transplant Research
CIOMS	Council for International Organizations of Medical Sciences
CNS	Central Nervous System
CR	Complete Response/ Remission
CRh	Complete Response / Remission with Partial Haematologic recovery
CRi	Complete Response / Remission with Incomplete Hematologic Recovery
CRO	Clinical Research Organization
DMP	Data Management Plan
EC	Ethics Committee
ECOG	Eastern Cooperative Oncology Group
eCRF	Electronic Case Report Form
EDC	Electronic Data Capture

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EFS	Event Free Survival
EMA	European Medicines Agency
EMR	Electronic Medical Records
ENCePP	European Network of Centres for Pharmacoepidemiology and Pharmacovigilance
FDA	US Food and Drug Administration
GDPR	General Data Protection Regulation
GPP	Good Pharmacoepidemiology Practices
HCP	Healthcare Provider
HIPAA	Health Insurance Portability and Accountability Act
HITECH	Health Information Technology for Economic and Clinical Health Act
HP SCT	Hematopoietic stem cell transplant
InO	Inotuzumab ozogamicin
IRB	Institutional review board
ISPOR	International Society for Pharmacoeconomics and Outcomes Research
IQR	Inter-quartile Range
KM	Kaplan-Meier (KM)
MRD	Minimal Residual Disease
OS	Overall Survival
PASS	Post-Authorisation Safety Study
R/R	Relapsed or Refractory
RFS	Relapse-Free/Recurrence-Free Survival
SAP	Statistical Analysis Plan

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SCT	Stem Cell Transplant
SDs	Standard Deviations
SEs	Standard Errors
SFTP	Secure File Transfer Protocol
TTNT	Time to Next Treatment
UK	United Kingdom
US	United States
VOD	Veno-Occlusive Disease
YRR	Your Reporting Responsibilities

3. INVESTIGATORS

The names, affiliations, and contact information of the investigators at each study site are listed in Appendix 3.1.

Principal Investigator(s) of the Protocol

Name, degree(s)	Title	Affiliation
Stephanie Nicole Dorman, PhD	Global Medical Strategy Director	Pfizer Canada
Alexander Russell- Smith, MSc, BA	Senior Director, Global HTA, Value and Evidence	Pfizer UK
Neil Reynolds, PhD	Observational Research Director	ARW
Ivana Rajkovic- Potjewyd, PhD	Senior Research Manager	ARW
Hannah Wallis, MSc	Associate Observational Research Manager	ARW
Mona Amet, MPH, BSc	Senior Research Executive	ARW

Lead Country Investigator(s) of the Protocol

Name, degree(s)	Title	Affiliation
Susana Pulido	Senior Medical Advisor	Pfizer Spain
Annie Fang	Clinical Scientist Oncology, Medical Evidence Generation	Pfizer US
Wei Jiang	US Medical Director	Pfizer US
Emma Reeves	Oncology Senior Medical Affairs Advisor	Pfizer UK
Salam Youssef	Oncology Senior Medical Affairs Advisor	Pfizer UK
Dr Ryan Cassaday	KOL Study Advisor	Fred Hutchinson Cancer Center, Seattle, US
Professor David Marks	KOL Study Advisor	N/A
Dr. Anna Castleton	KOL Study Advisor	The Christie NHS Foundation Trust, UK
Dr. Valentin Ortiz- Maldonado	KOL Study Advisor	Hospital Clínic de Barcelona, Spain

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4. OTHER RESPONSIBLE PARTIES

Responsible Party Name and Affiliation	Role in the Study
Redacted	Data Analysis

5. MILESTONES

Milestone	Planned Date	Actual Date	Comments
Date of independent ethics committee (IEC) or institutional review board (IRB) approval of protocol The IEC/IRB approval dates for the protocol and any amendments is provided in Appendix 3.2.	UK: September 2024 US: September 2024 Spain: September 2024	UK:10 September 2024 US: 13 November 2024 Spain: 30 September 2024	Ethics approval was sought from three independent ethics boards.
Start of data collection	16 December 2024	16 December 2024	The first patient in date across all sites.
End of data collection	16 June 2025	9 June 2025	The last patient in date across all sites.
Registration in the HMA-EMA Catalogues of RWD Studies	16 April 2024	First registration approved on: 24 May 2024. Protocol amendment approved in the HMA-EMA Catalogues of RWD Studies on: 10 March 2025	Delay in protocol finalization
Final report of study results	31 August 2025	TBC	SAP amendment was required

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Milestone	Planned Date	Actual Date	Comments
			following first round of feedback received on first report draft

6. RATIONALE AND BACKGROUND

Treatment of adult acute lymphoblastic leukaemia (ALL) typically consists of induction, consolidation and maintenance phases, with central nervous system (CNS) prophylaxis given throughout (1). Although 85-90% of patients achieve remission after induction, a subset remain refractory to initial treatment, and the majority of patients that do achieve complete remission (CR) eventually relapse (2). Options for salvage therapy for relapsed/refractory (R/R) disease include cytotoxic chemotherapy, reformulated single-agent chemotherapy (eg, clofarabine) and novel targets agents. Estimated remission rates for conventional cytotoxic agents are around 30%; though responses are typically short lived (3). Inotuzumab ozogamicin (InO), a CD22-targeted antibody drug conjugate, has been shown to produce substantial improvement in terms of response rates and attainment of minimal residual disease (MRD)-negativity (3).

InO was approved for use in Europe and the United States (US) in 2017 (4, 5) following promising results from the Phase III, INO-VATE trial, demonstrating improved CR, duration of remission and MRD negativity with InO vs standard-of-care chemotherapy in R/R ALL (all types of ALL) patients (6). More recently, the clinical development and market authorisation of CD19-directed chimeric antigen receptor T-cell (CAR-T) therapies has offered an additional salvage treatment option in adult R/R ALL patients (7). The ELIANA trial that led to the approval of tisagenlecleucel CAR-T cell therapy in R/R ALL (all types) excluded patients who had received prior CD19 targeted therapy. Furthermore, InO was not approved during this time and consequently there is limited published evidence regarding InO prior to or as a bridge to CD19 directed CAR-T cell therapy (8). Although it is clear that having <5% blasts at CAR-T infusion is associated with better outcomes, it is evident from existing literature that there is current uncertainty regarding the role of InO as a bridging therapy for CAR-T cell treatment. The pivotal phase 2 results of ZUMA-3 (9), an international, multicentre, single-arm, open-label study evaluated the efficacy and safety of the autologous anti-CD19 CAR-T therapy brexucabtagene autoleucel (KTE-X19) in adult patients with R/R B-cell ALL. The study revealed KTE-X19 showed a high rate of CR or CR with incomplete hematological recovery (CRi) in adult patients with R/R B-cell ALL. The median overall survival (OS) was not reached in responding patients, and the safety profile was manageable. These findings indicate that KTE-X19 has the potential to confer long-term clinical benefit to adult patients with R/R CD19 positive B-cell precursor acute lymphoblastic leukaemia (B-ALL). The study included patients with prior InO exposure, however sample size was small (n=12) and InO was not used as bridging therapy. Despite not having data for the use of InO as a bridge to KTE-X19 in ZUMA-3, there is a growing interest in using InO in this setting (10). In a retrospective multicentre analysis of 189 patients with R/R ALL treated with brexu-cel where over half of the patients received InO prior to brexu-cel (InO exposed), it was found that although InO exposure was associated with inferior survival outcomes after brexu-cel in unadjusted analyses, these associations were no longer significant in multivariate analyses, suggesting it is unlikely that InO negatively affects brexu-cel efficacy(11, 12). In the FELIX Phase Ib/II study, the safety and efficacy of obecabtagene autoleucel was evaluated in adult patients with R/R ALL. The results found bridging therapies with InO were effective in reducing disease burden prior to obecabtagene autoleucel infusion however there were only a small number of patients who received bridging therapies with InO (n =18/127) compared to those who received bridging therapies without InO (n=100/127) therefore further studies comparing bridging therapies with InO-containing therapies or chemotherapy are warranted(13). Due to the current paucity and lack of conclusive data demonstrating the use and outcomes of anti-CD22 antibody therapy i.e.



InO prior to or as a bridging therapy to CAR-T in ALL (all types) adult patients, particularly in the real-world setting, Pfizer conducted a non-interventional, retrospective chart review study (without any comparator group) to understand and describe the patient demographics, treatment patterns and clinical outcomes associated with InO when used as a bridging therapy prior to CD19 directed CAR-T cell treatment.

This non-interventional study was designated as a Post-Authorization Safety Study (PASS) by the Pfizer internal team, and is conducted voluntarily.

7. RESEARCH QUESTION AND OBJECTIVES

What are the demographics, clinical characteristics, treatment patterns and outcomes of R/R B-ALL patients treated with InO as a bridging therapy to CD19-directed CAR-T therapy in the RWD? This research question will be addressed through the following research objectives:

7.1 Primary Objective

- (Primary objective) To describe the demographics and clinical characteristics of R/R ALL patients treated with InO as a bridging therapy for CAR-T

7.2 Secondary Objectives

- (Secondary objective) To describe relevant treatment effectiveness outcomes for the study population, including response to treatment, time-to-next salvage treatment and survival
- (Secondary objective) To describe InO treatment patterns in the study population, including the use of InO in combination or monotherapy, timing of treatment and dosage information

8. AMENDMENTS AND UPDATES

Table 1. Amendments to the Protocol

Amendment Number	Date	Substantial or Administrative Amendment	Protocol Section(s) Changed	Summary of Amendment	Reason
2.0	09 May 2025	Administrative	Title page	Addition of the study sponsor's address based in US headquarters	Address was incorrect location based in Canada
2.0	09 May 2025	Administrative	Title page	Co-author details updated to Neil Reynold's details	Change in Director from Tom Bailey to Neil Reynolds
2.0	09 May 2025	Administrative	Title page	Title section updated	Titles combined from title page and abstract
2.0	09 May 2025	Administrative	Title page	Countries added	Countries to be included in study specified for completion
2.0	09 May 2025	Administrative	Section 1: Table of contents	Table of contents updated	Update required due to changes in rest of document
2.0	09 May 2025	Administrative	Section 2: List of Abbreviations	List of abbreviations table updated and where appropriate body of protocol	Some abbreviations were missing, others were not mentioned in body of protocol
2.0	09 May 2025	Administrative	Section 3: Responsible parties	Redacted [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED]	Change in current involved parties
2.0	09 May 2025	Substantial	Section 4: Abstract	Title update Study sample size updated Milestone dates updated	Titles combined from title page and abstract Ethics Committee (EC) requested sample size be updated to reflect that stated in Section 9.5

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					Dates updated as requested by Pfizer team to reflect current timelines
2.0	09 May 2025	Administrative	Section 6: Milestones	Milestones planned dates updated Additional text added regarding data collection	Milestones dates updated as requested by Pfizer team to reflect current timelines Additional text added requested by EC in Spain
2.0	09 May 2025	Administrative	Section 7: Rationale and Background	Text deleted	Duplication of text thus deleted
2.0	09 May 2025	Substantial	Section 9.3.2: Exclusion Criteria	Wording amended	Amended for clarity
2.0	09 May 2025	Administrative	Section 9.9	Wording added regarding data limitation	Data limitation described as requested by statistician
2.0	09 May 2025	Administrative	Section 10.1	Wording amended regarding personal data	Amended for clarity
2.0	09 May 2025	Administrative	Section 10.3: IRB/EC	Deletion of text regarding AEMPS	As requested by EC in Spain advising this text is now redundant as AEMPS classification is no longer required
2.0	09 May 2025	Administrative	Section 10.4: Ethical conduct of study	Addition of wording regarding ethical conduct of study, referencing the Declaration of Helsinki and Spanish Royal Decree	As requested by EC in Spain
2.0	09 May 2025	Administrative	Section 11.1: Human review of unstructured data	Addition of wording regarding AE reporting	As requested by EC in Spain
2.0	09 May 2025	Administrative	Section 12: Plans for disseminating and	Addition of study end definition	Definition requested by UK EC

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			communicating study results		
2.0	09 May 2025	Administrative	Annex 2: ENCEPP checklist for study protocols	Title amendment	Title from title page and abstract combined
2.0	09 May 2025	Administrative	Annex 3: Additional information	Addition of site names for sites in Spain, US and UK Addition of investigator names for sites in Spain	As requested by EC in Spain

9. RESEARCH METHODS

9.1. Study Design

All assessments described in the protocol for this study were performed as part of normal clinical practice or standard practice guidelines for the patient population and healthcare provider (HCP) specialty in the countries where this NIS was conducted.

The study was managed by Adelphi Real World, acting as the Clinical Research Organization (CRO) in collaboration with Pfizer. The protocol and study methods were reviewed by ethics committees in the United Kingdom (UK), United States (US) and Spain to ensure scientific and clinical merit. Prior to the ethics committee reviews, the protocol and study materials were also reviewed by senior clinicians consulting for Pfizer. Waivers of patient consent were applied for and received from supervising ethics committees in each of the three countries.

The following study was designed to address the lack of conclusive data demonstrating the use and outcomes of anti-CD22 antibody therapy as a bridging therapy to CAR-T in R/R B-ALL adult patients, particularly in the real-world setting. As a result of the rarity of the disease and limited patient numbers, Pfizer conducted an international, site-led (12 sites) non-interventional, retrospective chart review study (without any comparator group), assessing the characteristics and clinical outcomes of R/R B-ALL patients who received InO as a bridging therapy to CAR-T. A multi-country study was designed to gain sufficient sample size to address the research objectives described in Section 7.

Sites were based in the US, UK and Spain and were responsible for identifying eligible patients, electronic data abstraction and data query resolution. Clinicians and site staff abstracted data from adult R/R B-ALL eligible patients' medical records with index defined as those initiating InO treatment as a bridge to CAR-T (even if CAR-T was not administered) from index date 01 June 2017 and enter the required datapoints within an electronic data capture (EDC) system. Baseline patient demographics and clinical and molecular characteristics were evaluated at index whereas treatment patterns and effectiveness outcomes were described throughout the follow-up period. Patients included were required to have a minimum follow-up of 3 months defined as patients with 3 months of data following the first dose of InO to database extraction (patients who had died within 3-months of InO administration were considered eligible for inclusion).

The study aimed to assess the demographics and clinical and molecular characteristics of patients, as a primary objective. The study also aimed to describe treatment effectiveness and treatment patterns as secondary objectives. See Section 9.3 for a breakdown of the specific variables of interest. Details of the study period are shown in [Figure 1](#).

***Permitted exceptions to the minimum 3-month follow-up requirement include:**

- Patients who die within the 3 months
- Patients who proceed to a CD19 CAR-T clinical trial within the 3 months

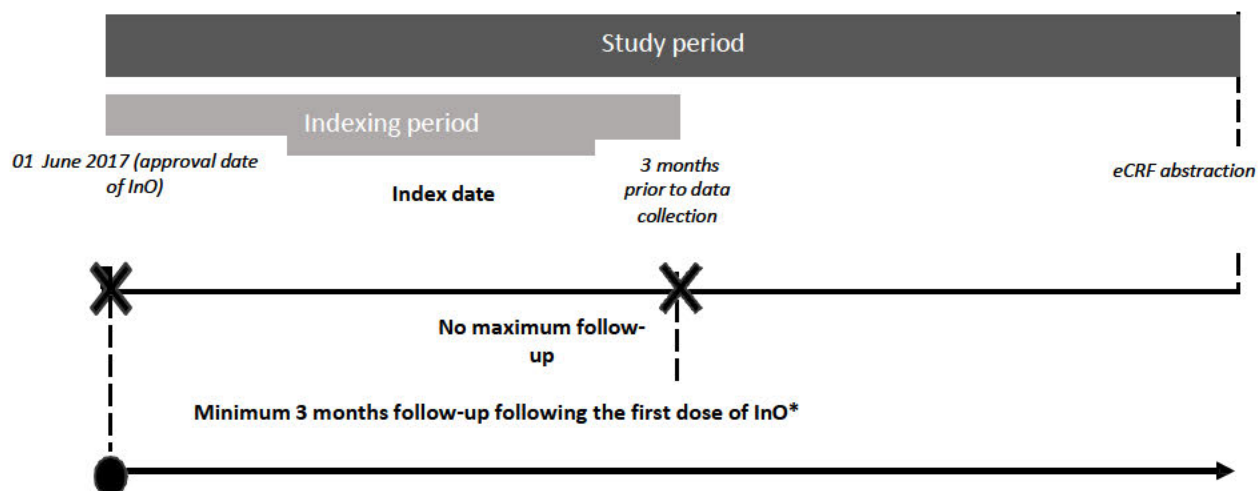


Figure 1: Study Schematic, eCRF Design

Abbreviations: eCRF = electronic Case Report Form; InO = Inotuzumab Ozogamicin.

9.2. Setting

The study focused on R/R B-ALL patients aged 18 years and above initiating InO treatment as a bridge to CD19-directed CAR-T from index date 01 June 2017 (first InO approval) in sites based in UK, US and Spain, using the inclusion and exclusion criteria specified below. The indexing period was defined as those initiating InO treatment as a bridge to CAR-T from the index date (01 June 2017) to data collection. The indexing period was selected to allow for a large proportion of patients treated with InO prior to CAR-T in these countries/sites to be gathered, following US Food and Drug Administration (FDA) and EMA approval of InO in 2017, and FDA CAR-T approval from 2017 (tisagenleclel received FDA approval in August 2017 and received EMA approval in August 2018 for patients up to 25 years of age, brexucabtagene autoleucl received FDA approval in October 2021 and received EMA approval in December 2020 for adults (18 years and older) and obecabtagene autoleucl received FDA approval in November 2024 and received EMA approval in July 2025 for adults). No formal sampling was conducted in any country. Sites selected for chart review methodology completed data collection for all eligible patients.

Potential sites participating in the retrospective chart review were invited to complete a short feasibility questionnaire prior to site selection. The feasibility questionnaire was used to confirm suitability of sites for inclusion, confirming study critical information such as InO patient caseload and data availability. Additionally, logistical information pertaining to site contracting and IRB processes were also assessed. A number of sites across the three countries were already assessed to provisionally confirm feasibility. Following completion of the feasibility phase of the study, approval of the sites by Pfizer and the subsequent contracting and formal greenlighting once set-up activities for selected sites were completed, electronic case report forms (eCRFs) were completed by clinicians and site staff at the sites for patients meeting the inclusion/exclusion criteria below.



Patients aged 18 years or older at the start of InO therapy with a clinical diagnosis of R/R B-ALL were identified within the sites using the inclusion and exclusion criteria specified below. There were minimal inclusion/exclusion criteria (Section 9.3.1 and 9.3.2) in order to maximise the number of InO-treated patients eligible for this study. Patients were required to have data available for a minimum of 3 months data from the first dose of InO, with permitted exceptions being patients who died within the 3 months and patients who proceeded to a CD19 CAR-T clinical trial within the 3 months, to capture data relating to effectiveness outcomes (e.g., time to next treatment, survival).

Each centre (except for those in the US) was expected to capture a (relatively) large proportion of InO-treated patients who may have been using InO as a bridging therapy to CAR-T in that country, hence their selection. Not all centres used InO as a bridging therapy to CAR-T, however, therefore knowledge of where InO was used as a bridging therapy to CAR-T also informed site selection. The UK, US and Spain centres were selected as they met the feasibility requirements (capture the relevant data variables) and due to the number and completeness of InO patients' medical records they hold.

R/R B-ALL diagnosis was captured within the screening questions of the eCRF and fully defined within the Statistical Analysis Plan (SAP). Baseline patient demographics and clinical and molecular characteristics were evaluated at index whereas treatment patterns and effectiveness outcomes were described throughout the follow-up period. Patients had a minimum follow-up of 3 months defined as patients with 3 months of data following the first dose of InO with permitted exceptions mentioned previously. This allowed for assessment of treatment patterns and early effectiveness outcomes. Follow-up ended with the following endpoints; death, loss of data (e.g., transfer to a new hospital) or end of the study period. Patients who were alive at the point of data capture using date of eCRF completion OR date the patient was lost to follow-up were right-censored for the purpose of survival outcome specific analysis. Patients who died within the 3-month follow-up period were considered eligible for inclusion in order to evaluate OS outcomes.

9.3. Subjects

9.3.1. Inclusion Criteria

Patients had to meet all the following inclusion criteria to be eligible for inclusion in the study:

1. Patient had a clinical diagnosis of R/R B-ALL
2. Patient was aged 18 years or older at start of InO therapy
3. Patient received InO treatment as a bridge to CD19-directed CAR-T cell therapy (was defined as either patient received InO immediately prior to apheresis, and/or patient received InO after apheresis and before CAR-T cell infusion. In either case, InO was used with the aim of preventing uncontrolled disease progression and facilitating successful progression to CAR-T cell therapy. Such patients were eligible to be included even if CAR-T was not ultimately administered from index date (01 June 2017))

4. Patients with data points available for a minimum of 3 months data from the first dose of InO were eligible for inclusion within the study. Permitted exceptions to the minimum 3-month follow-up requirement included:

- a. Patients who died within the 3 months
- b. Patients who proceeded to a CD19 CAR-T clinical trial within the 3 months

9.3.2. Exclusion Criteria

There were no exclusion criteria for this study.

9.4. Variables

The eCRF captured all data variables of interest therefore allowing research objectives to be addressed. Final variables can be found within the SAP (please also see tables below). The sites were selected following feasibility assessments, whereby the presence of the variables below were assessed within the data captured. Where 'bridging InO' is stated, this refers to InO prescribed as a bridge to CAR-T therapy.

Table 2: Screener

Variable	Role	Data Source(s)	Operational Definition	Time-Point
Has this patient been diagnosed with R/R B-cell ALL?	To determine eligibility for study	eCRF	R/R (B-cell precursor) ALL diagnosis	R/R (B-cell precursor) ALL diagnosis
Patient's age (or one categorical response if aged ≥90)	To determine eligibility for study	eCRF	Patients age at InO 1st dose	1st dose of InO (index)
Did the patient initiate InO treatment 01 June 2017 onwards as a bridging therapy to intended CAR-T?	To determine eligibility for study	eCRF	InO bridging initiation date	1st dose of InO (index)

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Variable	Role	Data Source(s)	Operational Definition	Time-Point
Is the patient currently alive?	To determine eligibility for study	eCRF	Patient's vital status	Anytime up to/including data collection
Does the patient have at least 3 months' follow up data from the first dose of InO to the date of last assessment? <i>Note: Patients who die within the 3 months or proceed to a CD19 CART clinical trial are eligible for inclusion within the study</i>	To determine eligibility for study	eCRF	Follow up status	1st dose of InO (index) to date of last assessment
Has the patient received at least one dose of InO bridging to CAR-T therapy and then completed CAR-T therapy (if they could receive it)?	To determine eligibility for study	eCRF	InO bridging therapy status	Anytime up to/including data collection

Abbreviations: ALL = Acute Lymphoblastic Leukaemia; CAR-T = Chimeric Antigen Receptor T-Cell; eCRF = Electronic Case Report Form; InO = Inotuzumab Ozogamicin; R/R= Relapsed/Refractory

Table 3: Patient Demographics

Variable	Role	Data Source(s)	Operational Definition	Time-Point
Patient's biological sex	Primary objective	eCRF	Patient's biological sex	N/A

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Variable	Role	Data Source(s)	Operational Definition	Time-Point
Patient's race/ethnicity	Primary objective	eCRF	Patient's race/ethnicity	N/A
Patient Hispanic/Latin/Spanish origin	Primary objective	eCRF	Origin	N/A
Patient's BMI	Primary objective	eCRF	Patient's BMI at index	1st dose of InO (index)
Date of patient's death (if applicable)	Primary objective	eCRF	Time since death	Anytime up to/including data collection
Primary cause of patient's death (if applicable)	Primary objective	eCRF	Primary cause of death	Anytime up to/including data collection
Is the patient actively being monitored or have they been lost to follow up	Primary objective	eCRF	Patient lost to follow up	Anytime up to/including data collection
Last date of activity for this patient (if lost to follow up)	Primary objective	eCRF	Time since last date of activity/ time since lost to follow up	Anytime up to/including data collection

Abbreviations: BMI = Body Mass Index; eCRF = Electronic Case Report Form; InO = Inotuzumab Ozogamicin; N/A = Not Applicable

Table 4: Clinical Characteristics

Variable	Role	Data Source(s)	Operational Definition	Time-Point
How many times has the patient received salvage therapy?	Primary objective	eCRF	Total number of salvage therapies received	Anytime up to/including data collection
On what date the patient received salvage therapy	Primary objective	eCRF	Date of each salvage therapy	Anytime up to/including data collection

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Variable	Role	Data Source(s)	Operational Definition	Time-Point
Was the patient relapsed or refractory on receipt of this salvage therapy	Primary objective	eCRF	Relapse or refractory specification for each salvage therapy	Anytime up to/including data collection
Duration of first remission following their ALL diagnosis before they relapsed (≥ 12 months or < 12 months)	Primary objective	eCRF	First remission duration	Since ALL diagnosis before relapse
Risk group of ALL based on cytogenetic findings including: Philadelphia chromosome status, and cytogenetic, molecular and EMR positive	Primary objective	eCRF	Risk group of ALL at initial diagnosis	Initial ALL diagnosis, 1st dose of InO (index)
ALL genetic alterations	Primary objective	eCRF	ALL genetic alterations at initial diagnosis	Initial ALL diagnosis, 1st dose of InO (index)
Laboratory test results	Primary objective	eCRF	Laboratory tests conducted at index	1st dose of InO (index), After the last dose of InO prior to planned CAR-T infusion
Concomitant conditions	Primary objective	eCRF	Concomitant conditions present at index	1st dose of InO (index)
ECOG performance status	Primary objective	eCRF	ECOG performance status at index	1st dose of InO (index)

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Variable	Role	Data Source(s)	Operational Definition	Time-Point
Patient diagnosed with VOD	Primary objective	eCRF	Presence of VOD at any time	Anytime up to/including data collection
How was the patient diagnosed with VOD?	Primary objective	eCRF	VOD diagnosis	Anytime up to/including data collection
Did the patient receive defibrotide to manage their VOD?	Primary objective	eCRF	Defibrotide received	Anytime up to/including data collection
Most severe grade of VOD patient diagnosed with	Primary objective	eCRF	VOD grade at index	Anytime up to/including data collection
Bilirubin measured at most severe VOD diagnosis	Primary objective	eCRF	Measurement of bilirubin at most severe VOD diagnosis	Anytime up to/including data collection
Bilirubin level at most severe VOD diagnosis	Primary objective	eCRF	Level of bilirubin at VOD diagnosis Anytime up t	Anytime up to/including data collection
Platelet count measured at most severe VOD diagnosis	Primary objective	eCRF	Platelet count at VOD diagnosis	Anytime up to/including data collection
Platelet count at most severe VOD diagnosis	Primary objective	eCRF	Platelet count result at VOD diagnosis	Anytime up to/including data collection
Diagnosis of neutropenic sepsis	Primary objective	eCRF	Diagnosis of neutropenic sepsis	Anytime up to/including data collection
Risk factors for VOD	Primary objective	eCRF	Presence of risk factors for VOD at index	1st dose of InO (index), Last dose of InO, At CAR-T apheresis, At CAR-T infusion

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Variable	Role	Data Source(s)	Operational Definition	Time-Point
EMD	Primary objective	eCRF	Presence of EMD at R/R ALL diagnosis	At R/R ALL diagnosis
Is the patient's EMD bulky (definition: presence of a nodal mass with a maximal dimension of >10 cm, or mediastinal mass >1/3 maximum transverse diameter of the chest)	Primary objective	eCRF	Bulky EMD at R/R ALL diagnosis	At R/R ALL diagnosis
Sites of EMD	Primary objective	eCRF	Location of EMD at R/R ALL diagnosis	At R/R ALL diagnosis
CNS disease	Primary objective	eCRF	Presence of CNS disease at R/R ALL diagnosis	At R/R ALL diagnosis
CNS disease status	Primary objective	eCRF	CNS disease status at R/R ALL diagnosis	At R/R ALL diagnosis

Abbreviations: ALL= Acute Lymphoblastic Leukaemia; CAR-T = Chimeric Antigen Receptor T-Cell; CNS = Central Nervous System; eCRF = Electronic Case Report Form; ECOG = Eastern Cooperative Oncology Group; EMD = Extramedullary Disease; InO = Inotuzumab Ozogamicin; R/R = Relapsed/ Refractory; VOD = Veno-Occlusive Disease

Table 5: Patient Treatments and Clinical Outcomes prior to CAR-T Treatment

Variable	Role	Data Source(s)	Operational Definition	Time-Point
Is the patient currently participating in a clinical trial other than a CD19 CAR-T trial?	Secondary objective 2	eCRF	Current clinical trial participation	At time of data collection

Variable	Role	Data Source(s)	Operational Definition	Time-Point
Treatments received	Secondary objective 2	eCRF	Treatments prior to bridging InO	Prior to bridging InO
At what date did this patient receive blinatumomab?	Secondary objective 2	eCRF	Date received (Blinatumomab)	Prior to bridging InO
Did the patient receive Blinatumomab for MRD conversion, R/R disease, frontline treatment or another reason?	Secondary objective 2	eCRF	Reason for Blinatumomab treatment	Prior to bridging InO
Was the patient refractory to blinatumomab?	Secondary objective 2	eCRF	Was the patient refractory to Blinatumomab treatment	Prior to bridging InO
At what date did this patient receive InO prior to bridging InO	Secondary objective 2	eCRF	Date received (InO)	Prior to bridging InO
Total cumulative dose (mg/m ²) of InO received?	Secondary objective 2	eCRF	Total cumulative dose (InO)	Prior to bridging InO
At what date did this patient receive HSCT?	Secondary objective 2	eCRF	Initiation of therapy (HSCT)	Prior to bridging InO
What was the patient's response to HSCT?	Secondary objective 2	eCRF	Response HSCT	Prior to bridging InO
Has the patient been treated with InO as a bridge to HSCT prior to bridging InO	Secondary objective 2	eCRF	InO bridge to HSCT	Prior to bridging InO
Use of InO as a bridge to CAR-T				
Number of cycles of InO treatment received	Secondary objective 2	eCRF	Total number of InO cycles received to date	Bridging InO received

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Variable	Role	Data Source(s)	Operational Definition	Time-Point
Did the patient receive bridging InO as an inpatient or outpatient?	Secondary objective 2	eCRF	InO bridging as inpatient/outpatient	Bridging InO received
Date of InO initiation (day 1 first dose for cycle 1)	Secondary objective 2	eCRF	Date of InO initiation	Bridging InO received
Number of doses of InO (show per cycle)	Secondary objective 2	eCRF	Number of InO doses per cycle	Bridging InO received
Dose of InO treatment (mg/m ² , show per dose per cycle)	Secondary objective 2	eCRF	Dose of InO per dose per cycle	Bridging InO received
Patients' best response after InO treatment (show for first and last cycle)	Secondary objective 1	eCRF	Best response after InO 1st and last cycle	Bridging InO received
Patients' ECOG performance status at InO treatment response evaluation (show at last cycle)	Secondary objective 1	eCRF	ECOG status after last cycle	Bridging InO received
Whether MRD was assessed following InO treatment (show at first and last InO cycle)	Secondary objective 1	eCRF	MRD assessment conducted per InO after 1st and last cycle	Bridging InO received
Date of MRD assessment following InO treatment (show for first and last InO cycle)	Secondary objective 1	eCRF	Date of MRD assessment per InO after 1st and last cycle (if assessed)	Bridging InO received
Method used to assess MRD after InO treatment (show for first and last InO cycle)	Secondary objective 2	eCRF	Method used to assess MRD after InO 1st and last cycle	Bridging InO received

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Variable	Role	Data Source(s)	Operational Definition	Time-Point
Result of MRD analysis after InO treatment (show for first and last InO cycle)	Secondary objective 1	eCRF	Result of MRD test after InO 1st and last cycle	Bridging InO received
Was InO prescribed in combination with chemotherapy, monotherapy and/or another combination agent e.g. TKI? (show for first and last InO cycle)	Secondary objective 2	eCRF	Prescription of chemotherapy/monotherapy/other combination agent alongside InO treatment (1st and last cycle)	Bridging InO received
Type of combination agent prescribed in combination with InO treatment (show for first and last InO cycle)	Secondary objective 2	eCRF	Combination agent type (1st and last cycle)	Bridging InO received
Dose of combination agent prescribed in combination with InO treatment (show for first and last InO cycle)	Secondary objective 2	eCRF	Dose of combination agent (1st and last cycle)	Bridging InO received
Date final dose of InO received	Secondary objectives 1 & 2	eCRF	InO final dose	Bridging InO received

Abbreviations: ALL= Acute Lymphoblastic Leukaemia; CAR-T = Chimeric Antigen Receptor T-Cell; eCRF = Electronic Case Report Form; ECOG = Eastern Cooperative Oncology Group; HSCT = Haematopoietic Stem Cell Transplant; InO = Inotuzumab Ozogamicin; MRD = Minimal Residual Disease; R/R = Relapsed/ Refractory; TKI = Tyrosine Kinase Inhibitor

Table 6: Patient Treatments and Clinical Outcomes during CAR-T Treatment

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Variable	Role	Data Source(s)	Operational Definition	Time-Point
Next step after bridging InO	Secondary objective 2	eCRF	Next step in treatment	Post bridging InO
Did the patient receive CAR-T as part of a clinical trial	Secondary objective 2	eCRF	Clinical trial involvement	Post bridging InO
Start date of next treatment	Secondary objectives 1 & 2s	eCRF	Start date of next treatment	Post bridging InO
Next treatment ongoing or discontinued	Secondary objective 1	eCRF	Ongoing/discontinuation of next treatment	Post bridging InO
Date of discontinuation of next treatment	Secondary objective 1	eCRF	End date of next treatment	Post bridging InO
Patients' best response to next treatment	Secondary objective 1	eCRF	Response to next treatment	Post bridging InO
Time from last dose of InO to CAR-T infusion	Secondary objective 2	eCRF	Time from last InO dose to CAR-T infusion	InO last dose to CAR-T infusion
Number of leukaphereses needed	Secondary objective 2	eCRF	Number of leukaphereses required for CAR-T	CAR-T apheresis
Date of leukapheresis	Secondary objective 2	eCRF	Date of leukapheresis for CAR-T	CAR-T apheresis
Was leukapheresis successful?	Secondary objective 2	eCRF	Leukapheresis success	CAR-T apheresis
Number of T-cells obtained (CAR-T)	Secondary objective 2	eCRF	T-cell number	CAR-T apheresis
Date of commencement of lymphodepletion	Secondary objective 2	eCRF	Date of lymphodepletion for CAR-T	CAR-T received post bridging InO

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Variable	Role	Data Source(s)	Operational Definition	Time-Point
Date of initiation of CAR-T cell infusion	Secondary objective 2	eCRF	Date of initiation of infusion for CAR-T	CAR-T infusion
Number of CAR-T cells administered in infusion (per kg of patient)	Secondary objective 2	eCRF	Number of CAR-T cells in infusion	CAR-T infusion
Most recently measured bone marrow blast count	Secondary objective 2	eCRF	Most recent bone marrow blast count (CAR-T infusion)	CAR-T infusion
MRD status	Secondary objective 2	eCRF	MRD status at CAR-T infusion	CAR-T infusion
EMD	Secondary objective 2	eCRF	Presence of EMD at CAR-T infusion	CAR-T infusion
Location of EMD	Secondary objective 2	eCRF	Location of EMD at CAR-T infusion	CAR-T infusion
CNS disease	Secondary objective 1	eCRF	Presence of CNS disease at CAR-T infusion	CAR-T infusion
Disease status (salvage 1 etc.)	Secondary objective 1	eCRF	Disease status at CAR-T infusion	CAR-T infusion
Type of CAR-T prescribed	Secondary objective 2	eCRF	Type of CAR-T prescribed	CAR-T received post bridging InO
B-cell recovery after CAR-T infusion	Secondary objective 1	eCRF	B-cell recovery post CAR-T infusion	CAR-T received post bridging InO
Duration of B-cell recovery (start & end dates captured)	Secondary objective 1	eCRF	B-cell recovery (duration (start & end date))	CAR-T received post bridging InO

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Variable	Role	Data Source(s)	Operational Definition	Time-Point
Patients' response to CAR-T after 1 month	Secondary objective 1	eCRF	Response to CAR-T (1 month)	CAR-T received post bridging InO
Patients' response to CAR-T after 3 months	Secondary objective 1	eCRF	Response to CAR-T (3 months)	CAR-T received post bridging InO
Patients' response to CAR-T after 6 months	Secondary objective 1	eCRF	Response to CAR-T (6 months)	CAR-T received post bridging InO
Patients' response to CAR-T after 12 months	Secondary objective 1	eCRF	Response to CAR-T (12 months)	CAR-T received post bridging InO
Most recent bone marrow blast count	Secondary objective 2	eCRF	Most recent bone marrow blast count post CAR-T therapy	Post CAR-T

Abbreviations: CAR-T = Chimeric Antigen Receptor T-Cell; CNS = ; eCRF = Electronic Case Report Form; EMD = Extramedullary Disease; InO = Inotuzumab Ozogamicin; Kg = Kilogram; MRD = Minimal Residual Disease

Table 7: Patient Treatments and Clinical Outcomes after CAR-T Treatment

Variable	Role	Data Source(s)	Operational Definition	Time-Point
Total number of treatment lines (i.e., number of salvage lines) received for ALL after CAR-T therapy	Secondary objectives 1 & 2	eCRF	Treatment lines received for ALL post CAR-T	Post CAR-T
Treatments or procedures received for ALL	Secondary objective 2	eCRF	Type of treatments/procedures received for ALL post CAR-T	Post CAR-T

Variable	Role	Data Source(s)	Operational Definition	Time-Point
Time to next treatment received (start date captured)	Secondary objective 2	eCRF	Time to next ALL treatment received post CAR-T	Post CAR-T
Number of HSCTs received	Secondary objective 2	eCRF	Total number of HSCTs received	Post CAR-T
Dates HSCTs received	Secondary objective 2	eCRF	Dates HSCTs received	Post CAR-T
Was MRD assessed before this patient's HSCT?	Secondary objective 1	eCRF	MRD assessment carried out before HSCT	Post CAR-T
Date of the MRD assessment before this patient's HSCT	Secondary objective 1	eCRF	Date of this MRD assessment	Post CAR-T
Method(s) used to assess MRD before this patient's HSCT	Secondary objectives 1 & 2	eCRF	Methods used to assess MRD	Post CAR-T
Result of the MRD analysis before this patient's HSCT	Secondary objective 1	eCRF	Result of MRD analysis	Post CAR-T
Patient's response to HSCT	Secondary objective 1	eCRF	Response to SCT	Post CAR-T
Patient diagnosed with GvHD following any of their HSCT(s)	Secondary objective 1	eCRF	Presence of GvHD following HSCT(s)	Post CAR-T
What type of GvHD was the patient diagnosed with following any of their HSCT(s)	Secondary objective 1	eCRF	GvHD classification following HSCT(s)	Post CAR-T

Abbreviations: ALL = Acute Lymphoblastic Leukaemia; CAR-T = Chimeric Antigen Receptor T-Cell; eCRF = Electronic Case Report Form; GvHD = Graft versus-Host Disease; HSCT = Haematopoietic Stem Cell Transplant; MRD = Minimal Residual Disease

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9.5. Data Sources and Measurement

9.5.1. UK, US and Spain Centres

For UK, US and Spain centres, an eCRF (Appendix 5. Sample Case Report Form CRF) was used by HCPs at study sites (who would routinely have access to those patients' medical records in their day to day role) to abstract data for patients who met the eligibility criteria outlined in Section 9.3.1 and Section 9.3.2. Data was collected in this way for all variables outlined in Section 9.4.

Each eligible site was required to complete a short screener for each patient to confirm their eligibility for the retrospective chart review, prior to abstracting data from electronic medical records (EMR) into the eCRF. Sites were instructed to refer to the patient's complete EMR whilst completing the eCRF and not to answer any question from memory or to include data not listed within the patients' EMR. Prior to site activation, all staff abstracting data attended remote Site Initiation calls where they were trained to abstract the data using a validated, standardised process. There was a full audit trail for each data entry point within the eCRF. Each individual eCRF was reviewed by at least two members of the Adelphi study team to check for logical and medical consistency. Queries were raised throughout the data management process and were only closed following the satisfactory correction or explanation by each site. Following the review and sign-off (following agreement on any initial disagreements) of each eCRF by at least two members of the Adelphi study team, the eCRF was locked and was not accessible for further data entry or changes.

Once the data were extracted, they were stored in a secure study database. Further details around the data management can be found in Section 9.8. No systematic review or meta-analysis was conducted as this was not within the scope of the study.

9.6. Bias

For the chart review, selection bias may have influenced the sample; site participation was influenced by willingness to take part, and may be based on workload, levels of consulting patients during the data collection period, or familiarity with the research nature of the study. It should also be noted that the sites that were eligible for inclusion in the study are those with whom Pfizer has existing relationships, and those ultimately selected for inclusion were deemed most suitable based on the feasibility assessment stage (i.e., those sites with higher numbers of patients or who are most suited to executed non-interventional data collection studies). These factors introduce a bias whereby patients from non-participating sites are not represented in the results. Nonetheless, this method of site selection was the most practical approach for a non-interventional study such as this, whereby resources and timelines, to some extent, dictate the sites that can be considered eligible for inclusion. The retrospective, non-interventional nature of the study meant that site participation was resource-dependent and could not be randomized. This bias could not be avoided.

The securing of waivers for informed consent helps to prevent the provision of consent from being a biasing factor, for example, patients who were particularly unwell or who had died without providing consent might have been unwilling/unable to consent which could have biased the living sample of patients towards those with a more positive prognosis. Since data were abstracted directly from medical records, this avoided reliance on patient memory, which may have been affected by disease burden or cognitive impairment.



Counts for missing data were reported for all variables and sites, ensuring missing data that could have caused bias was documented.

This retrospective chart review did not employ blinded determination of exposure or outcome, as the nature of the study design (secondary analysis of existing EMR data) and the need for site staff to abstract specific clinical variables made blinding impractical. However, to minimize information bias, the following measures were employed:

- Data abstractors were instructed to extract data objectively from documented EMR sources without clinical interpretation
- Independent dual review of all eCRFs by two study team members (without knowledge of the other reviewer's findings until independent review was complete) provided a form of adjudication to reduce individual reviewer bias
- Standardized eCRF instructions minimized subjective interpretation of data

Efforts were made, as described above, to minimize bias. In terms of assessing/addressing bias (eg, matching, adjudication) was not conducted as the study focused on descriptive analysis and objectives focused analysis. However, the results, e.g. patient demographics, were discussed in the context of published real-world data in the discussion Section 11.

9.7. Study Size

This study was purely descriptive and there was no limit on the sample size in terms of patients meeting the eligibility criteria in Section 9.3. The estimated number of patients based on the feasibility was expected to be n=79 and the final sample size was n=84.

9.8. Data Transformation

Detailed methodology for data transformations, particularly complex transformations (e.g., many raw variables used to derive an analytic variable), are documented in the SAP, which is dated, filed and maintained by the Sponsor (Appendix 4).

9.9. Statistical Methods

This study was non-comparative, descriptive in nature and included no hypothesis testing. Further details on analysis were documented in the SAP, see [Appendix 4. STATISTICAL ANALYSIS PLAN](#).

9.9.1. Main Summary Measures

Frequencies and percentages were reported for categorical variables, including the percentage of missing/unknown data, while counts, number of missing, means, medians, standard deviations (SDs), standard errors (SEs), first and third quartiles, minimum and maximum values were reported for continuous numeric variables (as detailed below). Where applicable, all estimates were described with accompanying 95% confidence intervals (CI).

- Sample size (counts)
- Number of missing/unknowns

- Mean, standard deviation
- Median, interquartile range (IQR)
- Minimum and maximum values

9.9.2. Main Statistical Methods

For time to event survival analyses only, Kaplan-Meier (KM) curves were developed with 95% CIs of the median estimated. Where median survival was not reached as <50% of patients achieve survival failure, KM curves and survival functions were still reported, but the absence of median survival is flagged.

9.9.3. Missing Values

All analyses were conducted on the full analysis set of patients. Where missing values were found in particular variables, these were reported as the number of patients with a missing data point. The counts of patients with missing data for each endpoint will be summarized. In cases where there are extreme levels of missing data or where the volume of missing data was differential between important clinical/prognostic groups, no imputation was carried out and patients with such missing data were excluded from the relevant outcome analyses.

9.9.4. Sensitivity Analyses

None.

9.9.5. Amendments to the Statistical Analysis Plan

The SAP was amended to include Section 4.7.5. Post-hoc analyses which contains subgroup analysis and additional variables..

9.10. Quality Control

Data from the eCRF was stored in the study database. The database was housed and managed by ARW during the study and analysis. Any data transfers to Pfizer were aggregated and carried out via a Secure File Transfer Protocol (SFTP) to ensure any international transfers are safeguarded. ARW's data server is based within the UK. Following completion of the study, the study database will be archived and subsequently permanently deleted, in accordance with ARW's and Pfizer's Master Services Agreement.

Version control was used during the development of all data collection materials to ensure there is an auditable record of requested updates and changes is available.

The eCRF data was captured within a password-protected, CFR Part 11 compliant EDC platform. The eCRF included data logic checks programmed within the forms as per the sponsor approved CRF design. In addition, each individual eCRF was reviewed by at least two members of the project team (who had completed internal data management training and followed the relevant Data Management SOP) to check for completeness, logical and medical consistency. Queries were raised throughout the data management process and were only closed following the satisfactory correction or explanation by each site. All queries were logged within the EDC as part of the audit trail, the Programming and Data Management Log and were also recorded within the Data Management Plan (DMP), therefore the quantity of queries raised and resolved was logged. The DMP describes the

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data checks that were conducted. Following the review, agreement and sign-off of each eCRF by at least two members of the project team, the eCRF was locked and was not accessible for further data entry or changes. Source Data Verification (SDV) was not conducted as this was not within the scope of the study, however the data management process described above was sufficient to verify data accuracy and completeness. Therefore, the readability or quality of original EMR records was not assessed.

When all checks were completed to the satisfaction of the Senior Project Manager, the database was considered complete, and the database was locked. This formally announced that there was no intention to make any further changes to the data and that data analysis could proceed. A database lock declaration section within the DMP was completed by the Project Manager and the document was kept in the study file. The locked database was saved into a folder with restricted access. A copy of the locked database was made available to the analyst.

All data analysis was conducted using Stata software, version 18 or the latest available version (StataCorp, College Station, Texas) (14).

9.11. Protection of Human Subjects

Subject information and consent

Not Applicable.

Independent Ethics Committee (IEC)/Institutional Review Board (IRB)

The Final Protocol, any amendments, and informed consent documentation were reviewed and approved by a IRB(s) and/or IEC(s) for each site participating in the study. (See Appendix 2 for the Final Protocol).

The Final Protocol, any amendments, and informed consent documentation were reviewed and approved by a local data protection agency for each site participating in the study.

A waiver of patient consent was applied for and granted by RECs/IRBs in Spain, UK and US.

Ethical conduct of the study

The study was conducted in compliance with the Declaration of Helsinki and the Spanish Royal Decree 957/2020, which regulates observational studies with medicines for human use. The study was conducted in accordance with legal and regulatory requirements, as well as with scientific purpose, value and rigor and followed generally accepted research practices described in:

- Guidelines for Good Pharmacoepidemiology Practices (GPP). Public Policy Committee, International Society of Pharmacoepidemiology. Pharmacoepidemiology and Drug Safety 2016; 25:2-10.
- Good Practices for Outcomes Research issued by the International Society for Pharmacoepidemiology and Outcomes Research (ISPOR)
- Good practices for real-world data studies of treatment and/or comparative

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effectiveness: Recommendations from the joint ISPOR-ISPE Special Task Force on real-world evidence in health care decision making

- International Ethical Guidelines for Epidemiological Studies issued by the Council for International Organizations of Medical Sciences (CIOMS)
- EMA European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) Guide on Methodological Standards in Pharmacoepidemiology
- The ENCePP Code of Conduct for scientific independence and transparency in the conduct of pharmacoepidemiological and pharmacovigilance studies
- FDA Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment
- FDA Guidance for Industry and FDA Staff: Best Practices for Conducting and Reporting Pharmacoepidemiologic Safety Studies Using Electronic Healthcare Data
- FDA Guidance for Industry: Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labelling Claims
<http://www.fda.gov/downloads/Drugs/Guidances/UCM193282.pdf>.

10. RESULTS

10.1. Participants

There was no limit on the sample size in terms of patients meeting the eligibility criteria. In total, 84 patients' data were included in the study. Please see breakdown in **Table 8** below.

Table 8: Study Subjects at each Stage of the Study

Site Number	Site Name	Country	Potentially Eligible Subjects from Site Feasibility Questionnaires	First Patient In (Start of Data Collection)	Entered Eligible Subjects	Screen Failures (if Applicable)	Last Patient In	Completed Subjects that Were Analysed
1	Hospital Gregorio Marañón	Spain	4	21/01/2025	5	0	27/05/2025	5
2	Hospital Vall d'Hebron	Spain	6-10	27/01/2025	10	1	18/05/2025	10
3	Hospital Virgen del Rocío	Spain	5	24/03/2025	6	0	09/06/2025	6
4	Hospital Universitario de Salamanca	Spain	2-3	04/02/2025	11	0	09/06/2025	11

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5	Hospital Clinic de Barcelona	Spain	Approximately 26	24/03/2025	16	0	06/06/2025	16
6	The Royal Marsden NHS Foundation Trust	UK	4	11/04/2025	3	0	25/04/2025	3
7	University Hospitals Birmingham NHS Foundation Trust	UK	5	19/12/2024	7	0	9/06/2025	7
8	University Hospital Southampton NHS Foundation Trust	UK	2	10/04/2025	3	0	29/05/2025	3
9	The Christie NHS Foundation Trust	UK	2-3	16/12/2024	7	2	1/05/2025	7
10	The Medical College of Wisconsin, Inc, Wisconsin	US	2-3	08/02/2025	6	0	9/06/2025	6
11	University of Washington, Seattle	US	Approximately 3-5	28/04/2025	5	2	17/05/2025	5
12	University of Colorado, Colorado	US	4	21/04/2025	5	0	12/05/2025	5

10.2. Descriptive Data

The EDC had CRFs for 84 patients collected from the 12 sites between the index date of 01 June 2017 and 09 June 2025 that met the inclusion criteria outlined in Section 9.3.1.

Demographic data is presented under the Primary Objective below.

10.3. Outcome Data

All patient data (n=84) was used for each objective.

10.4. Main Results

10.4.1. Primary Objective: To Describe the Demographics and Clinical Characteristics of R/R ALL Patients Treated with InO as a Bridging Therapy for CAR-T.

Overall, of the 84 patients analyzed the median (IQR) age was 40.0 (24.0, 59.0) years (minimum age was 18.0, maximum age was 76.0), 78.6% were White and 57.1% were male (see Table 9 below). Of the 149 individual salvage therapies recorded across the 84 patients, patient status at receipt of salvage therapy was reported as relapsed disease for 73.2% (n=109) and refractory for 25.5% (n=38) (see Table 9 Table 11 below). 20.2% of patients had extramedullary disease at their R/R B-ALL diagnosis. (see Table 10 below)

At index, 14.3% of patients were Philadelphia chromosome (Ph) positive, 44.0% were Ph negative, 6.0% were Ph-like and 25.0% of patients had other cytogenetic abnormalities (see Table 11 below). Median (IQR) bone marrow blast (BMB) count at index was 62.5% (n=48) (18.0%, 89.5%) (see Table 12 below). Median (IQR) BMB count after last dose of InO was 2.0% (n=47) (0.0%, 41.0%), and 66.0% (n=47) of patients had a BMB <5% (see Table 13).

Over half of the patients were alive at the time of data collection (56.0%, n=47/84) (see Table 9 below). Where patients were no longer alive the eCRF requested sites to select one of four options regarding the primary cause of death (see Table 9 below). Of those who died (41.7%, n=35/84), ALL disease progression was responsible in 82.9% (n=29/35) of patients while 11.4% (n=4/35) were reported to have died due to ALL treatment-related causes (see Table 9 below).

Veno-occlusive disease (VOD) was diagnosed in 7.1% of patients at any point during their ALL treatment; a further 4.8% had suspected VOD (see Table 14 below). 46.4% of patients were diagnosed with neutropenic sepsis at any point during their diagnosis and treatment (see Table 15 below).

Table 9: Primary Objective 1 - Patient Demographics

All patients	Total
Country	
n	84
Spain	48 (57.1%)
UK	20 (23.8%)
US	16 (19.0%)
Follow-up (days)	
n	84
Mean	488.5
Standard deviation	390.7
Standard error of the mean	42.63
Median	381.42
Interquartile range (IQR)	203.12, 703.78
Range	14, 1738.70
95% CI	403.7, 573.3

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Follow-up (months)	
n	84
Mean	16.1
Standard deviation	12.8
Standard error of the mean	1.40
Median	12.54
Interquartile range (IQR)	6.68, 23.14
Range	.46, 57.16
95% CI	13.3, 18.8
SQ3b - Patient age	
n	84
Mean	42.6
Standard deviation	18.8
Standard error of the mean	2.05
Median	40.
Interquartile range (IQR)	24, 59
Range	18, 76
95% CI	38.5, 46.7
SQ3b - Patient age on the date of first dose of InO (years), banded	
n	84
18-45	46 (54.8%)
46-65	23 (27.4%)
66-89	15 (17.9%)
AQ1 - Patient biological sex	
n	84
Female	36 (42.9%)
Male	48 (57.1%)
AQ2 - Patient Race/ethnicity*	
n	84
White	66 (78.6%)
Black or African or Caribbean or African American	2 (2.4%)
East or Southeast Asian	1 (1.2%)
South Asian (Indian subcontinent)	2 (2.4%)
Other	10 (11.9%)
Not known	4 (4.8%)
AQ3 - Patient of Hispanic, Latin or Spanish origin (Note: Question only shown to US sites)	
n	16
Yes	6 (37.5%)
No	10 (62.5%)
AQ4 - Patient BMI at index (initiation of InO), (Kg/m2)	
n	71
Mean	25.1

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Standard deviation	5.8
Standard error of the mean	0.69
Median	23.5
Interquartile range (IQR)	21, 27.7
Range	16.02, 41.1
95% CI	23.7, 26.5
AQ4 - Patient BMI at index (initiation of InO) (Kg/m2), banded	
n	84
(18.5, 25)	34 (40.5%)
(25, 30)	22 (26.2%)
30+	15 (17.9%)
Unknown	13 (15.5%)
SQ4 - Patient currently	
n	84
Alive	47 (56.0%)
Deceased	35 (41.7%)
Not known	2 (2.4%)
AQ5b - Patient primary cause of death	
n	35
As a direct cause of their ALL disease (i.e. death due to ALL disease progression)	29 (82.9%)
As an indirect cause of their ALL disease (i.e. non-relapsed mortality (treatment related))	4 (11.4%)
Another reason not related to their ALL disease	1 (2.9%)
Other	1 (2.9%)
AQ6a - Patient being actively monitored or lost to follow up	
n	47
Actively monitored	47 (100.0%)

* HCPs could select multiple response options

Abbreviations: ALL; Acute Lymphoblastic Leukaemia, BMI; Body Mass Index, 95% CI; 95% Confidence Intervals, InO; Inotuzumab-Ozogamicin, Interquartile range; IQR, UK; United Kingdom, US; United States.

Table 10: Primary Objective 1 - Patient Status at Receipt of Salvage Therapy and Diagnosis of Extramedullary Disease

BQ1b - Salvage therapies	Total
BQ1bii - Patient status at receipt of salvage therapy	
n	149
Relapsed	109 (73.2%)
Refractory	38 (25.5%)
Unknown	2 (1.3%)
BQ11a - Patient diagnosed with extramedullary disease at their R/R ALL diagnosis	
n	84
Yes	17 (20.2%)

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No	67 (79.8%)
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Abbreviations: ALL; Acute Lymphoblastic Leukaemia, R/R; Relapsed or Refractory

Table 11: Primary Objective 1 - Patient Risk Group at Index

BQ2b - Patient risk group at Index (initiation of InO)*	
n	84
Philadelphia chromosome negative	37 (44.0%)
B-cell ALL with amplification of a portion of chromosome 21	1 (1.2%)
BCR-ABL1-like ALL	5 (6.0%)
Other risk group not mentioned here	11 (13.1%)
None of the above	5 (6.0%)
Philadelphia chromosome positive	12 (14.3%)
B-cell ALL with hypodiploidy	3 (3.6%)
B-cell ALL with hyperdiploidy	3 (3.6%)
B-cell ALL with a translocation between chromosome 11 and another chromosome	7 (8.3%)
B-cell ALL with a translocation between chromosomes 12 and 21	1 (1.2%)
B-cell ALL with a translocation between chromosomes 1 and 19	6 (7.1%)
B-cell ALL with a translocation between chromosomes 9 and 22	1 (1.2%)
Not known/not recorded	2 (2.4%)

Abbreviations: ALL; Acute Lymphoblastic Leukaemia, InO; Inotuzumab-Ozogamicin.

Table 12: Primary Objective 1 - Patient Bone Marrow Blast Count at Index

BQ4b - Patient laboratory test result at index: Bone marrow blast count (%)	
n	48
Mean	55.4
Standard deviation	34.3
Standard error of the mean	4.95
Median	62.5
Interquartile range (IQR)	18, 89.5
Range	.0012, 99
95% CI	45.5, 65.4

Abbreviations: 95% CI; 95% Confidence Intervals, Interquartile range; IQR.

Table 13: Primary Objective 1 - Patient Bone Marrow Blast Count after Last Dose of InO Prior to Planned CAR-T Infusion

BQ5b - Patient laboratory test result after last dose of InO prior to planned CAR-T infusion: Bone marrow blast count (%)	
n	47
Mean	19.7
Standard deviation	30.5
Standard error of the mean	4.45
Median	2.
Interquartile range (IQR)	0, 41

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Range	0, 96
95% CI	10.7, 28.6
BQ5b - Patient laboratory test result after last dose of InO prior to planned CAR-T infusion: Bone marrow blast count (%)	
n	47
<5%	31 (66.0%)
>5%	16 (34.0%)

Abbreviations: CAR-T; Chimeric Antigen Receptor T-Cell, InO; Inotuzumab-Ozogamicin, IQR; Interquartile range, 95% CI: 95% Confidence Intervals.

Table 14: Primary Objective 1 - Patient VOD Diagnosis

BQ8a - Patient diagnosed with veno-occlusive disease (VOD) at any time (up to and including point of data collection) during their ALL diagnosis and treatment	
n	84
Yes	6 (7.1%)
No	74 (88.1%)
Only suspected VOD	4 (4.8%)

Abbreviations: ALL; Acute Lymphoblastic Leukaemia, VOD; Veno-occlusive Disease.

Table 15: Primary Objective 1 - Patient Neutropenic Sepsis Diagnosis

BQ9 - Patient diagnosed with neutropenic sepsis at any time (up to and including data collection) during their ALL diagnosis and treatment	
n	84
Yes	39 (46.4%)
No	40 (47.6%)
Not known	5 (6.0%)

Abbreviations: ALL; Acute Lymphoblastic Leukaemia.

10.4.2. Secondary Objective 1: To Describe Relevant Treatment Effectiveness Outcomes for the Study Population, Including Response to Treatment, Time-to-Next Salvage Treatment and Overall Survival (OS).

Upon InO completion, 46.5% of patients achieved CR, CR with partial haematologic recovery (CRh) or CR with incomplete haematologic recovery (CRi) (see Table 16 below). 26.2% of patients were refractory to InO and 9.5% had progressive disease (see Table 16 below). Of those assessed (n=65), 41.5% (n=27) tested negative for minimal residual disease (MRD) after their first and 43.1% (n=28) after their last cycle of InO (see Table 16Table 16 below).

Table 16: Secondary Objective 1 - Patient's Best Response and Result of MRD Analysis

All patients	Cycle of InO	
CQ3e - Patient's best response	After first cycle of bridging InO	After last cycle of bridging InO
n	84	84
Complete remission (CR)	26 (31.0%)	29 (34.5%)
CR with partial haematologic recovery (CRh)	3 (3.6%)	5 (6.0%)

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CR with incomplete hematologic recovery (CRi)	7 (8.3%)	5 (6.0%)
Morphologic leukaemia-free state (MLFS)	4 (4.8%)	4 (4.8%)
Refractory disease	23 (27.4%)	22 (26.2%)
Progressive disease (PD)	6 (7.1%)	8 (9.5%)
Relapsed disease	4 (4.8%)	3 (3.6%)
Uncertain response	4 (4.8%)	3 (3.6%)
Not applicable	6 (7.1%)	3 (3.6%)
Unknown	1 (1.2%)	1 (1.2%)
Not known/Not recorded	0 (0.0%)	1 (1.2%)
CQ3gv - Result of MRD analysis		
n	65	65
Positive	37 (56.9%)	35 (53.8%)
Negative	27 (41.5%)	28 (43.1%)
Not known/Not recorded	1 (1.5%)	2 (3.1%)

Abbreviations: CR; Complete Response/Remission, CRh; CR with partial haematologic recovery, CRi; CR with incomplete hematologic recovery, InO; Inotuzumab-Ozogamicin, MLFS; Morphologic leukaemia-free state, PD; Progressive Disease.

Overall, 76.7% (n=56/73) of patients achieved CR/CRh/CRi after CAR-T or another therapy. A further 6.8% (n=5) had refractory disease and 6.8% (n=5) had progressive disease (see Table 17 below)

Table 17: Secondary Objective 1 - Patient's Best Response to the Next Line of Treatment after InO Was Received as a Bridge to CAR-T

Patients who received CAR-T or another therapy	Total
DQ2d - Patient's best response to the next line of treatment after InO was received as a bridge to CAR-T	
n	73
Complete remission (CR)	50 (68.5%)
CR with partial haematologic recovery (CRh)	2 (2.7%)
CR with incomplete hematologic recovery (CRi)	4 (5.5%)
Morphologic leukaemia-free state (MLFS)	3 (4.1%)
Aplastic marrow	1 (1.4%)
Refractory disease	5 (6.8%)
Progressive disease (PD)	5 (6.8%)
Relapsed disease	3 (4.1%)

Abbreviations: CR; Complete Response/Remission, CRh; CR with partial haematologic recovery, CRi; CR with incomplete hematologic recovery, InO; Inotuzumab-Ozogamicin, MLFS; Morphologic leukaemia-free state, PD; Progressive Disease.

At 6 months follow-up post CAR-T infusion, 68.8% (n=44/64) of patients remained in CR and an estimated 87.9% of patients survived. After infusion, 35.9% (n=23/64) of patients had B-cell recovery with 14.1% (9/64) not known (see Table 18 below). At 12 months follow-up post CAR-T infusion, an estimated 72.5% patients survived and 62.4% had not initiated another salvage therapy. Median OS was not reached during the study observation period (see Table 20 and Table 21 below). Regarding OS from index to death in people

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who received InO pre-apheresis, at 6 months 93.1% survived and at 12 months 81.5% survived. Regarding OS from index to death in people who received InO post-apheresis, at 6 months 96.9% survived and at 12 months 72.0% survived. Regarding OS from CAR-T infusion to death in people who received InO pre-apheresis, at 6 months 85.5% survived and at 12 months 76.2% survived. Regarding OS from CAR-T infusion to death in people who received InO post-apheresis, at 12 months 67.1% survived.

Please see

, [Figure 3](#) and [Figure 4](#) Kaplan Meier curves below.

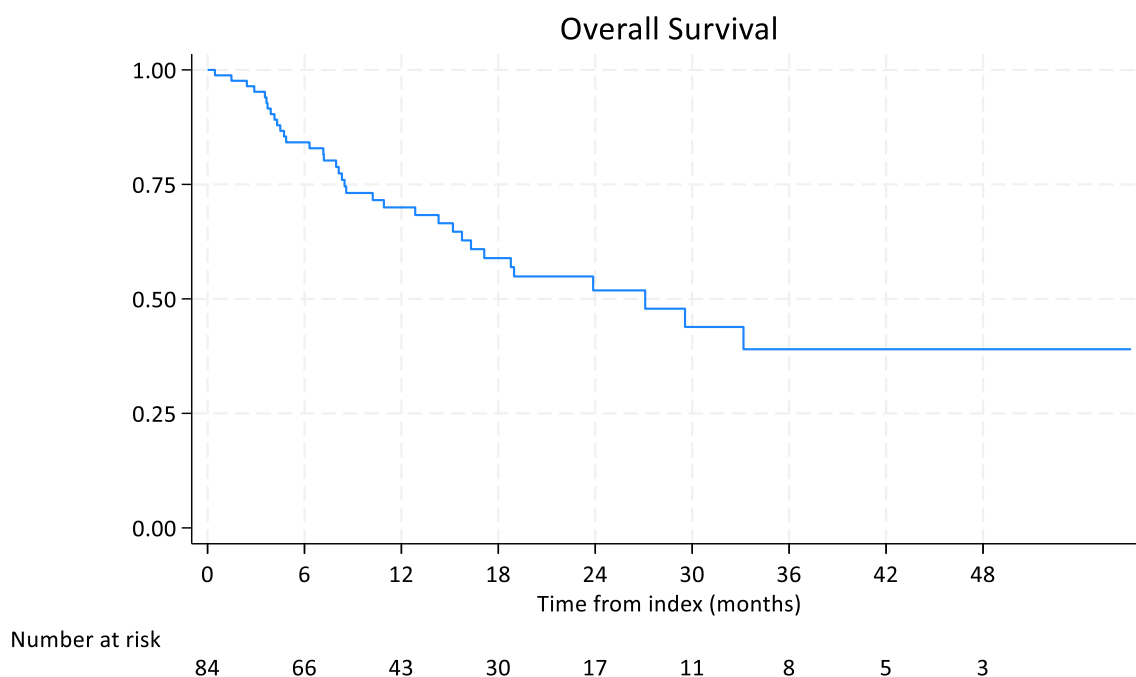


Figure 2: Overall Survival (OS) (from Index to Death)

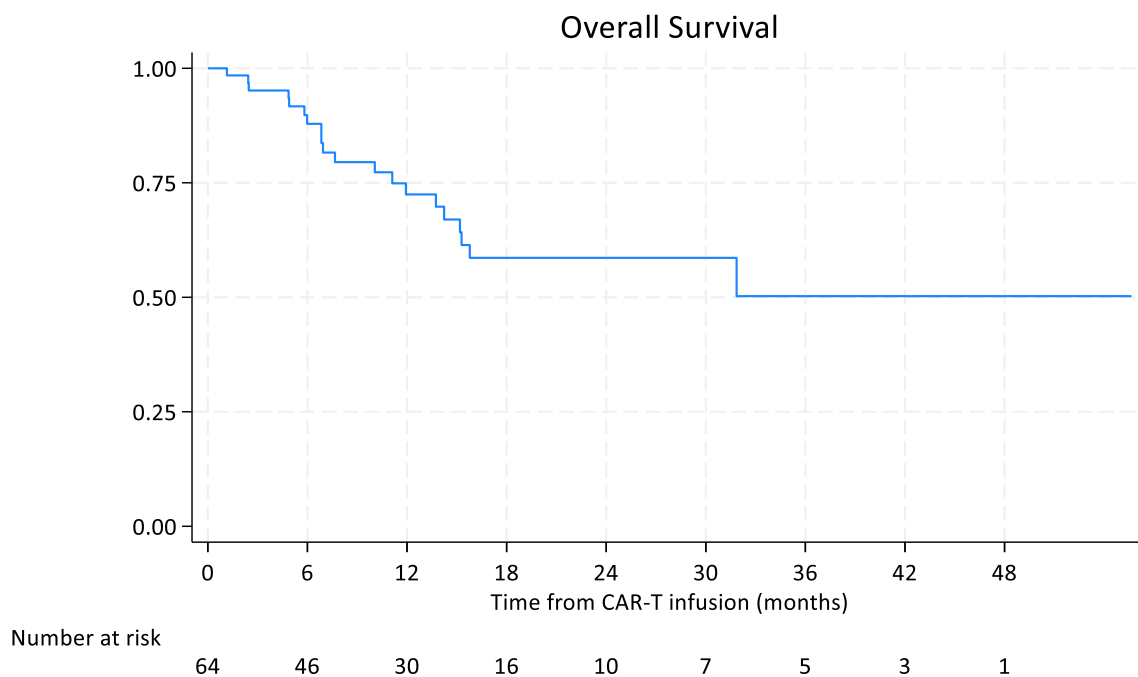


Figure 3: Overall Survival (OS) (from CAR-T Infusion to Death)

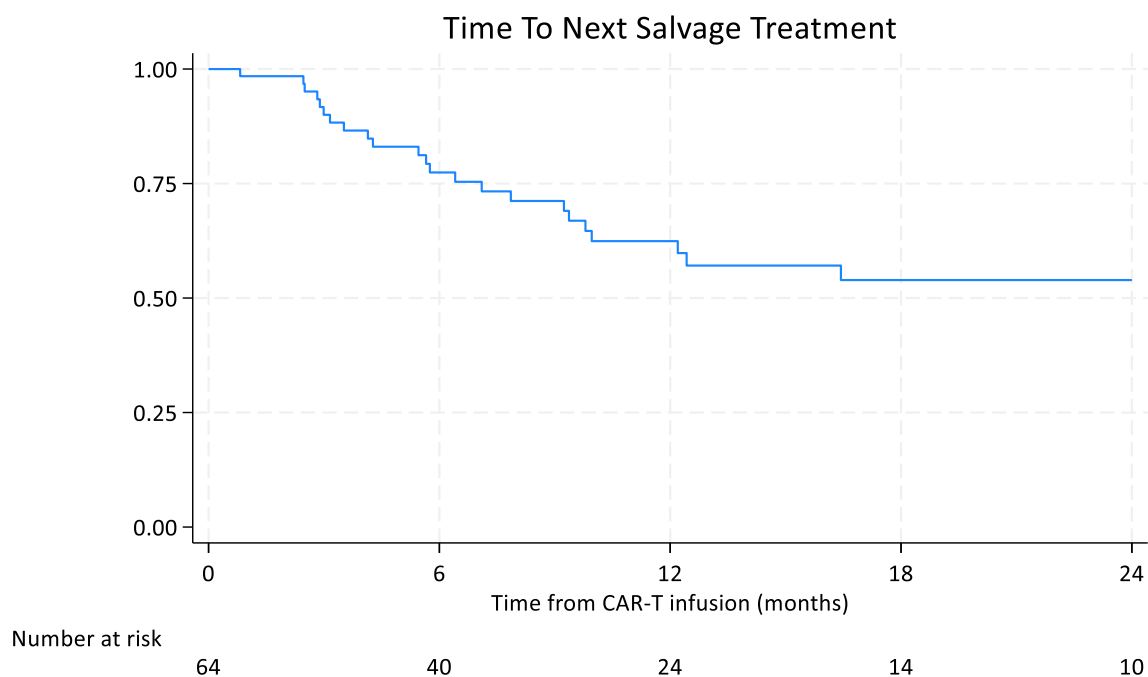


Figure 4: Time-to-Next Salvage Treatment (from CAR-T Infusion)

Table 18: Secondary Objective 1 - Patient Experience B-Cell Recovery after CAR-T Infusion

DQ11a - Patient experience B-cell recovery after CAR-T infusion	
n	64
Yes	23 (35.9%)
No	32 (50.0%)
Not known	9 (14.1%)

Abbreviations: CAR-T; Chimeric Antigen Receptor T-Cell

Table 19: Secondary Objective 1 - Overall Survival (from Index to Death)

Overall Survival (from index to death)	Total	
Number of observations	84	
Number of events	35	95% CIs
Number censored	49	lb
Median	27.0904078	16.30684753
Time points (month)	(%)	
6	84.2%	
12	70.0%	
18	58.9%	
24	51.9%	
30	43.9%	
36	39.0%	

Table 20: Secondary Objective 1 - Overall Survival (from CAR-T Infusion to Death)

Overall Survival (from CAR-T infusion to death)	Total	
Number of observations	64	
Number of events	20	95% CIs
Number censored	44	lb
Median	Not reached	15.18903943
Time points (month)	(%)	
6	87.9%	
12	72.5%	
18	58.6%	
24	58.6%	
30	58.6%	
36	50.2%	

Source: CAR-T Infusion (DQ4a) and Date of death (AQ5a)

Abbreviations: CAR-T; Chimeric Antigen Receptor T-Cell, 95% CI; 95% Confidence Intervals

Table 21: Secondary Objective 1 - Time-to-Next Salvage Treatment (from CAR-T Infusion)

Time-to-next Salvage Treatment (from CAR-T infusion)	Total	
Number of observations	64	
Number of events	23	95% CIs
Number censored	41	lb
Median	Not reached	9.961642744
Time points (month)	(%)	
6	77.4%	
12	62.4%	
18	53.9%	
24	53.9%	
30	53.9%	
36	53.9%	

Source: CAR-T Cell Infusion (DQ4a) and Start date of First Treatment Received Post CAR-T (EQ1c)

Abbreviations: CAR-T; Chimeric Antigen Receptor T-Cell, 95% CI; 95% Confidence Intervals

CAR-T treatment details were available for 64 patients. CAR-T was infused as salvage 1 (34.4%, n=22/64), salvage 2 (29.7%, n=19/64) or salvage 3 or later (26.6%, n=17/64) (see Table 22 below).

Table 22: Secondary Objective 1 - Patient Disease Status at CAR-T Infusion

DQ9 - Patient disease status at CAR-T infusion	
n	64
Salvage 1	22 (34.4%)
Salvage 2	19 (29.7%)
Salvage 3 or later	17 (26.6%)
Not known	6 (9.4%)

Abbreviations: CAR-T; Chimeric Antigen Receptor T-Cell,

10.4.3. Secondary Objective 2: To describe InO Treatment Patterns in the Study Population, Including the Use of InO in Combination with Other Therapies (e.g. Vincristine, Dexamethasone, Prednisolone etc., or as a Monotherapy, as Well as the Timing of Treatment and Dosage Information.

CAR-T treatment details were available for 64 patients, as data from those treated within a clinical trial in Spain were not permitted to be included. Median (IQR) TTNT was 35.0 (22.0, 57.0) days, inclusive of CAR-T initiation. Leukapheresis was performed successfully on all patients (n=64); For the next step in treatment after bridging InO was received, 84.5% (n=71/84) received CAR-T infusion, 10.7% (n=9/84) received another therapy and 4.8% (n=4/84) went into palliative care (see Table 23 below).

Table 23: Secondary Objective 2 - Next Step in Treatment after Bridging InO Was Received

All patients	Total
DQ1a - Next step in treatment after bridging InO was received	
n	84
Patient went on to receive CAR-T	71 (84.5%)
Patient received another therapy	9 (10.7%)
Patient went into palliative care	4 (4.8%)

Abbreviations: InO; Inotuzumab-Ozogamicin, CAR-T; Chimeric Antigen Receptor T-Cell.

Prior to index, 35.7% of patients received a HPSC, 31.0% received blinatumomab and 4.8% received InO (see Table 24 below).

Table 24: Secondary Objective 2 - Treatments Received Prior to Bridging InO

CQ2a - Treatments received prior to bridging InO*	
n	84
Vincristine	70 (83.3%)
Methotrexate	56 (66.7%)
Cytarabine	57 (67.9%)
Etoposide	2 (2.4%)
Mercaptopurine	26 (31.0%)
Intrathecal chemotherapy	56 (66.7%)
Radiation therapy	9 (10.7%)
Imatinib	7 (8.3%)
Dasatinib	10 (11.9%)
Ponatinib	8 (9.5%)
Nilotinib	1 (1.2%)
Dexamethasone	58 (69.0%)
Rituximab	4 (4.8%)
Blinatumomab	26 (31.0%)
Inotuzumab ozogamicin (<i>not including InO prescribed as bridge therapy to HPSC or CAR-T</i>)	4 (4.8%)
Hematopoietic stem cell transplant (HPSC)	30 (35.7%)
Other	25 (29.8%)
None of the above	2 (2.4%)
Prednisolone	36 (42.9%)
Methylprednisolone	9 (10.7%)
Hydrocortisone	7 (8.3%)
Doxorubicin	19 (22.6%)
Daunorubicin	42 (50.0%)
Cyclophosphamide	42 (50.0%)

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L-asparaginase	38 (45.2%)
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* HCPs could select multiple response options

Abbreviations: InO; Inotuzumab-Ozogamicin.

All patients underwent at least 1 cycle of InO prior to CAR-T, 21.4% received 2 cycles and 3.6% received ≥ 3 cycles (see Table 25 below). Most patients (73.8%) received InO as a monotherapy. Overall, 45.3% (n=29/64) of patients first received InO prior to apheresis and 54.7% (n=35/64) between apheresis and CAR-T infusion (see Table 26 below).

In total, the median (IQR) cumulative dose of InO over all cycles was 1.8 mg/m² (1.3, 2.5). The median (IQR) cumulative dose of InO over cycle 1 was 1.8 mg/m² (1.3, 1.8). The median (IQR) cumulative dose of InO over cycle 2 was 1.5 mg/m² (1.0, 1.8). The median (IQR) cumulative dose of InO over cycle 3 was 1.1 mg/m² (0.3, 1.8). The median (IQR) cumulative dose of InO over cycle 4 was 1.8 mg/m² (1.8, 1.8).

Table 25: Secondary Objective 2 -Total Number of Cycles of Bridging InO Treatment Patient Received

CQ3a -Total number of cycles of bridging InO treatment patient received	
n	84
1	63 (75.0%)
2	18 (21.4%)
3	1 (1.2%)
4	2 (2.4%)

Abbreviations: InO; Inotuzumab-Ozogamicin.

Table 26: Secondary Objective 2 - Timing of the InO First Dose

CQ3c- Timing of the InO first dose	
n	64
Before leukapheresis	29 (45.3%)
Between leukapheresis and CAR-T infusion	35 (54.7%)

Abbreviations: CAR-T; Chimeric Antigen Receptor T-Cell, InO; Inotuzumab-Ozogamicin

In total, the median (IQR) days between last dose of InO and leukapheresis was -10.5 (-20.0, 14.0).

CAR-T treatment details were available for 64 patients, as data from those treated within a clinical trial in Spain were not permitted to be included. Of these, 29.7% (n=19/64) received Kymriah (tisagenlecleucel), 34.4% (n=22/64) received Tecartus (brexucabtagene autoleucel) and 35.9% (n=23/64) received another CD19-directed CAR-T product (see Table 27 below).

Table 27: Secondary Objective 2 - Type of CAR-T Patient Received

DQ10 - Type of CAR-T prescribed	
n	64
Kymriah	19 (29.7%)

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Tecartus	22 (34.4%)
Other CD19-directed CAR T product	23 (35.9%)

Abbreviations: CAR-T; Chimeric Antigen Receptor T-Cell.



10.5. Other Analyses

All study analyses, including subgroup analyses, are presented below

Overall, the majority of patients (57.14%) were from sites in Spain (please see Table 28 below) reflecting the number of sites and the success of the feasibility exercise in identifying sites with higher qualifying patient numbers.

The mean (SD) follow up days was 488.47 (390.75) (please see Table 28 below).

Table 28: Patient Demographics including Age, Biological Sex, Race/Ethnicity, BMI at Index and Other Parameters including Time to Follow-Up and Primary Cause of Death.

	Overall	MRD status (1st cycle of InO)		MRD status (last cycle of InO)		MRD status (CAR-T infusion)		MRD status (prior to HPST)		BMI at index (initiation of InO)			InO received:	
	Total	Positive	Negative	Positive	Negative	Positive	Negative	Positive	Negative	(18.5, 25)	(25, 30)	30+	Pre-apheresis	Post-apheresis
Country, n (%)														
n	84	37	27	35	28	26	35	3	6	34	22	15	29	34
Spain	48 (57.14%)	23 (62.16%)	18 (66.67%)	21 (60.00%)	19 (67.86%)	12 (46.15%)	19 (54.29%)	0 (0.00%)	4 (66.67%)	21 (61.76%)	13 (59.09%)	5 (33.33%)	19 (65.52%)	12 (35.29%)
UK	20 (23.81%)	8 (21.62%)	4 (14.81%)	7 (20.00%)	4 (14.29%)	8 (30.77%)	8 (22.86%)	2 (66.67%)	1 (16.67%)	5 (14.71%)	6 (27.27%)	5 (33.33%)	2 (6.90%)	16 (47.06%)
US	16 (19.05%)	6 (16.22%)	5 (18.52%)	7 (20.00%)	5 (17.86%)	6 (23.08%)	8 (22.86%)	1 (33.33%)	1 (16.67%)	8 (23.53%)	3 (13.64%)	5 (33.33%)	8 (27.59%)	6 (17.65%)
Follow-up (days)														
n	84	37	27	35	28	26	35	3	6	34	22	15	29	34
Mean	488.47	478.03	573.60	437.76	618.81	451.33	554.37	617.42	693.80	463.08	572.34	453.27	586.27	431.58
Standard deviation	390.75	400.71	410.48	388.41	426.97	345.13	392.32	340.50	302.48	375.79	496.85	294.73	400.94	333.19
Standard error of the mean	42.63	65.88	79.00	65.65	80.69	67.69	66.31	196.59	123.49	64.45	105.93	76.10	74.45	57.14
Median	381.42	364.84	571.00	295.03	574.00	348.42	479.00	452.27	635.88	326.78	464.79	398.50	479.00	326.78
Interquartile	203.11 - 703.78	190.64 - 590.56	242.00 - 725.53	146.79 - 574.66	250.77 - 745.78	253.00 - 574.66	239.53 - 722.06	391.00 - 1009.00	496.00 - 804.68	146.79 - 633.76	219.00 - 605.72	247.00 - 722.06	289.58 - 722.06	219.00 - 602.51

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Range (IQR)														
Range	14.00 - 1738.69	74.00 - 1714.43	140.83 - 1738.69	74.00 - 1714.43	140.83 - 1738.69	85.43 - 1714.43	91.63 - 1464.57	391.00 - 1009.00	364.84 - 1225.52	45.00 - 1444.78	91.63 - 1738.69	113.00 - 1151.68	113.00 - 1464.57	85.43 - 1714.43
95% CI	403.68 - 573.27	344.43 - 611.64	411.22 - 735.98	304.33 - 571.18	453.25 - 784.37	311.93 - 590.73	419.60 - 689.13	-228.41 - 1463.26	376.36 - 1011.24	331.96 - 594.20	352.05 - 792.63	290.06 - 616.49	433.77 - 738.78	315.33 - 547.84
Follow-up (months)														
n	84	37	27	35	28	26	35	3	6	34	22	15	29	34
Mean	16.06	15.72	18.86	14.39	20.34	14.84	18.23	20.30	22.81	15.22	18.82	14.90	19.27	14.19
Standard deviation	12.85	13.17	13.50	12.77	14.04	11.35	12.90	11.19	9.94	12.35	16.33	9.69	13.18	10.95
Standard error of the mean	1.40	2.17	2.60	2.16	2.65	2.23	2.18	6.46	4.06	2.12	3.48	2.50	2.45	1.88
Median	12.54	11.99	18.77	9.70	18.87	11.45	15.75	14.87	20.91	10.74	15.28	13.10	15.75	10.74
Interquartile Range (IQR)	6.68 - 23.14	6.27 - 19.42	7.96 - 23.85	4.83 - 18.89	8.24 - 24.52	8.32 - 18.89	7.87 - 23.74	12.85 - 33.17	16.31 - 26.46	4.83 - 20.84	7.20 - 19.91	8.12 - 23.74	9.52 - 23.74	7.20 - 19.81
Range	0.46 - 57.16	2.43 - 56.36	4.63 - 57.16	2.43 - 56.36	4.63 - 57.16	2.81 - 56.36	3.01 - 48.15	12.85 - 33.17	11.99 - 40.29	1.48 - 47.50	3.01 - 57.16	3.72 - 37.86	3.72 - 48.15	2.81 - 56.36
95% CI	13.27 - 18.85	11.32 - 20.11	13.52 - 24.20	10.01 - 18.78	14.90 - 25.79	10.26 - 19.42	13.80 - 22.66	-7.51 - 48.11	12.37 - 33.25	10.91 - 19.54	11.57 - 26.06	9.54 - 20.27	14.26 - 24.29	10.37 - 18.01
1.3 Please specify the age.														
n	84	37	27	35	28	26	35	3	6	34	22	15	29	34
Mean	42.58	36.97	47.04	40.00	46.14	38.27	44.83	27.00	43.50	45.62	37.32	45.67	51.14	35.74
Standard deviation	18.77	17.19	18.27	17.96	18.43	20.21	18.17	7.81	20.67	21.24	17.73	12.74	17.14	18.04
Standard error of the mean	2.05	2.83	3.52	3.04	3.48	3.96	3.07	4.51	8.44	3.64	3.78	3.29	3.18	3.09
Median	40.00	33.00	46.00	39.00	43.00	28.00	44.00	23.00	48.00	49.50	34.00	42.00	55.00	25.50
Interquartile Range (IQR)	24.00 - 59.00	22.00 - 50.00	31.00 - 61.00	21.00 - 58.00	32.00 - 61.00	21.00 - 58.00	26.00 - 61.00	22.00 - 36.00	23.00 - 61.00	23.00 - 69.00	22.00 - 55.00	36.00 - 58.00	37.00 - 66.00	21.00 - 49.00
Range	18.00 - 76.00	18.00 - 72.00	20.00 - 76.00	18.00 - 72.00	20.00 - 76.00	18.00 - 74.00	20.00 - 76.00	22.00 - 36.00	18.00 - 63.00	19.00 - 76.00	18.00 - 72.00	23.00 - 66.00	19.00 - 76.00	18.00 - 74.00
95% CI	38.51 - 46.66	31.24 - 42.70	39.81 - 54.27	33.83 - 46.17	39.00 - 53.29	30.11 - 46.43	38.59 - 51.07	7.60 - 46.40	21.81 - 65.19	38.21 - 53.03	29.46 - 45.18	38.61 - 52.72	44.62 - 57.66	29.44 - 42.03
Patient's age on the date of first														

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dose of InO, n (%)														
n	84	37	27	35	28	26	35	3	6	34	22	15	29	34
18-45	46 (54.76%)	25 (67.57%)	13 (48.15%)	20 (57.14%)	15 (53.57%)	17 (65.38%)	18 (51.43%)	3 (100.00%)	3 (50.00%)	15 (44.12%)	15 (68.18%)	9 (60.00%)	11 (37.93%)	24 (70.59%)
46-65	23 (27.38%)	8 (21.62%)	8 (29.63%)	11 (31.43%)	7 (25.00%)	4 (15.38%)	11 (31.43%)	0 (0.00%)	3 (50.00%)	9 (26.47%)	5 (22.73%)	5 (33.33%)	10 (34.48%)	6 (17.65%)
66-89	15 (17.86%)	4 (10.81%)	6 (22.22%)	4 (11.43%)	6 (21.43%)	5 (19.23%)	6 (17.14%)	0 (0.00%)	0 (0.00%)	10 (29.41%)	2 (9.09%)	1 (6.67%)	8 (27.59%)	4 (11.76%)
2.1 What is the patient's biological sex, as stated in their medical record?, n (%)														
n	84	37	27	35	28	26	35	3	6	34	22	15	29	34
Female	36 (42.86%)	18 (48.65%)	11 (40.74%)	16 (45.71%)	12 (42.86%)	13 (50.00%)	15 (42.86%)	1 (33.33%)	2 (33.33%)	14 (41.18%)	9 (40.91%)	8 (53.33%)	13 (44.83%)	17 (50.00%)
Male	48 (57.14%)	19 (51.35%)	16 (59.26%)	19 (54.29%)	16 (57.14%)	13 (50.00%)	20 (57.14%)	2 (66.67%)	4 (66.67%)	20 (58.82%)	13 (59.09%)	7 (46.67%)	16 (55.17%)	17 (50.00%)
Race/ethnic ity														
n	84	37	27	35	28	26	35	3	6	34	22	15	29	34
White	66 (78.57%)	29 (78.38%)	23 (85.19%)	27 (77.14%)	24 (85.71%)	20 (76.92%)	30 (85.71%)	2 (66.67%)	5 (83.33%)	28 (82.35%)	17 (77.27%)	10 (66.67%)	27 (93.10%)	24 (70.59%)
Black or African or Caribbean or African American	2 (2.38%)	0 (0.00%)	2 (7.41%)	0 (0.00%)	2 (7.14%)	1 (3.85%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (13.33%)	1 (3.45%)	1 (2.94%)
East or Southeast Asian	1 (1.19%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	1 (3.57%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.94%)
South Asian (Indian subcontine nt)	2 (2.38%)	1 (2.70%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	1 (4.55%)	0 (0.00%)	0 (0.00%)	2 (5.88%)

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Middle Eastern or North African	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Other	10 (11.90%)	6 (16.22%)	2 (7.41%)	7 (20.00%)	2 (7.14%)	3 (11.54%)	2 (5.71%)	0 (0.00%)	1 (16.67%)	4 (11.76%)	3 (13.64%)	3 (20.00%)	2 (6.90%)	3 (8.82%)
American Indian, Indigenous American, or Alaska Native	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
South or Central American Native	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Native Hawaiian or Pacific Islander	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Not known	4 (4.76%)	1 (2.70%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (7.69%)	1 (2.86%)	1 (33.33%)	0 (0.00%)	1 (2.94%)	1 (4.55%)	0 (0.00%)	0 (0.00%)	3 (8.82%)
2.2 Is the patient of Hispanic, Latin or Spanish origin?, n (%)														
n	16	6	5	7	5	6	8	1	1	8	3	5	8	6
Yes	6 (37.50%)	2 (33.33%)	0 (0.00%)	3 (42.86%)	1 (20.00%)	3 (50.00%)	2 (25.00%)	1 (100.00%)	1 (100.00%)	3 (37.50%)	1 (33.33%)	2 (40.00%)	2 (25.00%)	3 (50.00%)
No	10 (62.50%)	4 (66.67%)	5 (100.00%)	4 (57.14%)	4 (80.00%)	3 (50.00%)	6 (75.00%)	0 (0.00%)	0 (0.00%)	5 (62.50%)	2 (66.67%)	3 (60.00%)	6 (75.00%)	3 (50.00%)
2.3 What was the patient's BMI at index (initiation of InO)?														
n	71	31	25	32	26	23	33	1	6	34	22	15	28	30
Mean	25.08	24.94	25.10	25.53	25.12	25.58	24.66	27.08	26.82	21.34	24.74	34.02	25.57	24.98



Standard deviation	5.81	6.11	5.31	6.57	5.26	7.10	4.80	.	7.52	1.72	4.35	3.71	5.47	5.97
Standard error of the mean	0.69	1.10	1.06	1.16	1.03	1.48	0.84	.	3.07	0.30	0.93	0.96	1.03	1.09
Median	23.50	23.00	23.50	23.25	23.75	23.50	24.00	27.08	26.30	21.60	26.80	32.10	24.58	23.50
Interquartile Range (IQR)	21.00 - 27.70	20.00 - 27.50	21.20 - 27.70	20.58 - 29.35	21.20 - 27.70	19.72 - 30.00	21.20 - 27.00	27.08 - 27.08	21.60 - 31.29	19.86 - 23.00	25.00 - 27.30	30.63 - 37.40	21.35 - 27.45	19.00 - 28.70
Range	16.02 - 41.10	17.00 - 41.10	19.00 - 37.40	17.00 - 41.10	19.00 - 37.40	17.00 - 41.10	16.07 - 37.40	27.08 - 27.08	17.00 - 38.46	18.59 - 24.16	16.02 - 28.70	30.00 - 41.10	19.00 - 38.46	16.07 - 41.10
95% CI	23.70 - 26.45	22.70 - 27.18	22.91 - 27.29	23.16 - 27.89	23.00 - 27.25	22.51 - 28.65	22.96 - 26.36	- -	18.93 - 34.72	20.74 - 21.95	22.82 - 26.67	31.96 - 36.07	23.45 - 27.69	22.75 - 27.21
BMI at index (initiation of InO), n (%)														
n	71	31	25	32	26	23	33	1	6	34	22	15	28	30
(18.5, 25)	34 (47.89%)	15 (48.39%)	14 (56.00%)	15 (46.88%)	14 (53.85%)	10 (43.48%)	16 (48.48%)	0 (0.00%)	1 (16.67%)	34 (100.00%)	0 (0.00%)	0 (0.00%)	14 (50.00%)	13 (43.33%)
(25, 30)	22 (30.99%)	10 (32.26%)	6 (24.00%)	9 (28.12%)	7 (26.92%)	7 (30.43%)	12 (36.36%)	1 (100.00%)	3 (50.00%)	0 (0.00%)	22 (100.00%)	0 (0.00%)	9 (32.14%)	10 (33.33%)
30+	15 (21.13%)	6 (19.35%)	5 (20.00%)	8 (25.00%)	5 (19.23%)	6 (26.09%)	5 (15.15%)	0 (0.00%)	2 (33.33%)	0 (0.00%)	0 (0.00%)	15 (100.00%)	5 (17.86%)	7 (23.33%)
BMI at index (initiation of InO), n (%)														
n	84	37	27	35	28	26	35	3	6	34	22	15	29	34
(18.5, 25)	34 (40.48%)	15 (40.54%)	14 (51.85%)	15 (42.86%)	14 (50.00%)	10 (38.46%)	16 (45.71%)	0 (0.00%)	1 (16.67%)	34 (100.00%)	0 (0.00%)	0 (0.00%)	14 (48.28%)	13 (38.24%)
(25, 30)	22 (26.19%)	10 (27.03%)	6 (22.22%)	9 (25.71%)	7 (25.00%)	7 (26.92%)	12 (34.29%)	1 (33.33%)	3 (50.00%)	0 (0.00%)	22 (100.00%)	0 (0.00%)	9 (31.03%)	10 (29.41%)
30+	15 (17.86%)	6 (16.22%)	5 (18.52%)	8 (22.86%)	5 (17.86%)	6 (23.08%)	5 (14.29%)	0 (0.00%)	2 (33.33%)	0 (0.00%)	0 (0.00%)	15 (100.00%)	5 (17.24%)	7 (20.59%)
Unknown	13 (15.48%)	6 (16.22%)	2 (7.41%)	3 (8.57%)	2 (7.14%)	3 (11.54%)	2 (5.71%)	2 (66.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.45%)	4 (11.76%)
1.4 Is the patient														



currently: , n (%)														
n	84	37	27	35	28	26	35	3	6	34	22	15	29	34
Alive	47 (55.95%)	16 (43.24%)	20 (74.07%)	16 (45.71%)	21 (75.00%)	16 (61.54%)	25 (71.43%)	1 (33.33%)	4 (66.67%)	20 (58.82%)	14 (63.64%)	10 (66.67%)	18 (62.07%)	25 (73.53%)
Deceased	35 (41.67%)	20 (54.05%)	6 (22.22%)	18 (51.43%)	6 (21.43%)	9 (34.62%)	10 (28.57%)	2 (66.67%)	2 (33.33%)	14 (41.18%)	6 (27.27%)	5 (33.33%)	11 (37.93%)	9 (26.47%)
Not known	2 (2.38%)	1 (2.70%)	1 (3.70%)	1 (2.86%)	1 (3.57%)	1 (3.85%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
2.5]Please select the primary cause of death., n (%)														
n	35	20	6	18	6	9	10	2	2	14	6	5	11	9
As a direct cause of their ALL disease (i.e. death due to ALL disease progression)	29 (82.86%)	15 (75.00%)	5 (83.33%)	14 (77.78%)	5 (83.33%)	7 (77.78%)	8 (80.00%)	1 (50.00%)	1 (50.00%)	12 (85.71%)	5 (83.33%)	4 (80.00%)	9 (81.82%)	7 (77.78%)
As an indirect cause of their ALL disease (i.e. non- relapsed mortality (treatment related))	4 (11.43%)	4 (20.00%)	0 (0.00%)	3 (16.67%)	0 (0.00%)	2 (22.22%)	0 (0.00%)	1 (50.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	2 (22.22%)
Another reason not related to their ALL disease	1 (2.86%)	1 (5.00%)	0 (0.00%)	1 (5.56%)	0 (0.00%)	0 (0.00%)	1 (10.00%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	0 (0.00%)	1 (9.09%)	0 (0.00%)
Other	1 (2.86%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	1 (10.00%)	0 (0.00%)	1 (50.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	1 (9.09%)	0 (0.00%)
2.6]Is the patient														



being actively monitored or have they been lost to follow up?, n (%)														
n	47	16	20	16	21	16	25	1	4	20	14	10	18	25
Actively monitored	(100.00 %)	(100.00 %)	(100.00 %)	(100.00 %)	(100.00 %)	(100.00 %)	(100.00 %)	(100.00 %)	(100.00 %)	(100.00 %)	(100.00 %)	(100.00 %)	(100.00 %)	(100.00 %)

Overall (n=83), the mean (SD) number of times the patient received salvage therapy was 1.78 (1.19) (please see **Table 29** below). Of the patients with a positive MRD status prior to HPSCT, the mean (SD) was 4.00 (4.36) (please see **Table 29** below).

Table 29: Number of Times Patient Received Salvage Therapy

	Overall	MRD status (1st cycle of InO)		MRD status (last cycle of InO)		MRD status (CAR-T infusion)		MRD status (prior to HPSCT)		BMI at index (initiation of InO)			InO received:	
	Total	Positive	Negative	Positive	Negative	Positive	Negative	Positive	Negative	(18.5, 25)	(25, 30)	30+	Pre-apheresis	Post-apheresis
3.1 How many times has the patient received salvage therapy?														
n	83	37	26	34	28	26	35	3	6	34	22	15	29	34
Mean	1.78	2.00	1.58	1.76	1.64	1.96	1.83	4.00	1.50	1.82	1.59	1.67	1.83	1.94
Standard deviation	1.19	1.47	0.95	0.89	0.95	1.68	0.98	4.36	0.55	1.03	0.85	0.72	1.04	1.50
Standard error of the mean	0.13	0.24	0.19	0.15	0.18	0.33	0.17	2.52	0.22	0.18	0.18	0.19	0.19	0.26
Median	2.00	2.00	1.00	2.00	1.00	2.00	2.00	2.00	1.50	2.00	1.00	2.00	2.00	2.00
Interquartile Range(IQR)	1.00 - 2.00	1.00 - 2.00	1.00 - 2.00	1.00 - 2.00	1.00 - 2.00	1.00 - 2.00	1.00 - 2.00	1.00 - 9.00	1.00 - 2.00	1.00 - 2.00	1.00 - 2.00	1.00 - 2.00	1.00 - 2.00	1.00 - 2.00



Range	1.00 - 9.00	1.00 - 9.00	1.00 - 5.00	1.00 - 5.00	1.00 - 5.00	1.00 - 9.00	1.00 - 5.00	1.00 - 9.00	1.00 - 2.00	1.00 - 5.00	1.00 - 4.00	1.00 - 3.00	1.00 - 5.00	1.00 - 9.00
95% CI	1.52 - 2.04	1.51 - 2.49	1.20 - 1.96	1.45 - 2.08	1.27 - 2.01	1.28 - 2.64	1.49 - 2.17	-6.83 - 14.83	0.93 - 2.07	1.46 - 2.18	1.21 - 1.97	1.27 - 2.07	1.43 - 2.22	1.42 - 2.46
3.1 Number of times the patient received salvage therapy not known., n (%)														
	1	0	1	1	0	0	0	0	0	0	0	0	0	0
Not known	1 (100.00%)	0 (.)	1 (100.00%)	1 (100.00%)	0 (.)	0 (.)	0 (.)	0 (.)	0 (.)	0 (.)	0 (.)	0 (.)	0 (.)	0 (.)

Of the patients that their MRD was relapsed at receipt of salvage therapy, 84.0% had a BMI at index of 30+ (please see **Table 30** below). Of the patients whose MRD status was refractory at receipt of salvage, 58.33% were MRD positive prior to HPSCt (please see **Table 30** below).

Table 30: MRD Status at Receipt of Salvage Therapy

	Overall	MRD status (1st cycle of InO)		MRD status (last cycle of InO)		MRD status (CAR-T infusion)		MRD status (prior to HPSCt)		BMI at index (initiation of InO)			InO received:	
	Total	Positive	Negative	Positive	Negative	Positive	Negative	Positive	Negative	(18.5, 25)	(25, 30)	30+	Pre-apheresis	Post-apheresis
Status at receipt of salvage therapy, n (%)														
n	149.00	74.00	42.00	61.00	46.00	51.00	64.00	12.00	9.00	62.00	35.00	25.00	53.00	66.00
Relapsed	109.00 (73.15%)	49.00 (66.22%)	38.00 (90.48%)	43.00 (70.49%)	40.00 (86.96%)	31.00 (60.78%)	49.00 (76.56%)	5.00 (41.67%)	8.00 (88.89%)	50.00 (80.65%)	23.00 (65.71%)	21.00 (84.00%)	37.00 (69.81%)	47.00 (71.21%)



Refractory	38.00 (25.50%)	25.00 (33.78%)	3.00 (7.14%)	17.00 (27.87%)	6.00 (13.04%)	19.00 (37.25%)	15.00 (23.44%)	7.00 (58.33%)	1.00 (11.11%)	12.00 (19.35%)	12.00 (34.29%)	4.00 (16.00%)	16.00 (30.19%)	18.00 (27.27%)
Unknown	2.00 (1.34%)	0.00 (0.00%)	1.00 (2.38%)	1.00 (1.64%)	0.00 (0.00%)	1.00 (1.96%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (1.52%)

Overall, just over half (51.1%) of the patients had their first remission following their ALL diagnosis before they relapsed last ≥ 12 months (please see **Table 31** below). Of the patients whose MRD status prior to HPSCt was negative, 66.7% had their first remission following their ALL diagnosis last ≥ 12 months before they relapsed (please see **Table 31** below).

Table 31: Duration of Patient's First Remission, Risk Group/ Genetic Alterations at ALL Diagnosis and Index

	Overall	MRD status (1st cycle of InO)		MRD status (last cycle of InO)		MRD status (CAR-T infusion)		MRD status (prior to HPSCt)		BMI at index (initiation of InO)			InO received:	
	Total	Positive	Negative	Positive	Negative	Positive	Negative	Positive	Negative	(18.5, 25)	(25, 30)	30+	Pre-apheresis	Post-apheresis
3.3 What was the duration of the patient's first remission following their ALL diagnosis before they relapsed?, n (%)														
n	84	37	27	35	28	26	35	3	6	34	22	15	29	34
≥ 12 months	43 (51.19%)	17 (45.95%)	13 (48.15%)	15 (42.86%)	16 (57.14%)	10 (38.46%)	20 (57.14%)	1 (33.33%)	4 (66.67%)	16 (47.06%)	16 (72.73%)	6 (40.00%)	15 (51.72%)	17 (50.00%)
< 12 months	34 (40.48%)	17 (45.95%)	12 (44.44%)	16 (45.71%)	11 (39.29%)	13 (50.00%)	13 (37.14%)	2 (66.67%)	2 (33.33%)	15 (44.12%)	5 (22.73%)	8 (53.33%)	13 (44.83%)	13 (38.24%)
Patient did not experience remission	6 (7.14%)	3 (8.11%)	1 (3.70%)	3 (8.57%)	1 (3.57%)	3 (11.54%)	2 (5.71%)	0 (0.00%)	0 (0.00%)	3 (8.82%)	1 (4.55%)	1 (6.67%)	1 (3.45%)	4 (11.76%)
Don't know	1 (1.19%)	0 (0.00%)	1 (3.70%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Risk group at original ALL diagnosis														
n	84	37	27	35	28	26	35	3	6	34	22	15	29	34



Philadelphia chromosome negative	35 (41.67%)	17 (45.95%)	12 (44.44%)	16 (45.71%)	13 (46.43%)	10 (38.46%)	14 (40.00%)	0 (0.00%)	3 (50.00%)	14 (41.18%)	11 (50.00%)	5 (33.33%)	12 (41.38%)	13 (38.24%)
Philadelphia chromosome positive	15 (17.86%)	4 (10.81%)	7 (25.93%)	4 (11.43%)	6 (21.43%)	5 (19.23%)	7 (20.00%)	2 (66.67%)	0 (0.00%)	8 (23.53%)	1 (4.55%)	5 (33.33%)	5 (17.24%)	7 (20.59%)
B-cell ALL with hypodiploidy	3 (3.57%)	1 (2.70%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	1 (3.85%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (5.88%)	0 (0.00%)	0 (0.00%)	1 (3.45%)	1 (2.94%)
B-cell ALL with hyperdiploidy	3 (3.57%)	1 (2.70%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (13.64%)	0 (0.00%)	1 (3.45%)	1 (2.94%)
B-cell ALL with a translocation between chromosome 11 and another chromosome	7 (8.33%)	5 (13.51%)	1 (3.70%)	5 (14.29%)	1 (3.57%)	2 (7.69%)	2 (5.71%)	0 (0.00%)	0 (0.00%)	3 (8.82%)	1 (4.55%)	2 (13.33%)	3 (10.34%)	2 (5.88%)
B-cell ALL with a translocation between chromosomes 12 and 21	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
B-cell ALL with a translocation between chromosomes 1 and 19	6 (7.14%)	3 (8.11%)	1 (3.70%)	4 (11.43%)	1 (3.57%)	5 (19.23%)	1 (2.86%)	0 (0.00%)	2 (33.33%)	3 (8.82%)	0 (0.00%)	2 (13.33%)	3 (10.34%)	3 (8.82%)
B-cell ALL with a translocation between chromosomes 5 and 14	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
B-cell ALL with a translocation between chromosomes 9 and 22	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
B-cell ALL with amplification of a portion of chromosome 21	1 (1.19%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	1 (3.57%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.94%)
BCR-ABL1-like ALL	6 (7.14%)	3 (8.11%)	2 (7.41%)	3 (8.57%)	3 (10.71%)	1 (3.85%)	3 (8.57%)	0 (0.00%)	0 (0.00%)	3 (8.82%)	0 (0.00%)	3 (20.00%)	3 (10.34%)	1 (2.94%)
Other risk group not mentioned here	7 (8.33%)	4 (10.81%)	2 (7.41%)	4 (11.43%)	2 (7.14%)	2 (7.69%)	3 (8.57%)	0 (0.00%)	0 (0.00%)	2 (5.88%)	1 (4.55%)	2 (13.33%)	0 (0.00%)	5 (14.71%)



None of the above	6 (7.14%)	3 (8.11%)	1 (3.70%)	1 (2.86%)	1 (3.57%)	2 (7.69%)	4 (11.43%)	1 (33.33%)	1 (16.67%)	1 (2.94%)	3 (13.64%)	0 (0.00%)	3 (10.34%)	3 (8.82%)
Not known/not recorded	4 (4.76%)	3 (8.11%)	1 (3.70%)	3 (8.57%)	1 (3.57%)	2 (7.69%)	1 (2.86%)	0 (0.00%)	1 (16.67%)	2 (5.88%)	2 (9.09%)	0 (0.00%)	0 (0.00%)	2 (5.88%)
Risk group at Index (initiation of InO)														
n	84	37	27	35	28	26	35	3	6	34	22	15	29	34
Philadelphia chromosome negative	37 (44.05%)	17 (45.95%)	13 (48.15%)	16 (45.71%)	14 (50.00%)	10 (38.46%)	15 (42.86%)	0 (0.00%)	3 (50.00%)	14 (41.18%)	12 (54.55%)	6 (40.00%)	10 (34.48%)	15 (44.12%)
Philadelphia chromosome positive	12 (14.29%)	2 (5.41%)	7 (25.93%)	2 (5.71%)	6 (21.43%)	4 (15.38%)	7 (20.00%)	2 (66.67%)	0 (0.00%)	7 (20.59%)	1 (4.55%)	3 (20.00%)	6 (20.69%)	5 (14.71%)
B-cell ALL with hypodiploidy	3 (3.57%)	1 (2.70%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	1 (3.85%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (5.88%)	0 (0.00%)	0 (0.00%)	1 (3.45%)	1 (2.94%)
B-cell ALL with hyperdiploidy	3 (3.57%)	2 (5.41%)	0 (0.00%)	2 (5.71%)	0 (0.00%)	1 (3.85%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (13.64%)	0 (0.00%)	0 (0.00%)	2 (5.88%)
B-cell ALL with a translocation between chromosome 11 and another chromosome	7 (8.33%)	6 (16.22%)	1 (3.70%)	6 (17.14%)	1 (3.57%)	2 (7.69%)	2 (5.71%)	0 (0.00%)	0 (0.00%)	4 (11.76%)	1 (4.55%)	1 (6.67%)	3 (10.34%)	1 (2.94%)
B-cell ALL with a translocation between chromosomes 12 and 21	1 (1.19%)	1 (2.70%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	1 (3.85%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.94%)
B-cell ALL with a translocation between chromosomes 1 and 19	6 (7.14%)	3 (8.11%)	1 (3.70%)	4 (11.43%)	1 (3.57%)	5 (19.23%)	1 (2.86%)	0 (0.00%)	2 (33.33%)	3 (8.82%)	0 (0.00%)	2 (13.33%)	3 (10.34%)	3 (8.82%)
B-cell ALL with a translocation between chromosomes 5 and 14	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
B-cell ALL with a translocation between chromosomes 9 and 22	1 (1.19%)	1 (2.70%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.67%)	0 (0.00%)	0 (0.00%)

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B-cell ALL with amplification of a portion of chromosome 21	1 (1.19%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	1 (3.57%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.94%)
BCR-ABL1-like ALL	5 (5.95%)	3 (8.11%)	1 (3.70%)	3 (8.57%)	2 (7.14%)	1 (3.85%)	2 (5.71%)	0 (0.00%)	0 (0.00%)	3 (8.82%)	0 (0.00%)	2 (13.33%)	2 (6.90%)	1 (2.94%)
Other risk group not mentioned here	11 (13.10%)	6 (16.22%)	3 (11.11%)	6 (17.14%)	3 (10.71%)	3 (11.54%)	4 (11.43%)	0 (0.00%)	0 (0.00%)	4 (11.76%)	3 (13.64%)	2 (13.33%)	1 (3.45%)	5 (14.71%)
None of the above	5 (5.95%)	2 (5.41%)	1 (3.70%)	0 (0.00%)	1 (3.57%)	1 (3.85%)	4 (11.43%)	1 (33.33%)	1 (16.67%)	1 (2.94%)	2 (9.09%)	0 (0.00%)	3 (10.34%)	2 (5.88%)
98	2 (2.38%)	1 (2.70%)	1 (3.70%)	1 (2.86%)	1 (3.57%)	1 (3.85%)	1 (2.86%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	1 (4.55%)	1 (6.67%)	1 (3.45%)	1 (2.94%)
ALL genetic alterations at original ALL diagnosis														
n	84	37	27	35	28	26	35	3	6	34	22	15	29	34
IKZF1 N159Y	4 (4.76%)	1 (2.70%)	2 (7.41%)	1 (2.86%)	2 (7.14%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	1 (4.55%)	2 (13.33%)	0 (0.00%)	2 (5.88%)
P2RY8-CRLF2	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
KMT2A rearrangement	7 (8.33%)	5 (13.51%)	2 (7.41%)	5 (14.29%)	2 (7.14%)	3 (11.54%)	2 (5.71%)	0 (0.00%)	0 (0.00%)	3 (8.82%)	1 (4.55%)	2 (13.33%)	3 (10.34%)	2 (5.88%)
JAK2r	1 (1.19%)	0 (0.00%)	1 (3.70%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
EPORr	1 (1.19%)	1 (2.70%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	1 (3.85%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.94%)
ABL1-class fusion	1 (1.19%)	1 (2.70%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
ABL2-class fusion	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
CSF1R	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
MEF2D rearrangement	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
DUX4 rearrangement	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
ERG-DUX4 fusion mutation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
NUTM1 rearrangement	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

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ZNF384 rearrangement	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
MEF2D rearrangement	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
BCL11B rearrangement	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
PAX5 P80R	1 (1.19%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.67%)	0 (0.00%)	1 (2.94%)
BCR/ABL1-Like	5 (5.95%)	2 (5.41%)	1 (3.70%)	2 (5.71%)	2 (7.14%)	1 (3.85%)	2 (5.71%)	0 (0.00%)	0 (0.00%)	2 (5.88%)	0 (0.00%)	3 (20.00%)	2 (6.90%)	1 (2.94%)
Other mutation	15 (17.86%)	5 (13.51%)	3 (11.11%)	7 (20.00%)	2 (7.14%)	7 (26.92%)	4 (11.43%)	0 (0.00%)	2 (33.33%)	4 (11.76%)	3 (13.64%)	6 (40.00%)	2 (6.90%)	10 (29.41%)
None of the above	46 (54.76%)	17 (45.95%)	19 (70.37%)	12 (34.29%)	21 (75.00%)	12 (46.15%)	25 (71.43%)	3 (100.00%)	3 (50.00%)	17 (50.00%)	15 (68.18%)	5 (33.33%)	21 (72.41%)	18 (52.94%)
Not known/Not recorded	8 (9.52%)	6 (16.22%)	1 (3.70%)	6 (17.14%)	1 (3.57%)	3 (11.54%)	2 (5.71%)	0 (0.00%)	1 (16.67%)	5 (14.71%)	3 (13.64%)	0 (0.00%)	1 (3.45%)	3 (8.82%)
ALL genetic alterations at Index (initiation of InO)														
n	84	37	27	35	28	26	35	3	6	34	22	15	29	34
IKZF1 N159Y	3 (3.57%)	0 (0.00%)	2 (7.41%)	0 (0.00%)	2 (7.14%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	1 (4.55%)	1 (6.67%)	0 (0.00%)	2 (5.88%)
P2RY8-CRLF2	1 (1.19%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.55%)	0 (0.00%)	1 (3.45%)	0 (0.00%)
KMT2A rearrangement	7 (8.33%)	5 (13.51%)	2 (7.41%)	5 (14.29%)	2 (7.14%)	3 (11.54%)	2 (5.71%)	0 (0.00%)	0 (0.00%)	3 (8.82%)	1 (4.55%)	2 (13.33%)	3 (10.34%)	2 (5.88%)
JAK2r	1 (1.19%)	0 (0.00%)	1 (3.70%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
EPORr	1 (1.19%)	1 (2.70%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	1 (3.85%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.94%)
ABL1-class fusion	1 (1.19%)	1 (2.70%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
ABL2-class fusion	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
CSF1R	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
MEF2D rearrangement	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
DUX4 rearrangement	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)



ERG-DUX4 fusion mutation	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
NUTM1 rearrangement	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
ZNF384 rearrangement	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
MEF2D rearrangement	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
BCL11B rearrangement	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
PAX5 P80R	2 (2.38%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.85%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	0 (0.00%)	1 (6.67%)	0 (0.00%)	2 (5.88%)
BCR/ABL1-Like	5 (5.95%)	2 (5.41%)	1 (3.70%)	2 (5.71%)	2 (7.14%)	1 (3.85%)	2 (5.71%)	0 (0.00%)	0 (0.00%)	2 (5.88%)	0 (0.00%)	3 (20.00%)	2 (6.90%)	1 (2.94%)
Other mutation	17 (20.24%)	6 (16.22%)	3 (11.11%)	8 (22.86%)	2 (7.14%)	7 (26.92%)	5 (14.29%)	0 (0.00%)	2 (33.33%)	5 (14.71%)	4 (18.18%)	6 (40.00%)	3 (10.34%)	10 (29.41%)
None of the above	46 (54.76%)	17 (45.95%)	20 (74.07%)	12 (34.29%)	22 (78.57%)	13 (50.00%)	25 (71.43%)	3 (100.00%)	3 (50.00%)	18 (52.94%)	14 (63.64%)	5 (33.33%)	20 (68.97%)	18 (52.94%)
Not known/Not recorded	6 (7.14%)	5 (13.51%)	0 (0.00%)	5 (14.29%)	0 (0.00%)	2 (7.69%)	1 (2.86%)	0 (0.00%)	1 (16.67%)	3 (8.82%)	3 (13.64%)	0 (0.00%)	1 (3.45%)	3 (8.82%)
Test results available at Index (initiation of InO)														
n	84	37	27	35	28	26	35	3	6	34	22	15	29	34
Haemoglobin	70 (83.33%)	29 (78.38%)	23 (85.19%)	29 (82.86%)	23 (82.14%)	20 (76.92%)	29 (82.86%)	2 (66.67%)	5 (83.33%)	29 (85.29%)	15 (68.18%)	14 (93.33%)	21 (72.41%)	29 (85.29%)
Thrombocytes	11 (13.10%)	6 (16.22%)	1 (3.70%)	5 (14.29%)	1 (3.57%)	3 (11.54%)	1 (2.86%)	0 (0.00%)	1 (16.67%)	3 (8.82%)	2 (9.09%)	0 (0.00%)	1 (3.45%)	3 (8.82%)
Leukocytes	68 (80.95%)	29 (78.38%)	23 (85.19%)	29 (82.86%)	23 (82.14%)	20 (76.92%)	28 (80.00%)	2 (66.67%)	5 (83.33%)	29 (85.29%)	14 (63.64%)	14 (93.33%)	21 (72.41%)	28 (82.35%)
Absolute neutrophil count (ANC)	64 (76.19%)	28 (75.68%)	20 (74.07%)	27 (77.14%)	20 (71.43%)	19 (73.08%)	25 (71.43%)	2 (66.67%)	4 (66.67%)	27 (79.41%)	15 (68.18%)	11 (73.33%)	17 (58.62%)	28 (82.35%)
Platelet cell count	66 (78.57%)	25 (67.57%)	23 (85.19%)	26 (74.29%)	23 (82.14%)	19 (73.08%)	28 (80.00%)	2 (66.67%)	4 (66.67%)	27 (79.41%)	14 (63.64%)	14 (93.33%)	20 (68.97%)	29 (85.29%)
Bilirubin	68 (80.95%)	28 (75.68%)	22 (81.48%)	28 (80.00%)	22 (78.57%)	19 (73.08%)	28 (80.00%)	2 (66.67%)	4 (66.67%)	28 (82.35%)	14 (63.64%)	14 (93.33%)	19 (65.52%)	29 (85.29%)



Bone marrow blast count	48 (57.14 %)	22 (59.46 %)	20 (74.07 %)	22 (62.86 %)	20 (71.43 %)	14 (53.85 %)	22 (62.86 %)	1 (33.33%)	4 (66.67 %)	24 (70.59 %)	15 (68.18 %)	7 (46.67 %)	20 (68.97%)	15 (44.12%)
Total lymphocyte count	51 (60.71 %)	24 (64.86 %)	11 (40.74 %)	22 (62.86 %)	12 (42.86 %)	11 (42.31 %)	20 (57.14 %)	1 (33.33%)	2 (33.33 %)	17 (50.00 %)	15 (68.18 %)	8 (53.33 %)	11 (37.93%)	22 (64.71%)
Alanine transaminase (ALT)	66 (78.57 %)	29 (78.38 %)	22 (81.48 %)	29 (82.86 %)	22 (78.57 %)	19 (73.08 %)	28 (80.00 %)	2 (66.67%)	4 (66.67 %)	26 (76.47 %)	15 (68.18 %)	14 (93.33 %)	19 (65.52%)	29 (85.29%)
Aspartate aminotransferase (AST)	50 (59.52 %)	22 (59.46 %)	14 (51.85 %)	22 (62.86 %)	14 (50.00 %)	14 (53.85 %)	18 (51.43 %)	1 (33.33%)	3 (50.00 %)	22 (64.71 %)	11 (50.00 %)	8 (53.33 %)	16 (55.17%)	17 (50.00%)
Alkaline phosphatase (ALP)	61 (72.62 %)	26 (70.27 %)	20 (74.07 %)	25 (71.43 %)	21 (75.00 %)	15 (57.69 %)	28 (80.00 %)	1 (33.33%)	3 (50.00 %)	25 (73.53 %)	15 (68.18 %)	13 (86.67 %)	17 (58.62%)	28 (82.35%)
Gamma-glutamyltransferase (GGT)	37 (44.05 %)	17 (45.95 %)	10 (37.04 %)	15 (42.86 %)	11 (39.29 %)	9 (34.62 %)	12 (34.29 %)	0 (0.00%)	2 (33.33 %)	16 (47.06 %)	9 (40.91 %)	4 (26.67 %)	8 (27.59%)	14 (41.18%)
Lactate Dehydrogenase (LDH)	63 (75.00 %)	27 (72.97 %)	22 (81.48 %)	25 (71.43 %)	23 (82.14 %)	15 (57.69 %)	28 (80.00 %)	1 (33.33%)	4 (66.67 %)	26 (76.47 %)	15 (68.18 %)	12 (80.00 %)	19 (65.52%)	26 (76.47%)
CD22 expression	11 (13.10 %)	9 (24.32 %)	0 (0.00%)	9 (25.71 %)	0 (0.00%)	5 (19.23 %)	0 (0.00%)	0 (0.00%)	1 (16.67 %)	5 (14.71 %)	4 (18.18 %)	2 (13.33 %)	1 (3.45%)	4 (11.76%)
CD19 expression	15 (17.86 %)	9 (24.32 %)	2 (7.41%)	9 (25.71 %)	2 (7.14%)	6 (23.08 %)	1 (2.86%)	0 (0.00%)	1 (16.67 %)	8 (23.53 %)	4 (18.18 %)	3 (20.00 %)	0 (0.00%)	8 (23.53%)
CD3+ count	12 (14.29 %)	7 (18.92 %)	3 (11.11 %)	7 (20.00 %)	3 (10.71 %)	4 (15.38 %)	3 (8.57%)	0 (0.00%)	1 (16.67 %)	4 (11.76 %)	4 (18.18 %)	4 (26.67 %)	2 (6.90%)	5 (14.71%)
CD4+ count	10 (11.90 %)	6 (16.22 %)	2 (7.41%)	6 (17.14 %)	2 (7.14%)	2 (7.69%)	3 (8.57%)	0 (0.00%)	1 (16.67 %)	3 (8.82%)	3 (13.64 %)	4 (26.67 %)	2 (6.90%)	3 (8.82%)
CD8+ count	10 (11.90 %)	6 (16.22 %)	2 (7.41%)	6 (17.14 %)	2 (7.14%)	2 (7.69%)	3 (8.57%)	0 (0.00%)	1 (16.67 %)	3 (8.82%)	3 (13.64 %)	4 (26.67 %)	2 (6.90%)	3 (8.82%)
Not known/Not recorded	5 (5.95%)	3 (8.11%)	1 (3.70%)	2 (5.71%)	1 (3.57%)	3 (11.54 %)	2 (5.71%)	1 (33.33%)	1 (16.67 %)	4 (11.76 %)	0 (0.00%)	0 (0.00%)	3 (10.34%)	2 (5.88%)

For the patients whose MRD status at CAR-T infusion was positive, the mean (SD) haemoglobin test result at index was 7.30 (4.53) (please see [Table 32](#) below). For patients whose BMI at index was (18.5, 25), the mean (SD) haemoglobin test result at index was 21.20 (69.66) (please see [Table 32](#) below).



Table 32: Laboratory Test Results at Index

Test result at index:	Overall	MRD status (1 st cycle of InO)		MRD status (last cycle of InO)		MRD status (CAR-T infusion)		MRD status (prior to HPSCt)		BMI at index (initiation of InO)			InO received:	
	Total	Positive	Negative	Positive	Negative	Positive	Negative	Positive	Negative	(18.5, 25)	(25, 30)	30+	Pre-apheresis	Post-apheresis
Haemoglobin.														
n	70	29	23	29	23	20	29	2	5	29	15	14	21	29
Mean	13.77	6.78	11.24	6.87	11.05	7.30	10.43	11.28	6.42	21.20	8.44	10.87	12.16	19.83
Standard deviation	45.31	3.08	10.86	3.15	10.86	4.53	9.85	7.53	6.27	69.66	4.35	14.09	11.22	69.94
Standard error of the mean	5.42	0.57	2.26	0.58	2.27	1.01	1.83	5.33	2.80	12.93	1.12	3.77	2.45	12.99
Median	7.38	6.52	9.70	6.58	9.68	7.36	9.40	11.28	6.21	8.60	6.70	7.63	11.10	6.50
Interquartile Range (IQR)	5.83 - 10.30	5.59 - 8.50	6.21 - 12.20	5.59 - 9.20	6.21 - 11.10	3.54 - 10.50	5.90 - 11.10	5.95 - 16.60	1.09 - 8.20	6.02 - 11.10	5.83 - 10.30	5.27 - 10.60	8.50 - 13.00	5.40 - 10.00
Range	0.61 - 383.00	0.61 - 12.10	1.43 - 58.33	0.61 - 12.10	1.43 - 58.33	0.61 - 16.60	1.43 - 58.33	5.95 - 16.60	0.61 - 16.00	0.62 - 383.00	0.61 - 16.60	1.09 - 58.33	1.09 - 58.33	0.61 - 383.00
95% CI	2.96 - 24.57	5.61 - 7.95	6.55 - 15.94	5.67 - 8.06	6.35 - 15.75	5.18 - 9.42	6.69 - 14.18	-56.39 - 78.94	-1.36 - 14.20	-5.29 - 47.70	6.03 - 10.85	2.74 - 19.01	7.05 - 17.27	-6.77 - 46.44
Thrombocytes.														
n	11	6	1	5	1	3	1	0	1	3	2	0	1	3
Mean	133.36	155.83	338.00	138.80	374.00	138.33	205.00		240.00	31.00	134.00		205.00	130.67
Standard deviation	136.47	141.01	.	142.43	.	106.27	.		.	31.48	149.91		.	118.35
Standard error of the mean	41.15	57.57	.	63.69	.	61.35	.		.	18.18	106.00		.	68.33
Median	66.00	135.50	338.00	66.00	374.00	147.00	205.00		240.00	22.00	134.00		205.00	147.00
Interquartile Range (IQR)	22.00 - 240.00	28.00 - 240.00	338.00 - 338.00	28.00 - 240.00	374.00 - 374.00	28.00 - 240.00	205.00 - 205.00		240.00 - 240.00	5.00 - 66.00	28.00 - 240.00		205.00 - 205.00	5.00 - 240.00
Range	5.00 - 374.00	22.00 - 374.00	338.00 - 338.00	22.00 - 338.00	374.00 - 374.00	28.00 - 240.00	205.00 - 205.00		240.00 - 240.00	5.00 - 66.00	28.00 - 240.00		205.00 - 205.00	5.00 - 240.00
95% CI	41.68 - 225.05	7.85 - 303.82	.	-38.05 - 315.65	.	-125.64 - 402.31	.		.	-47.20 - 109.20	1212.86 - 1480.86		.	-163.33 - 424.66
Leukocytes.														
n	68	29	23	29	23	20	28	2	5	29	14	14	21	28
Mean	10.67	7.48	14.39	7.63	9.29	9.03	11.22	5.00	5.46	14.17	5.97	12.10	13.38	7.87



Standard deviation	18.99	11.98	24.86	11.96	10.47	14.00	21.61	4.53	2.27	26.21	3.00	16.95	24.61	12.08
Standard error of the mean	2.30	2.22	5.18	2.22	2.18	3.13	4.08	3.20	1.01	4.87	0.80	4.53	5.37	2.28
Median	6.02	4.20	9.02	4.20	7.20	5.88	7.33	5.00	4.85	5.99	6.04	6.68	7.94	5.27
Interquartile Range (IQR)	3.56 - 9.80	3.20 - 7.45	4.70 - 11.00	3.40 - 7.94	4.30 - 10.50	3.60 - 8.99	3.46 - 10.75	1.80 - 8.20	3.80 - 6.20	2.25 - 11.27	3.40 - 8.20	4.79 - 10.50	4.70 - 11.20	3.31 - 8.84
Range	0.25 - 118.00	0.25 - 67.05	0.60 - 118.00	0.25 - 67.05	0.60 - 50.00	1.70 - 67.05	0.25 - 118.00	1.80 - 8.20	3.41 - 9.02	0.25 - 118.00	1.70 - 11.20	1.32 - 67.05	0.60 - 118.00	0.25 - 67.05
95% CI	6.07 - 15.26	2.93 - 12.04	3.64 - 25.14	3.08 - 12.18	4.76 - 13.81	2.47 - 15.58	2.84 - 19.60	-35.66 - 45.66	2.64 - 8.27	4.20 - 24.14	4.23 - 7.70	2.32 - 21.89	2.18 - 24.58	3.19 - 12.55
Test result at index: Absolute neutrophil count (ANC).														
n	64	28	20	27	20	19	25	2	4	27	15	11	17	28
Mean	2885.74	2203.21	3929.00	2466.30	3231.00	3414.74	3087.09	2930.00	2172.50	2662.59	2977.16	3800.00	3173.37	3286.07
Standard deviation	2491.68	2001.47	2751.33	2284.61	2299.47	2291.27	2703.12	2503.16	1545.78	2482.88	2346.73	2222.83	2716.93	2408.48
Standard error of the mean	311.46	378.24	615.22	439.67	514.18	525.65	540.62	1770.00	772.89	477.83	605.92	670.21	658.95	455.16
Median	2200.00	1595.00	3660.00	1800.00	2835.00	2700.00	2570.00	2930.00	2385.00	2200.00	2400.00	3100.00	2500.00	3010.00
Interquartile Range (IQR)	1050.00 - 4150.00	1050.00 - 2650.00	1720.00 - 6260.00	1000.00 - 3200.00	1370.00 - 4975.00	1340.00 - 5100.00	800.00 - 4550.00	1160.00 - 4700.00	1150.00 - 3195.00	800.00 - 3500.00	1110.00 - 4700.00	1500.00 - 5920.00	1110.00 - 3900.00	1250.00 - 4900.00
Range	0.00 - 9400.00	30.00 - 8730.00	0.00 - 9400.00	30.00 - 8730.00	0.00 - 7400.00	100.00 - 7360.00	0.00 - 9400.00	1160.00 - 4700.00	100.00 - 3820.00	0.00 - 9400.00	7.35 - 7300.00	1100.00 - 7240.00	7.35 - 9400.00	0.00 - 7400.00
95% CI	2263.34 - 3508.14	1427.12 - 2979.30	2641.34 - 5216.66	1562.53 - 3370.06	2154.82 - 4307.18	2310.38 - 4519.09	1971.30 - 4202.89	2.0e+04 - 25419.98	-287.18 - 4632.18	1680.40 - 3644.79	1677.58 - 4276.73	2306.68 - 5293.32	1776.46 - 4570.29	2352.16 - 4219.98
Test result at index: Platelet cell count.														
n	66	25	23	26	23	19	28	2	4	27	14	14	20	29
Mean	5.3e+06	90145.16	1.5e+07	88062.65	1.5e+07	1.3e+05	1.2e+07	2.0e+05	1.1e+05	1.0e+05	1.1e+05	2.4e+07	1.7e+07	1.3e+05
Standard deviation	4.2e+07	89305.28	7.1e+07	87810.10	7.1e+07	1.2e+05	6.4e+07	20506.10	87595.19	1.2e+05	82337.72	9.1e+07	7.6e+07	1.1e+05
Standard error of the mean	5.1e+06	17861.06	1.5e+07	17220.98	1.5e+07	26943.90	1.2e+07	14500.00	43797.59	23204.20	22005.68	2.4e+07	1.7e+07	21203.10

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Median	67500.0 0	50000.0 0	87000.0 0	47000.0 0	1.3e+05	68000.0 0	75500.00	2.0e+05	98000.0 0	40000.0 0	1.1e+05	71000.0 0	63500.0 0	87000.0 0
Interquartile Range (IQR)	29600.0 0 - 1.9e+05	33000.0 0 - 1.3e+05	31000.0 0 - 2.1e+05	29600.0 0 - 1.3e+05	40000.0 0 - 2.2e+05	29000.0 0 - 1.9e+05	30300.00 - 1.9e+05	1.9e+05 - 2.2e+05	42000.0 0 - 1.8e+05	20000.0 0 - 1.3e+05	29600.0 0 - 1.9e+05	44000.0 0 - 2.4e+05	24800.0 0 - 1.4e+05	31000.0 0 - 2.1e+05
Range	29.00 - 3.4e+08	29.00 - 3.7e+05	10000.0 0 - 3.4e+08	29.00 - 3.4e+05	10000.0 0 - 3.4e+08	29.00 - 4.1e+05	228.00 - 3.4e+08	1.9e+05 - 2.2e+05	20000.0 0 - 2.2e+05	5000.00 - 4.1e+05	29.00 - 2.4e+05	19000.0 0 - 3.4e+08	228.00 - 3.4e+08	29.00 - 4.1e+05
95% CI	- 5.0e+06 - 1.6e+07	53281.7 5 - 1.3e+05	- 1.6e+07 - 4.6e+07	52595.3 9 - 1.2e+05	- 1.6e+07 - 4.6e+07	71236.5 9 - 1.8e+05	- 1.3e+07 - 3.7e+07	16260.03 - 3.8e+05	- 3.0e+04 - 2.5e+05	54562.3 5 - 1.5e+05	63877.9 7 - 1.6e+05	- 2.8e+07 - 7.7e+07	- 1.8e+07 - 5.3e+07	89637.3 8 - 1.8e+05
Test result at index: Bilirubin.														
n	68	28	22	28	22	19	28	2	4	28	14	14	19	29
Mean	7.56	8.47	7.03	8.74	7.08	7.78	7.11	10.60	8.38	7.62	6.78	9.40	7.51	7.23
Standard deviation	3.79	3.92	2.91	3.87	2.88	3.66	3.96	0.48	2.85	4.08	3.38	3.68	3.86	4.05
Standard error of the mean	0.46	0.74	0.62	0.73	0.61	0.84	0.75	0.34	1.43	0.77	0.90	0.98	0.89	0.75
Median	6.92	8.55	6.84	8.55	6.84	8.55	6.84	10.60	8.72	6.84	6.93	9.23	5.99	6.84
Interquartile Range (IQR)	5.13 - 10.13	5.90 - 10.43	5.13 - 8.55	6.33 - 10.77	5.13 - 8.55	5.13 - 10.26	5.13 - 8.55	10.26 - 10.94	5.99 - 10.77	5.13 - 9.45	5.13 - 9.41	6.84 - 12.65	5.13 - 8.55	5.13 - 10.00
Range	0.58 - 18.81	1.71 - 18.81	3.42 - 17.10	1.71 - 18.81	3.42 - 17.10	1.71 - 15.73	0.58 - 18.81	10.26 - 10.94	5.13 - 10.94	1.71 - 18.81	0.58 - 11.97	3.42 - 15.73	3.25 - 17.10	0.58 - 18.81
95% CI	6.65 - 8.48	6.95 - 9.99	5.74 - 8.32	7.24 - 10.24	5.80 - 8.36	6.02 - 9.55	5.58 - 8.65	6.26 - 14.95	3.84 - 12.92	6.04 - 9.21	4.83 - 8.74	7.28 - 11.53	5.64 - 9.37	5.69 - 8.77
Test result at index: Bone marrow blast count.														
n	48	22	20	22	20	14	22	1	4	24	15	7	20	15
Mean	55.41	64.82	54.42	60.32	54.88	56.71	54.27	10.00	54.50	53.76	53.75	64.71	60.70	48.27
Standard deviation	34.27	29.35	37.26	31.38	37.76	32.40	35.75	.	38.32	36.87	31.38	32.62	33.23	36.06
Standard error of the mean	4.95	6.26	8.33	6.69	8.44	8.66	7.62	.	19.16	7.53	8.10	12.33	7.43	9.31
Median	62.50	71.00	67.00	66.00	67.00	60.00	62.50	10.00	62.50	70.50	52.00	65.00	74.50	49.00
Interquartile Range (IQR)	18.00 - 89.50	49.00 - 90.00	8.00 - 89.50	43.00 - 90.00	8.00 - 90.15	32.00 - 88.00	9.00 - 89.00	10.00 - 10.00	26.00 - 83.00	10.50 - 89.50	37.00 - 84.00	55.00 - 90.00	39.00 - 88.50	10.00 - 90.00
Range	0.00 - 99.00	10.00 - 99.00	2.00 - 95.00	0.00 - 94.00	2.00 - 99.00	2.00 - 93.00	2.00 - 99.00	10.00 - 10.00	3.00 - 90.00	2.00 - 95.00	2.00 - 99.00	0.00 - 93.00	2.00 - 99.00	2.00 - 95.00
95% CI	45.46 - 65.36	51.80 - 77.83	36.99 - 71.86	46.41 - 74.23	37.20 - 72.55	38.01 - 75.42	38.42 - 70.12	-	-6.47 - 115.47	38.19 - 69.33	36.37 - 71.13	34.55 - 94.88	45.15 - 76.25	28.30 - 68.23

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Test result at index: Total lymphocyte count.														
n	51	24	11	22	12	11	20	1	2	17	15	8	11	22
Mean	3.75	1.62	7.52	1.60	5.57	1.13	5.00	0.29	1.02	5.10	1.66	7.65	3.69	3.48
Standard deviation	9.39	1.46	14.58	1.46	13.27	0.91	10.91	.	1.03	12.01	1.63	15.95	6.10	9.77
Standard error of the mean	1.31	0.30	4.40	0.31	3.83	0.27	2.44	.	0.72	2.91	0.42	5.64	1.84	2.08
Median	1.32	1.19	1.87	1.18	2.04	0.80	1.62	0.29	1.02	0.86	1.32	2.40	1.75	1.35
Interquartile Range (IQR)	0.60 - 2.62	0.60 - 2.42	0.70 - 3.00	0.60 - 2.24	0.93 - 2.88	0.50 - 1.65	0.93 - 2.69	0.29 - 0.29	0.30 - 1.75	0.60 - 2.24	0.50 - 1.90	1.41 - 3.17	0.70 - 2.62	0.50 - 1.90
Range	0.10 - 47.60	0.21 - 6.72	0.10 - 47.60	0.21 - 6.72	0.10 - 47.60	0.29 - 3.35	0.10 - 47.03	0.29 - 0.29	0.30 - 1.75	0.10 - 47.60	0.20 - 6.72	0.21 - 47.03	0.10 - 21.30	0.29 - 47.03
95% CI	1.11 - 6.39	1.00 - 2.24	-2.27 - 17.32	0.95 - 2.24	-2.86 - 14.01	0.52 - 1.74	-0.10 - 10.11	. - .	-8.19 - 10.24	-1.07 - 11.28	0.76 - 2.56	-5.68 - 20.98	-0.41 - 7.79	-0.85 - 7.81
Test result at index: Alanine transaminase (ALT).														
n	66	29	22	29	22	19	28	2	4	26	15	14	19	29
Mean	37.82	41.07	38.18	39.69	38.18	41.21	37.29	57.00	24.25	41.23	26.20	51.00	30.16	46.45
Standard deviation	33.12	33.00	39.16	33.45	39.15	34.69	35.60	9.90	11.59	38.51	17.68	41.21	30.17	37.28
Standard error of the mean	4.08	6.13	8.35	6.21	8.35	7.96	6.73	7.00	5.79	7.55	4.56	11.01	6.92	6.92
Median	25.00	27.00	25.00	23.00	25.00	23.00	26.00	57.00	20.00	23.50	18.00	33.00	22.00	37.00
Interquartile Range (IQR)	17.00 - 45.00	17.00 - 51.00	20.00 - 37.00	17.00 - 51.00	19.00 - 37.00	17.00 - 57.00	17.50 - 41.50	50.00 - 64.00	16.50 - 32.00	17.00 - 57.00	14.00 - 41.00	25.00 - 51.00	16.00 - 27.00	19.00 - 56.00
Range	8.00 - 162.00	12.00 - 138.00	8.00 - 162.00	8.00 - 138.00	9.00 - 162.00	11.00 - 138.00	9.00 - 162.00	50.00 - 64.00	16.00 - 41.00	9.00 - 162.00	9.00 - 64.00	17.00 - 139.00	9.00 - 138.00	11.00 - 162.00
95% CI	29.68 - 45.96	28.52 - 53.62	20.82 - 55.55	26.97 - 52.41	20.82 - 55.54	24.49 - 57.93	23.48 - 51.09	-31.94 - 145.94	5.81 - 42.69	25.68 - 56.79	16.41 - 35.99	27.20 - 74.80	15.62 - 44.70	32.27 - 60.63
Test result at index: Aspartate aminotransferase (AST).														
n	50	22	14	22	14	14	18	1	3	22	11	8	16	17
Mean	34.94	30.68	37.86	28.73	37.64	32.29	35.28	41.00	25.67	37.82	27.36	27.88	33.56	34.65
Standard deviation	25.78	18.96	31.58	17.84	31.92	19.97	28.76	.	17.95	28.09	15.90	12.35	29.17	19.87
Standard error of the mean	3.65	4.04	8.44	3.80	8.53	5.34	6.78	.	10.37	5.99	4.79	4.36	7.29	4.82
Median	27.50	25.00	28.50	21.50	28.50	25.00	28.50	41.00	19.00	31.00	22.00	24.00	25.50	29.00



Interquartile Range (IQR)	20.00 - 43.00	19.00 - 45.00	21.00 - 41.00	19.00 - 34.00	16.00 - 41.00	19.00 - 45.00	16.00 - 41.00	41.00 - 41.00	12.00 - 46.00	21.00 - 45.00	12.00 - 43.00	19.50 - 30.50	15.50 - 36.50	21.00 - 43.00
Range	9.00 - 132.00	9.00 - 83.00	12.00 - 128.00	9.00 - 83.00	12.00 - 128.00	11.00 - 83.00	9.00 - 128.00	41.00 - 41.00	12.00 - 46.00	10.00 - 128.00	9.00 - 53.00	19.00 - 56.00	9.00 - 128.00	14.00 - 83.00
95% CI	27.61 - 42.27	22.28 - 39.09	19.62 - 56.09	20.82 - 36.64	19.21 - 56.07	20.75 - 43.82	20.97 - 49.58	. - .	-18.93 - 70.27	25.36 - 50.27	16.69 - 38.04	17.55 - 38.20	18.02 - 49.11	24.43 - 44.86
Test result at index: Alkaline phosphatase (ALP).														
n	61	26	20	25	21	15	28	1	3	25	15	13	17	28
Mean	121.39	109.92	150.00	113.76	150.52	105.47	132.75	72.00	151.67	149.80	105.40	99.38	115.65	133.46
Standard deviation	110.05	57.38	175.46	56.60	172.58	54.60	152.23	.	79.20	157.37	62.52	45.06	98.98	139.47
Standard error of the mean	14.09	11.25	39.23	11.32	37.66	14.10	28.77	.	45.73	31.47	16.14	12.50	24.01	26.36
Median	94.00	93.50	101.00	102.00	93.00	93.00	92.00	72.00	110.00	105.00	91.00	93.00	93.00	100.00
Interquartile Range (IQR)	70.00 - 129.00	63.00 - 155.00	78.50 - 129.00	80.00 - 155.00	78.00 - 129.00	78.00 - 105.00	66.50 - 117.50	72.00 - 72.00	102.00 - 243.00	81.00 - 131.00	63.00 - 110.00	78.00 - 110.00	66.00 - 114.00	78.00 - 127.50
Range	35.00 - 799.00	35.00 - 243.00	53.00 - 799.00	35.00 - 243.00	53.00 - 799.00	42.00 - 243.00	40.00 - 799.00	72.00 - 72.00	102.00 - 243.00	53.00 - 799.00	40.00 - 243.00	35.00 - 203.00	40.00 - 466.00	42.00 - 799.00
95% CI	93.21 - 149.58	86.75 - 133.10	67.88 - 232.12	90.40 - 137.12	71.97 - 229.08	75.23 - 135.70	73.72 - 191.78	. - .	-45.07 - 348.41	84.84 - 214.76	70.78 - 140.02	72.16 - 126.61	64.76 - 166.54	79.38 - 187.55
Test result at index: Gamma-glutamyltransferase (GGT).														
n	37	17	10	15	11	9	12	0	2	16	9	4	8	14
Mean	113.95	108.47	159.70	118.00	149.45	118.00	131.00		120.00	134.38	79.22	166.75	44.00	185.71
Standard deviation	183.27	107.34	319.58	111.03	305.08	123.96	295.72		73.54	257.75	103.30	109.88	44.28	275.87
Standard error of the mean	30.13	26.03	101.06	28.67	91.99	41.32	85.37	.	52.00	64.44	34.43	54.94	15.66	73.73
Median	47.00	47.00	34.50	48.00	37.00	37.00	27.50	.	120.00	40.50	27.00	175.50	23.00	45.50
Interquartile Range (IQR)	24.00 - 143.00	27.00 - 172.00	19.00 - 92.00	24.00 - 208.00	19.00 - 92.00	24.00 - 172.00	17.00 - 58.00	. - .	68.00 - 172.00	21.50 - 108.50	24.00 - 68.00	85.50 - 248.00	17.00 - 58.00	27.00 - 288.00
Range	11.00 - 1049.00	13.00 - 321.00	16.00 - 1049.00	13.00 - 321.00	16.00 - 1049.00	11.00 - 321.00	13.00 - 1049.00		68.00 - 172.00	16.00 - 1049.00	13.00 - 321.00	28.00 - 288.00	13.00 - 143.00	11.00 - 1049.00
95% CI	52.84 - 175.05	53.28 - 163.66	-68.92 - 388.32	56.51 - 179.49	-55.50 - 354.41	22.71 - 213.29	-56.89 - 318.89	. - .	-540.72 - 780.72	-2.97 - 271.72	-0.18 - 158.63	-8.09 - 341.59	6.98 - 81.02	26.43 - 345.00
Test result at index: Lactate Dehydrogenase (LDH).														
n	63	27	22	25	23	15	28	1	4	26	15	12	19	26



Mean	519.97	500.70	518.73	519.68	419.70	641.00	490.04	288.00	1083.25	616.54	418.20	504.42	542.89	530.42
Standard deviation	514.02	544.49	479.39	562.16	312.27	685.35	449.00	.	1059.02	600.78	567.77	385.40	551.47	523.32
Standard error of the mean	64.76	104.79	102.21	112.43	65.11	176.96	84.85	.	529.51	117.82	146.60	111.26	126.52	102.63
Median	315.00	286.00	370.50	286.00	315.00	359.00	312.50	288.00	947.50	359.50	230.00	426.50	281.00	337.00
Interquartile Range (IQR)	189.00 - 612.00	164.00 - 519.00	189.00 - 639.00	164.00 - 519.00	176.00 - 553.00	177.00 - 1286.00	182.50 - 625.50	288.00 - 288.00	202.00 - 1964.50	177.00 - 1050.00	158.00 - 436.00	233.00 - 551.50	176.00 - 738.00	205.00 - 553.00
Range	96.00 - 2315.00	96.00 - 2315.00	115.00 - 2151.00	96.00 - 2315.00	115.00 - 1120.00	118.00 - 2315.00	96.00 - 2151.00	288.00 - 288.00	123.00 - 2315.00	110.00 - 2151.00	96.00 - 2315.00	205.00 - 1614.00	96.00 - 2151.00	118.00 - 2315.00
95% CI	390.51 - 649.42	285.31 - 716.09	306.18 - 731.28	287.63 - 751.73	284.66 - 554.73	261.47 - 1020.53	315.93 - 664.14	.	-601.89 - 2768.39	373.88 - 859.20	103.78 - 732.62	259.55 - 749.29	277.09 - 808.70	319.05 - 741.80
Test result at index: CD22 expression.														
n	6	4	0	4	0	4	0	0	0	2	3	1	1	3
Mean	78.08	90.00		90.00		90.00				52.50	97.17	72.00	72.00	96.00
Standard deviation	35.39	12.44		12.44		12.44				61.52	4.48	.	.	4.00
Standard error of the mean	14.45	6.22	.	6.22	.	6.22	.	.	.	43.50	2.59	.	.	2.31
Median	94.00	94.00	.	94.00	.	94.00	.	.	.	52.50	99.50	72.00	72.00	96.00
Interquartile range (IQR)	72.00 - 99.50	82.00 - 98.00	.	82.00 - 98.00	.	82.00 - 98.00	.	.	.	9.00 - 96.00	92.00 - 100.00	72.00 - 72.00	72.00 - 72.00	92.00 - 100.00
Range	9.00 - 100.00	72.00 - 100.00		72.00 - 100.00		72.00 - 100.00				9.00 - 96.00	92.00 - 100.00	72.00 - 72.00	72.00 - 72.00	92.00 - 100.00
95% CI	40.94 - 115.23	70.21 - 109.79	.	70.21 - 109.79	.	70.21 - 109.79	.	.	.	-500.22 - 605.22	86.03 - 108.30	.	.	86.06 - 105.94
Test result at index: CD22 expression not known., n (%)														
n	5	5	0	5	0	1	0	0	1	3	1	1	0	1
Not known	5 (100.00 %)	5 (100.00 %)	0 (.)	5 (100.00 %)	0 (.)	1 (100.00 %)	0 (.)	0 (.)	1 (100.00 %)	3 (100.00 %)	1 (100.00 %)	1 (100.00 %)	0 (.)	1 (100.00 %)
CD22 positive (20%+), n (%)														
n	6	4	0	4	0	4	0	0	0	2	3	1	1	3
Negative	1 (16.67 %)	0 (0.00%)	0 (.)	0 (0.00%)	0 (.)	0 (0.00%)	0 (.)	0 (.)	0 (.)	1 (50.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)



Positive	5 (83.33%)	4 (100.00%)	0 (0.00%)	4 (100.00%)	0 (0.00%)	4 (100.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (50.00%)	3 (100.00%)	1 (100.00%)	1 (100.00%)	3 (100.00%)
Test result at index: CD19 expression.														
n	9	4	1	4	1	4	1	0	0	4	2	3	0	6
Mean	50.16	78.25	0.00	78.25	0.00	60.75	7.26			36.00	99.00	36.49		42.08
Standard deviation	47.36	42.18	.	42.18	.	44.60	.			43.75	1.41	55.06		45.09
Standard error of the mean	15.79	21.09	.	21.09	.	22.30	.	.	.	21.87	1.00	31.79	.	18.41
Median	30.00	99.00	0.00	99.00	0.00	64.00	7.26	.	.	22.50	99.00	7.26	.	22.50
Interquartile Range (IQR)	7.26 - 99.00	56.50 - 100.00	0.00 - 0.00	56.50 - 100.00	0.00 - 0.00	22.50 - 99.00	7.26 - 7.26	.	.	7.50 - 64.50	98.00 - 100.00	2.20 - 100.00	.	7.26 - 98.00
Range	0.00 - 100.00	15.00 - 100.00	0.00 - 0.00	15.00 - 100.00	0.00 - 0.00	15.00 - 100.00	7.26 - 7.26			0.00 - 99.00	98.00 - 100.00	100.00 - 100.00		2.20 - 100.00
95% CI	13.76 - 86.56	11.14 - 145.36	.	11.14 - 145.36	.	-10.21 - 131.71	.	.	.	-33.61 - 105.61	86.29 - 111.71	-100.30 - 173.27	.	-5.24 - 89.39
Test result at index: CD19 expression not known., n (%)														
n	6	5	1	5	1	2	0	0	1	4	2	0	0	2
Not known	6 (100.00%)	5 (100.00%)	1 (100.00%)	5 (100.00%)	1 (100.00%)	2 (100.00%)	0 (0.00%)	0 (0.00%)	1 (100.00%)	4 (100.00%)	2 (100.00%)	0 (0.00%)	0 (0.00%)	2 (100.00%)
Test result at index: CD3+ count.														
n	12	7	3	7	3	4	3	0	1	4	4	4	2	5
Mean	4603.63	1155.37	1626.33	1155.37	1626.33	915.58	14538.42		470.00	1348.25	681.64	11781.00	1052.63	9079.86
Standard deviation	11650.47	998.06	482.66	998.06	482.66	517.65	23375.96		.	649.22	622.93	19838.21	1293.11	18133.63
Standard error of the mean	3363.20	377.23	278.67	377.23	278.67	258.83	13496.12	.	.	324.61	311.46	9919.11	914.37	8109.61
Median	1326.15	560.00	1838.00	560.00	1838.00	807.00	1967.00	.	470.00	1456.00	505.00	2423.50	1052.63	1074.00
Interquartile Range (IQR)	550.00 - 1944.00	470.00 - 1921.00	1074.00 - 1967.00	470.00 - 1921.00	1074.00 - 1967.00	505.00 - 1326.15	138.26 - 41510.00	.	470.00 - 470.00	817.00 - 1879.50	304.13 - 1059.15	1367.00 - 22195.00	138.26 - 1967.00	767.00 - 1578.30
Range	138.26 - 41510.00	138.26 - 2880.00	1074.00 - 1967.00	138.26 - 2880.00	1074.00 - 1967.00	470.00 - 1578.30	138.26 - 41510.00		470.00 - 470.00	560.00 - 1921.00	138.26 - 1578.30	767.00 - 41510.00	138.26 - 1967.00	470.00 - 41510.00

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	- 2798.73 -						- 4.4e+0 4 - 72607. 53					- 2.0e+04 -	- 1.1e+04 -	- 1.3e+04 -
95% CI	12005.9 9	232.31 - 2078.42	427.33 - 2825.34	232.31 - 2078.42	427.33 - 2825.34	91.87 - 1739.28				315.20 - 2381.30	-309.58 -	43348.0 2	12670.8 0	31595.7 4
Test result at index: CD4+ count.														
n	10	6	2	6	2	2	3	0	1	3	3	4	2	3
Mean	2058.43	365.72	923.00	365.72	923.00	255.00	5881.4 5		290.00	402.00	203.45	4692.00	762.17	5611.33
Standard deviation	4955.20	251.08	708.52	251.08	708.52	49.50	8891.5 1		.	119.26	95.90	7629.82	935.96	9101.02
Standard error of the mean	1566.97	102.50	501.00	102.50	501.00	35.00	5133.5 2	.	.	68.86	55.37	3814.91	661.82	5254.48
Median	423.00	282.00	923.00	282.00	923.00	255.00	1424.0 0	.	290.00	422.00	220.00	1112.00	762.17	424.00
Interquartile Range (IQR)	274.00 - 800.00	220.00 - 510.00	422.00 - 1424.00	220.00 - 510.00	422.00 - 1424.00	220.00 - 290.00	100.35 - 16120. 00		290.00 - 290.00	274.00 - 510.00	100.35 - 290.00	612.00 - 8772.00	100.35 - 1424.00	290.00 - 16120.0 0
Range	100.35 - 16120.0 0	100.35 - 800.00	422.00 - 1424.00	100.35 - 800.00	422.00 - 1424.00	220.00 - 290.00	100.35 - 16120. 00		290.00 - 290.00	274.00 - 510.00	100.35 - 290.00	424.00 - 16120.0 0	100.35 - 1424.00	290.00 - 16120.0 0
95% CI	- 1486.30 -		- 5442.81 -		- 5442.81 -		1.6e+0 4 - 27969. 18					7448.75 -	- 7647.11 -	- 1.7e+04 -
Test result at index: CD8+ count.	5603.17	102.23 - 629.22	7288.81	102.23 - 629.22	7288.81	-189.72 - 699.72				105.73 - 698.27	-34.78 - 441.68	16832.7 5	9171.46	28219.5 2
n	10	6	2	6	2	2	3	0	1	3	3	4	2	3
Mean	3020.24	692.07	860.00	692.07	860.00	230.00	8141.8 2		160.00	989.00	164.48	6685.50	222.72	8163.33
Standard deviation	7397.00	865.17	633.57	865.17	633.57	98.99	13717. 57		.	798.79	133.33	11554.9 3	267.68	13697.9 6
Standard error of the mean	2339.14	353.20	448.00	353.20	448.00	70.00	7919.8 5	.	.	461.18	76.98	5777.46	189.27	7908.52
Median	381.00	230.00	860.00	230.00	860.00	230.00	412.00	.	160.00	1308.00	160.00	1206.00	222.72	350.00
Interquartile Range (IQR)	160.00 - 1579.00	80.00 - 1579.00	412.00 - 1308.00	80.00 - 1579.00	412.00 - 1308.00	160.00 - 300.00	33.45 - 23980. 00		160.00 - 160.00	80.00 - 1579.00	33.45 - 300.00	381.00 - 12990.0 0	33.45 - 412.00	160.00 - 23980.0 0
Range	33.45 - 23980.0 0	33.45 - 2000.00	412.00 - 1308.00	33.45 - 2000.00	412.00 - 1308.00	160.00 - 300.00	33.45 - 23980. 00		160.00 - 160.00	80.00 - 1579.00	33.45 - 300.00	350.00 - 23980.0 0	33.45 - 412.00	160.00 - 23980.0 0



	-	-	-	-	-	-	-	-	-	-	-	-	-
	2271.25	-215.86	4832.38	-215.86	4832.38	-659.43	2.6e+04			-995.31		1.2e+04	-
	-	-	-	-	-	-	4 -			-	-166.73	-	2182.24
95% CI	8311.74	1600.01	6552.38	1600.01	6552.38	1119.43	42218.16	-	-	2973.31	-495.70	25071.97	42190.96

For those whose MRD status at CAR-T infusion was negative, 94.3% had their absolute neutrophil count test results available after InO prior to CAR-T (please see **Table 33** below). For those whose MRD status at the last cycle of InO was negative, 100% had their bilirubin bone marrow blast count test results available after InO, prior to CAR-T (please see **Table 33** below).

Table 33: Laboratory Test Results Available after InO, Prior to CAR-T

Test results available after InO, prior to CAR-T	Overall	MRD status (1st cycle of InO)		MRD status (last cycle of InO)		MRD status (CAR-T infusion)		MRD status (prior to HPSCt)		BMI at index (initiation of InO)			InO received:	
	Total	Positive	Negative	Positive	Negative	Positive	Negative	Positive	Negative	(18.5, 25)	(25, 30)	30+	Pre-apheresis	Post-apheresis
n	84	37	27	35	28	26	35	3	6	34	22	15	29	34
Haemoglobin	77 (91.67%)	33 (89.19%)	27 (100.00%)	31 (88.57%)	28 (100.00%)	22 (84.62%)	34 (97.14%)	3 (100.00%)	6 (100.00%)	32 (94.12%)	19 (86.36%)	13 (86.67%)	27 (93.10%)	29 (85.29%)
Thrombocytes	14 (16.67%)	8 (21.62%)	2 (7.41%)	7 (20.00%)	2 (7.14%)	4 (15.38%)	2 (5.71%)	0 (0.00%)	1 (16.67%)	5 (14.71%)	3 (13.64%)	0 (0.00%)	3 (10.34%)	3 (8.82%)
Leukocytes	74 (88.10%)	32 (86.49%)	27 (100.00%)	31 (88.57%)	28 (100.00%)	21 (80.77%)	33 (94.29%)	2 (66.67%)	6 (100.00%)	32 (94.12%)	18 (81.82%)	13 (86.67%)	27 (93.10%)	27 (79.41%)
Absolute neutrophil count (ANC)	72 (85.71%)	30 (81.08%)	27 (100.00%)	28 (80.00%)	28 (100.00%)	20 (76.92%)	33 (94.29%)	3 (100.00%)	6 (100.00%)	30 (88.24%)	19 (86.36%)	11 (73.33%)	26 (89.66%)	27 (79.41%)
Platelet cell count	71 (84.52%)	28 (75.68%)	26 (96.30%)	27 (77.14%)	27 (96.43%)	21 (80.77%)	32 (91.43%)	3 (100.00%)	5 (83.33%)	29 (85.29%)	17 (77.27%)	13 (86.67%)	25 (86.21%)	29 (85.29%)
Bilirubin	77 (91.67%)	33 (89.19%)	27 (100.00%)	31 (88.57%)	28 (100.00%)	23 (88.46%)	33 (94.29%)	3 (100.00%)	6 (100.00%)	32 (94.12%)	19 (86.36%)	13 (86.67%)	27 (93.10%)	29 (85.29%)
Bone marrow blast count	47 (55.95%)	26 (70.27%)	18 (66.67%)	25 (71.43%)	18 (64.29%)	15 (57.69%)	21 (60.00%)	0 (0.00%)	4 (66.67%)	26 (76.47%)	13 (59.09%)	6 (40.00%)	23 (79.31%)	12 (35.29%)
Total lymphocyte count	57 (67.86%)	28 (75.68%)	14 (51.85%)	27 (77.14%)	14 (50.00%)	15 (57.69%)	21 (60.00%)	2 (66.67%)	4 (66.67%)	21 (61.76%)	16 (72.73%)	7 (46.67%)	16 (55.17%)	21 (61.76%)



Alanine transaminase (ALT)	74 (88.10%)	33 (89.19%)	27 (100.00%)	32 (91.43%)	28 (100.00%)	21 (80.77%)	34 (97.14%)	2 (66.67%)	6 (100.00%)	30 (88.24%)	20 (90.91%)	13 (86.67%)	27 (93.10%)	28 (82.35%)
Aspartate aminotransferase (AST)	60 (71.43%)	27 (72.97%)	20 (74.07%)	25 (71.43%)	21 (75.00%)	18 (69.23%)	25 (71.43%)	2 (66.67%)	4 (66.67%)	26 (76.47%)	17 (77.27%)	7 (46.67%)	23 (79.31%)	20 (58.82%)
Alkaline phosphatase (ALP)	69 (82.14%)	30 (81.08%)	26 (96.30%)	29 (82.86%)	27 (96.43%)	17 (65.38%)	33 (94.29%)	2 (66.67%)	5 (83.33%)	29 (85.29%)	19 (86.36%)	12 (80.00%)	24 (82.76%)	27 (79.41%)
Gamma-glutamyltransferase (GGT)	49 (58.33%)	23 (62.16%)	17 (62.96%)	20 (57.14%)	18 (64.29%)	12 (46.15%)	19 (54.29%)	1 (33.33%)	4 (66.67%)	22 (64.71%)	14 (63.64%)	3 (20.00%)	17 (58.62%)	14 (41.18%)
Lactate Dehydrogenase (LDH)	73 (86.90%)	34 (91.89%)	24 (88.89%)	31 (88.57%)	26 (92.86%)	22 (84.62%)	31 (88.57%)	2 (66.67%)	6 (100.00%)	32 (94.12%)	19 (86.36%)	12 (80.00%)	27 (93.10%)	27 (79.41%)
CD22 expression	11 (13.10%)	11 (29.73%)	0 (0.00%)	11 (31.43%)	0 (0.00%)	7 (26.92%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	6 (17.65%)	3 (13.64%)	2 (13.33%)	3 (10.34%)	3 (8.82%)
CD19 expression	12 (14.29%)	11 (29.73%)	1 (3.70%)	11 (31.43%)	1 (3.57%)	7 (26.92%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	7 (20.59%)	3 (13.64%)	2 (13.33%)	2 (6.90%)	4 (11.76%)
CD3+ count	11 (13.10%)	6 (16.22%)	5 (18.52%)	6 (17.14%)	5 (17.86%)	3 (11.54%)	5 (14.29%)	0 (0.00%)	0 (0.00%)	8 (23.53%)	2 (9.09%)	1 (6.67%)	6 (20.69%)	2 (5.88%)
CD4+ count	6 (7.14%)	4 (10.81%)	2 (7.41%)	4 (11.43%)	2 (7.14%)	2 (7.69%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	5 (14.71%)	1 (4.55%)	0 (0.00%)	2 (6.90%)	1 (2.94%)
CD8+ count	6 (7.14%)	4 (10.81%)	2 (7.41%)	4 (11.43%)	2 (7.14%)	2 (7.69%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	5 (14.71%)	1 (4.55%)	0 (0.00%)	2 (6.90%)	1 (2.94%)
Not known/Not recorded	2 (2.38%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.85%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	0 (0.00%)	1 (6.67%)	0 (0.00%)	2 (5.88%)
Test result after last dose of InO: Haemoglobin.														
n	77	33	27	31	28	22	34	3	6	32	19	13	27	29
Mean	14.45	7.13	12.13	7.21	12.33	7.19	11.04	7.54	9.13	21.94	9.07	12.74	12.04	22.15
Standard deviation	49.70	2.90	12.50	2.66	12.21	4.01	11.40	7.34	4.86	76.19	3.06	18.20	12.60	80.25
Standard error of the mean	5.66	0.51	2.40	0.48	2.31	0.85	1.96	4.24	1.99	13.47	0.70	5.05	2.43	14.90
Median	7.70	6.83	10.00	7.26	10.60	7.36	9.75	5.46	8.90	8.05	9.00	8.80	11.10	7.26
Interquartile Range (IQR)	5.52 - 11.10	5.46 - 8.90	7.70 - 12.70	5.59 - 8.90	8.91 - 12.65	4.59 - 9.80	6.27 - 12.60	1.46 - 15.70	7.45 - 13.90	5.71 - 12.60	6.14 - 11.50	6.27 - 10.10	7.70 - 12.60	5.52 - 9.80
Range	1.15 - 439.00	1.46 - 13.20	1.52 - 72.61	1.15 - 13.20	1.52 - 72.61	1.15 - 15.70	1.49 - 72.61	1.46 - 15.70	1.15 - 14.50	1.49 - 439.00	4.96 - 15.70	1.15 - 72.61	1.15 - 72.61	1.46 - 439.00

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95% CI	3.17 - 25.73	6.10 - 8.16	7.19 - 17.07	6.24 - 8.19	7.59 - 17.06	5.41 - 8.97	7.06 - 15.02	-10.71 - 25.79	4.03 - 14.24	-5.53 - 49.41	7.60 - 10.55	1.74 - 23.74	7.05 - 17.02	-8.37 - 52.68
Test result after last dose of InO: Thrombocytes.														
n	14	8	2	7	2	4	2	0	1	5	3	0	3	3
Mean	59.43	60.38	111.50	49.29	163.50	52.50	26.00		19.00	22.40	33.67		32.33	43.67
Standard deviation	80.21	91.07	96.87	58.87	170.41	38.00	11.31		.	16.07	12.86		13.58	55.29
Standard error of the mean	21.44	32.20	68.50	22.25	120.50	19.00	8.00	.	.	7.19	7.42	.	7.84	31.92
Median	33.00	33.00	111.50	32.00	163.50	42.00	26.00	.	19.00	18.00	39.00	.	34.00	19.00
Interquartile Range (IQR)	12.00 - 45.00	18.50 - 42.00	43.00 - 180.00	18.00 - 45.00	43.00 - 284.00	29.00 - 76.00	18.00 - 34.00	..	19.00 - 19.00	12.00 - 32.00	19.00 - 43.00	..	18.00 - 45.00	5.00 - 107.00
Range	2.00 - 284.00	12.00 - 284.00	43.00 - 180.00	12.00 - 180.00	43.00 - 284.00	19.00 - 107.00	18.00 - 34.00		19.00 - 19.00	5.00 - 45.00	19.00 - 43.00		18.00 - 45.00	5.00 - 107.00
95% CI	13.12 - 105.74	-15.76 - 136.51	-758.88 - 981.88	-5.16 - 103.73	-1367.60 - 1694.60	-7.96 - 112.96	-75.65 - 127.65	..	..	2.44 - 42.36	1.73 - 65.61	..	-1.39 - 66.06	-93.69 - 181.02
Test result after last dose of InO: Leukocytes.														
n	74	32	27	31	28	21	33	2	6	32	18	13	27	27
Mean	3.42	3.26	3.91	3.21	3.98	3.95	3.60	3.90	4.17	3.51	3.15	3.40	3.61	3.85
Standard deviation	2.58	2.47	2.86	2.50	2.83	2.63	2.35	2.55	4.17	2.67	2.74	1.95	2.41	2.53
Standard error of the mean	0.30	0.44	0.55	0.45	0.53	0.57	0.41	1.80	1.70	0.47	0.65	0.54	0.46	0.49
Median	3.10	2.73	3.19	2.70	3.50	3.35	3.48	3.90	2.95	3.15	2.92	3.76	3.72	3.30
Interquartile Range (IQR)	1.55 - 4.60	1.44 - 4.27	1.78 - 5.29	1.32 - 4.65	1.84 - 4.95	2.30 - 5.59	1.78 - 4.60	2.10 - 5.70	1.40 - 5.56	1.61 - 4.99	1.18 - 3.89	1.68 - 4.50	1.67 - 4.60	2.10 - 5.59
Range	0.28 - 11.86	0.28 - 9.80	0.28 - 11.86	0.28 - 9.80	0.28 - 11.86	0.28 - 10.52	0.28 - 11.86	2.10 - 5.70	0.28 - 11.86	0.28 - 10.52	0.28 - 11.86	0.49 - 7.51	0.49 - 11.86	0.28 - 10.52
95% CI	2.82 - 4.02	2.37 - 4.15	2.78 - 5.04	2.30 - 4.13	2.88 - 5.07	2.75 - 5.15	2.77 - 4.43	-18.97 - 26.77	-0.21 - 8.54	2.55 - 4.48	1.78 - 4.51	2.22 - 4.57	2.66 - 4.57	2.84 - 4.85
Test result after last dose of InO: Absolute neutrophil count (ANC).														
n	72	30	27	28	28	20	33	3	6	30	19	11	26	27
Mean	1635.80	1648.33	1964.64	1329.48	2091.07	2261.00	1813.70	3413.33	1743.33	1800.00	1359.07	1822.73	1978.55	1978.89
Standard deviation	1571.99	1603.77	1696.80	1410.42	1631.27	2020.91	1372.22	2272.12	1820.82	1805.32	1280.91	1181.97	1578.51	1738.74

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Standard error of the mean	185.26	292.81	326.55	266.55	308.28	451.89	238.87	1311.81	743.35	329.61	293.86	356.38	309.57	334.62
Median	1200.00	1250.00	1670.00	1000.00	1985.00	1770.00	1670.00	2500.00	1295.00	1250.00	1200.00	1400.00	1985.00	1400.00
Interquartile Range (IQR)	450.00 - 2500.00	410.00 - 2000.00	600.00 - 2780.00	300.00 - 1850.00	720.00 - 2845.00	860.00 - 2830.00	600.00 - 2520.00	1740.00 - 6000.00	800.00 - 1870.00	300.00 - 2400.00	410.00 - 2000.00	800.00 - 2780.00	520.00 - 2500.00	780.00 - 2600.00
Range	0.00 - 7100.00	0.00 - 6000.00	5.40 - 7100.00	0.00 - 5300.00	30.00 - 7100.00	0.00 - 7100.00	2.20 - 5200.00	1740.00 - 6000.00	0.00 - 5200.00	0.00 - 7100.00	0.00 - 5200.00	400.00 - 3800.00	2.20 - 5300.00	0.00 - 7100.00
95% CI	1266.40 - 2005.20	1049.47 - 2247.19	1293.41 - 2635.88	782.57 - 1876.38	1458.53 - 2723.61	1315.19 - 3206.81	1327.14 - 2300.27	2230.93 - 9057.59	-167.50 - 3654.17	1125.88 - 2474.12	741.69 - 1976.45	1028.67 - 2616.78	1340.97 - 2616.12	1291.07 - 2666.71
Test result after last dose of InO: Platelet cell count.														
n	71	28	26	27	27	21	32	3	5	29	17	13	25	29
Mean	95043.65	95322.89	1.2e+05	77779.30	1.3e+05	90525.76	1.2e+05	1.8e+05	1.1e+05	78206.90	1.1e+05	1.0e+05	1.1e+05	1.0e+05
Standard deviation	90225.75	98850.11	81640.20	70291.78	98333.30	82193.01	95492.19	1.5e+05	76103.22	70482.21	1.0e+05	84422.17	94203.68	89225.01
Standard error of the mean	10707.83	18680.91	16010.96	13527.66	18924.25	17935.99	16880.79	84200.82	34034.39	13088.22	24785.91	23414.50	18840.74	16568.67
Median	64000.00	57000.00	1.2e+05	51000.00	1.2e+05	68000.00	96500.00	2.1e+05	1.4e+05	68000.00	64000.00	75000.00	69000.00	1.0e+05
Interquartile Range (IQR)	15000.00 - 1.6e+05	25500.00 - 1.4e+05	55000.00 - 1.7e+05	16000.00 - 1.3e+05	40000.00 - 1.8e+05	23000.00 - 1.5e+05	31500.00 - 1.8e+05	23000.00 - 3.1e+05	43000.00 - 1.7e+05	13000.00 - 1.2e+05	19000.00 - 1.7e+05	50000.00 - 1.4e+05	40000.00 - 1.7e+05	19000.00 - 1.5e+05
Range	41.00 - 3.6e+05	41.00 - 3.6e+05	3000.00 - 3.0e+05	41.00 - 2.5e+05	3000.00 - 3.6e+05	41.00 - 3.1e+05	58.00 - 3.6e+05	23000.00 - 3.1e+05	12000.00 - 1.8e+05	3000.00 - 2.2e+05	41.00 - 3.6e+05	6000.00 - 3.0e+05	58.00 - 3.6e+05	41.00 - 3.1e+05
95% CI	73687.56 - 1.2e+05	56992.82 - 1.3e+05	83832.50 - 1.5e+05	49972.79 - 1.1e+05	88952.49 - 1.7e+05	53111.95 - 1.3e+05	81541.96 - 1.5e+05	1.8e+05 - 5.4e+05	13705.37 - 2.0e+05	51396.90 - 1.1e+05	55050.28 - 1.6e+05	53522.66 - 1.6e+05	66596.95 - 1.4e+05	68820.65 - 1.4e+05
Test result after last dose of InO: Bilirubin.														
n	77	33	27	31	28	23	33	3	6	32	19	13	27	29
Mean	10.54	10.55	12.15	11.12	12.26	11.17	10.77	6.70	12.79	11.18	10.33	11.84	12.87	8.99
Standard deviation	8.35	6.95	10.61	6.94	10.37	7.92	9.87	4.52	7.07	9.60	7.28	8.44	11.44	5.80
Standard error of the mean	0.95	1.21	2.04	1.25	1.96	1.65	1.72	2.61	2.89	1.70	1.67	2.34	2.20	1.08
Median	8.55	8.55	10.26	10.26	10.26	8.55	8.55	8.55	11.71	8.55	8.55	11.90	10.26	8.55



Interquartile Range (IQR)	5.99 - 11.97	5.99 - 13.68	6.84 - 13.17	5.99 - 14.00	6.84 - 12.57	5.99 - 14.00	6.67 - 11.97	1.55 - 10.00	8.55 - 14.00	6.84 - 13.68	5.99 - 11.97	6.84 - 14.00	6.84 - 13.68	4.96 - 11.97
Range	1.55 - 58.14	1.55 - 35.91	3.42 - 58.14	1.71 - 35.91	3.42 - 58.14	1.55 - 35.91	1.71 - 58.14	1.55 - 10.00	5.13 - 25.65	1.71 - 58.14	1.71 - 29.07	3.42 - 35.91	3.42 - 58.14	1.55 - 25.65
95% CI	8.65 - 12.44	8.09 - 13.02	7.95 - 16.34	8.57 - 13.67	8.24 - 16.28	7.74 - 14.59	7.28 - 14.27	-4.53 - 17.93	5.37 - 20.21	7.72 - 14.64	6.82 - 13.84	6.74 - 16.95	8.34 - 17.40	6.78 - 11.19
Test result after last dose of InO: Bone marrow blast count.														
n	47	26	18	25	18	15	21	0	4	26	13	6	23	12
Mean	19.66	31.42	2.22	32.68	2.22	21.33	3.43		13.62	21.96	13.04	22.08	5.59	20.38
Standard deviation	30.51	35.65	4.65	35.79	4.65	32.85	6.23		24.93	35.08	18.87	33.97	16.06	31.94
Standard error of the mean	4.45	6.99	1.10	7.16	1.10	8.48	1.36	.	12.47	6.88	5.23	13.87	3.35	9.22
Median	2.00	11.00	0.50	19.00	0.50	1.50	0.00	.	1.75	1.50	3.00	1.25	1.00	3.00
Interquartile Range (IQR)	0.00 - 41.00	1.00 - 69.00	0.00 - 3.00	1.00 - 69.00	0.00 - 3.00	1.00 - 51.00	0.00 - 3.00	.-.	0.75 - 26.50	0.00 - 41.00	1.50 - 19.00	0.00 - 54.00	0.00 - 3.00	0.50 - 35.50
Range	0.00 - 96.00	0.00 - 96.00	0.00 - 20.00	0.00 - 96.00	0.00 - 20.00	0.00 - 86.00	0.00 - 20.00		0.00 - 51.00	0.00 - 96.00	0.00 - 54.00	0.00 - 76.00	0.00 - 76.00	0.00 - 86.00
95% CI	10.70 - 28.62	17.03 - 45.82	-0.09 - 4.53	17.91 - 47.45	-0.09 - 4.53	3.14 - 39.53	0.59 - 6.27	.-.	-26.05 - 53.30	7.79 - 36.13	1.64 - 24.44	-13.56 - 57.73	-1.36 - 12.53	0.08 - 40.67
Test result after last dose of InO: Bone marrow blast count, n (%)														
n	47	26	18	25	18	15	21	0	4	26	13	6	23	12
<5%	31 (65.96%)	13 (50.00%)	17 (94.44%)	12 (48.00%)	17 (94.44%)	10 (66.67%)	18 (85.71%)	0 (%)	3 (75.00%)	18 (69.23%)	8 (61.54%)	4 (66.67%)	20 (86.96%)	8 (66.67%)
>5%	16 (34.04%)	13 (50.00%)	1 (5.56%)	13 (52.00%)	1 (5.56%)	5 (33.33%)	3 (14.29%)	0 (%)	1 (25.00%)	8 (30.77%)	5 (38.46%)	2 (33.33%)	3 (13.04%)	4 (33.33%)
Test result after last dose of InO: Total lymphocyte count.														
n	56	28	14	27	14	15	20	2	4	21	15	7	15	21
Mean	2.67	1.01	0.77	0.84	1.08	0.99	5.82	2.08	1.34	0.91	7.37	0.71	7.56	0.87
Standard deviation	13.27	1.04	0.75	0.75	1.01	0.99	22.18	2.61	1.21	0.78	25.64	0.49	25.59	0.93
Standard error of the mean	1.77	0.20	0.20	0.14	0.27	0.25	4.96	1.84	0.61	0.17	6.62	0.19	6.61	0.20

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Median	0.50	0.60	0.63	0.50	0.83	0.98	0.63	2.08	1.08	0.76	0.50	0.48	0.91	0.50
Interquartile Range (IQR)	0.30 - 1.26	0.30 - 1.29	0.30 - 1.10	0.34 - 1.27	0.30 - 1.25	0.24 - 1.40	0.23 - 1.42	0.24 - 3.93	0.48 - 2.21	0.30 - 1.30	0.20 - 1.20	0.34 - 1.25	0.25 - 1.60	0.24 - 1.06
Range	0.00 - 100.00	0.00 - 3.93	0.05 - 3.01	0.00 - 3.20	0.05 - 3.35	0.00 - 3.93	0.05 - 100.00	0.24 - 3.93	0.20 - 3.01	0.00 - 3.20	0.00 - 100.00	0.10 - 1.40	0.00 - 100.00	0.00 - 3.93
95% CI	-0.88 - 6.23	0.61 - 1.42	0.34 - 1.21	0.54 - 1.13	0.49 - 1.66	0.45 - 1.54	-4.57 - 16.20	-21.36 - 25.53	-0.59 - 3.28	0.55 - 1.26	-6.82 - 21.57	0.26 - 1.17	-6.61 - 21.73	0.45 - 1.30
Test result after last dose of InO not known: Total lymphocyte count., n (%)														
n	1	0	0	0	0	0	1	0	0	0	1	0	1	0
Not known/Not recorded	1 (100.00 %)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (100.00 %)	0 (%)	0 (%)	0 (%)	1 (100.00 %)	0 (%)	1 (100.00 %)	0 (%)
Test result after last dose of InO: Alanine transaminase (ALT).														
n	74	33	27	32	28	21	34	2	6	30	20	13	27	28
Mean	46.68	52.36	47.93	51.53	48.43	62.48	46.62	39.00	40.33	61.23	40.25	30.38	33.89	71.64
Standard deviation	70.61	96.08	46.69	97.67	46.02	119.04	44.61	14.14	32.28	105.54	26.16	26.02	25.15	108.03
Standard error of the mean	8.21	16.73	8.98	17.27	8.70	25.98	7.65	10.00	13.18	19.27	5.85	7.22	4.84	20.42
Median	29.50	32.00	30.00	31.00	31.00	32.00	29.50	39.00	33.50	31.00	40.00	24.00	28.00	46.50
Interquartile Range (IQR)	17.00 - 55.00	17.00 - 57.00	24.00 - 55.00	15.50 - 53.50	24.00 - 55.00	16.00 - 62.00	17.00 - 57.00	29.00 - 49.00	17.00 - 40.00	18.00 - 59.00	13.50 - 56.00	15.00 - 30.00	16.00 - 41.00	25.50 - 69.00
Range	10.00 - 573.00	10.00 - 573.00	10.00 - 239.00	10.00 - 573.00	10.00 - 239.00	10.00 - 573.00	10.00 - 239.00	29.00 - 49.00	15.00 - 103.00	10.00 - 573.00	10.00 - 103.00	11.00 - 113.00	10.00 - 103.00	10.00 - 573.00
95% CI	30.32 - 63.03	18.29 - 86.43	29.46 - 66.39	16.32 - 86.75	30.58 - 66.27	8.29 - 116.66	31.05 - 62.18	-88.06 - 166.06	6.45 - 74.21	21.82 - 100.64	28.01 - 52.49	14.66 - 46.11	23.94 - 43.84	29.75 - 113.53
Test result after last dose of InO: Aspartate aminotransferase (AST).														
n	60	27	20	25	21	18	25	2	4	26	17	7	23	20
Mean	51.95	58.59	48.05	56.04	52.33	68.22	44.20	36.00	29.50	64.73	40.18	24.57	37.04	73.95
Standard deviation	73.88	103.86	34.58	107.78	35.62	126.68	33.15	7.07	20.82	107.17	22.16	13.34	18.09	122.17
Standard error of the mean	9.54	19.99	7.73	21.56	7.77	29.86	6.63	5.00	10.41	21.02	5.38	5.04	3.77	27.32
Median	34.50	35.00	38.50	30.00	43.00	33.00	37.00	36.00	25.00	37.00	34.00	24.00	35.00	34.00

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Interquartile Range (IQR)	21.50 - 50.50	21.00 - 50.00	29.50 - 54.00	21.00 - 46.00	30.00 - 65.00	21.00 - 49.00	24.00 - 50.00	31.00 - 41.00	13.50 - 45.50	21.00 - 50.00	23.00 - 51.00	11.00 - 35.00	24.00 - 45.00	21.50 - 59.50
Range	10.00 - 563.00	10.00 - 563.00	16.00 - 177.00	10.00 - 563.00	16.00 - 177.00	11.00 - 563.00	16.00 - 177.00	31.00 - 41.00	11.00 - 57.00	19.00 - 563.00	16.00 - 94.00	10.00 - 46.00	16.00 - 94.00	11.00 - 563.00
95% CI	32.87 - 71.03	17.51 - 99.68	31.87 - 64.23	11.55 - 100.53	36.12 - 68.55	5.23 - 131.22	30.52 - 57.88	-27.53 - 99.53	-3.64 - 62.64	21.44 - 108.02	28.78 - 51.57	12.23 - 36.91	29.22 - 44.87	16.77 - 131.13
Test result after last dose of InO: Alkaline phosphatase (ALP).														
n	69	30	26	29	27	17	33	2	5	29	19	12	24	27
Mean	141.20	149.97	142.58	149.03	150.89	157.00	137.55	83.50	122.40	151.76	145.68	103.58	149.17	145.15
Standard deviation	98.96	119.48	94.19	113.77	100.30	127.73	94.63	10.61	39.26	123.43	89.14	38.79	92.20	120.88
Standard error of the mean	11.91	21.81	18.47	21.13	19.30	30.98	16.47	7.50	17.56	22.92	20.45	11.20	18.82	23.26
Median	109.00	107.50	117.50	108.00	118.00	107.00	117.00	83.50	118.00	109.00	108.00	111.50	136.50	100.00
Interquartile Range (IQR)	87.00 - 153.00	75.00 - 150.00	91.00 - 158.00	75.00 - 150.00	92.00 - 160.00	76.00 - 150.00	77.00 - 153.00	76.00 - 91.00	108.00 - 143.00	77.00 - 147.00	88.00 - 174.00	69.00 - 134.00	86.00 - 159.00	76.00 - 123.00
Range	35.00 - 504.00	35.00 - 477.00	54.00 - 504.00	35.00 - 477.00	65.00 - 504.00	40.00 - 477.00	54.00 - 504.00	76.00 - 91.00	69.00 - 174.00	43.00 - 504.00	40.00 - 387.00	35.00 - 156.00	54.00 - 444.00	40.00 - 504.00
95% CI	117.43 - 164.98	105.35 - 194.58	104.53 - 180.62	105.76 - 192.31	111.21 - 190.57	91.33 - 222.67	103.99 - 171.10	-11.80 - 178.80	73.65 - 171.15	104.81 - 198.71	102.72 - 188.65	78.94 - 128.23	110.23 - 188.10	97.33 - 192.97
Test result after last dose of InO: Gamma-glutamyltransferase (GGT).														
n	48	23	17	20	18	12	18	1	4	22	13	3	16	14
Mean	145.44	199.35	108.76	186.50	142.61	262.50	124.94	107.00	63.50	182.95	132.38	113.33	102.25	270.64
Standard deviation	297.31	407.72	146.33	423.16	193.81	536.14	199.78	.	42.65	414.66	182.61	101.69	164.84	507.64
Standard error of the mean	42.91	85.02	35.49	94.62	45.68	154.77	47.09	.	21.32	88.41	50.65	58.71	41.21	135.67
Median	61.50	68.00	62.00	56.50	69.00	99.50	30.00	107.00	67.00	54.50	61.00	92.00	44.50	82.50
Interquartile Range (IQR)	27.00 - 124.00	30.00 - 224.00	24.00 - 136.00	29.00 - 166.00	24.00 - 143.00	48.50 - 191.00	18.00 - 87.00	107.00 - 107.00	29.50 - 97.50	30.00 - 81.00	28.00 - 143.00	24.00 - 224.00	22.00 - 89.50	24.00 - 312.00
Range	12.00 - 1942.00	13.00 - 1942.00	12.00 - 560.00	13.00 - 1942.00	12.00 - 676.00	24.00 - 1942.00	12.00 - 676.00	107.00 - 107.00	12.00 - 108.00	12.00 - 1942.00	13.00 - 676.00	24.00 - 224.00	12.00 - 676.00	16.00 - 1942.00
95% CI	59.11 - 231.77	23.04 - 375.66	33.53 - 184.00	-11.55 - 384.55	46.23 - 238.99	-78.15 - 603.15	25.60 - 224.29	. - .	-4.37 - 131.37	-0.90 - 366.81	22.03 - 242.74	-139.28 - 365.95	14.41 - 190.09	-22.46 - 563.75
Test result after last dose of InO not known: Gamma-glutamyltransferase														

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ase (GGT)., n (%)														
n	1	0	0	0	0	0	1	0	0	0	1	0	1	0
Not known/Not recorded	1 (100.00 %)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (100.00 %)	0 (%)	0 (%)	0 (%)	1 (100.00 %)	0 (%)	1 (100.00 %)	0 (%)
Test result after last dose of InO: Lactate Dehydrogenase (LDH).														
n	73	34	24	31	26	22	31	2	6	32	19	12	27	27
Mean	498.34	722.09	242.58	765.45	238.50	874.32	255.61	549.00	378.50	682.41	290.68	422.08	340.52	675.33
Standard deviation	1216.12	1758.70	83.25	1838.14	82.92	2097.76	105.58	541.64	277.04	1816.14	149.15	342.03	279.25	1903.36
Standard error of the mean	142.34	301.61	16.99	330.14	16.26	447.24	18.96	383.00	113.10	321.05	34.22	98.74	53.74	366.30
Median	269.00	281.50	220.00	282.00	213.50	284.00	214.00	549.00	288.50	227.50	251.00	286.50	265.00	281.00
Interquartile Range (IQR)	196.00 - 343.00	195.00 - 343.00	200.50 - 282.50	196.00 - 343.00	195.00 - 283.00	202.00 - 901.00	182.00 - 308.00	166.00 - 932.00	229.00 - 329.00	172.50 - 302.50	195.00 - 329.00	216.50 - 418.00	200.00 - 317.00	183.00 - 344.00
Range	101.00 - 10145.00	101.00 - 10145.00	127.00 - 493.00	101.00 - 10145.00	127.00 - 493.00	121.00 - 10145.00	127.00 - 566.00	166.00 - 932.00	200.00 - 936.00	101.00 - 10145.00	156.00 - 767.00	182.00 - 1291.00	127.00 - 1291.00	121.00 - 10145.00
95% CI	214.60 - 782.08	108.45 - 1335.73	207.43 - 277.74	91.21 - 1439.69	205.01 - 271.99	-55.78 - 1804.41	216.88 - 294.34	4317.48 - 5415.48	87.77 - 669.23	27.62 - 1337.19	218.79 - 362.57	204.77 - 639.40	230.05 - 450.98	-77.61 - 1428.28
Test result after last dose of InO: CD22 expression.														
n	5	5	0	5	0	4	0	0	0	3	1	1	3	1
Mean	32.80	32.80		32.80		31.00				44.00	2.00	30.00	40.67	2.00
Standard deviation	37.38	37.38		37.38		42.91				46.13	.	.	46.92	.
Standard error of the mean	16.72	16.72	.	16.72	.	21.46	.	.	.	26.63	.	.	27.09	.
Median	30.00	30.00	.	30.00	.	16.00	.	.	.	40.00	2.00	30.00	30.00	2.00
Interquartile Range (IQR)	2.00 - 40.00	2.00 - 40.00	.-.	2.00 - 40.00	.-.	1.00 - 61.00	.-.	.-.	.-.	0.00 - 92.00	2.00 - 2.00	30.00 - 30.00	0.00 - 92.00	2.00 - 2.00
Range	0.00 - 92.00	0.00 - 92.00		0.00 - 92.00		0.00 - 92.00				0.00 - 92.00	2.00 - 2.00	30.00 - 30.00	0.00 - 92.00	2.00 - 2.00
95% CI	-13.61 - 79.21	-13.61 - 79.21	.-.	-13.61 - 79.21	.-.	-37.28 - 99.28	.-.	.-.	.-.	-70.59 - 158.59	.-.	.-.	-75.89 - 157.22	.-.
Test result after last dose of InO: CD22														

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expression not known., n (%)														
n	6	6	0	6	0	3	0	0	1	3	2	1	0	2
Not known	6 (100.00%)	6 (100.00%)	0 (0.00%)	6 (100.00%)	0 (0.00%)	3 (100.00%)	0 (0.00%)	0 (0.00%)	1 (100.00%)	3 (100.00%)	2 (100.00%)	1 (100.00%)	0 (0.00%)	2 (100.00%)
CD22 positive (20%+), n (%)														
n	5	5	0	5	0	4	0	0	0	3	1	1	3	1
Negative	2 (40.00%)	2 (40.00%)	0 (0.00%)	2 (40.00%)	0 (0.00%)	2 (50.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)	1 (100.00%)	0 (0.00%)	1 (33.33%)	1 (100.00%)
Positive	3 (60.00%)	3 (60.00%)	0 (0.00%)	3 (60.00%)	0 (0.00%)	2 (50.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (66.67%)	0 (0.00%)	1 (100.00%)	2 (66.67%)	0 (0.00%)
Test result after last dose of InO: CD19 expression.														
n	5	4	1	4	1	4	0	0	0	3	1	1	2	2
Mean	57.40	71.75	0.00	71.75	0.00	71.75				61.33	3.00	100.00	100.00	43.50
Standard deviation	51.46	46.45	.	46.45	.	46.45				53.72	.	.	0.00	57.28
Standard error of the mean	23.01	23.22	.	23.22	.	23.22	.	.	.	31.01	.	.	0.00	40.50
Median	84.00	92.00	0.00	92.00	0.00	92.00	.	.	.	84.00	3.00	100.00	100.00	43.50
Interquartile Range (IQR)	3.00 - 100.00	43.50 - 100.00	0.00 - 0.00	43.50 - 100.00	0.00 - 0.00	43.50 - 100.00	. - .	. - .	. - .	0.00 - 100.00	3.00 - 3.00	100.00 - 100.00	100.00 - 100.00	3.00 - 84.00
Range	0.00 - 100.00	3.00 - 100.00	0.00 - 0.00	3.00 - 100.00	0.00 - 0.00	3.00 - 100.00				0.00 - 100.00	3.00 - 3.00	100.00 - 100.00	100.00 - 100.00	3.00 - 84.00
95% CI	-6.49 - 121.29	-2.16 - 145.66	. - .	-2.16 - 145.66	. - .	-2.16 - 145.66	. - .	. - .	. - .	-72.10 - 194.77	. - .	. - .	100.00 - 100.00	-471.10 - 558.10
Test result after last dose of InO: CD19 expression not known., n (%)														
n	7	7	0	7	0	3	0	0	1	4	2	1	0	2
Not known	7 (100.00%)	7 (100.00%)	0 (0.00%)	7 (100.00%)	0 (0.00%)	3 (100.00%)	0 (0.00%)	0 (0.00%)	1 (100.00%)	4 (100.00%)	2 (100.00%)	1 (100.00%)	0 (0.00%)	2 (100.00%)
Test result after last dose of InO: CD3+ count.														
n	11	6	5	6	5	3	5	0	0	8	2	1	6	2
Mean	876.99	913.00	833.78	913.00	833.78	724.00	978.58			703.61	1457.50	1103.00	738.81	1316.00

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Standard deviation	545.44	648.25	462.81	648.25	462.81	213.50	811.03			434.11	830.85	.	506.19	1030.96
Standard error of the mean	164.46	264.65	206.98	264.65	206.98	123.27	362.70	.	.	153.48	587.50	.	206.65	729.00
Median	870.00	792.50	870.00	792.50	870.00	615.00	1103.00	.	.	608.00	1457.50	1103.00	792.50	1316.00
Interquartile Range (IQR)	587.00 - 1111.00	587.00 - 1111.00	601.00 - 1103.00	587.00 - 1111.00	601.00 - 1103.00	587.00 - 970.00	194.88 - 1400.00	.-.	.-.	390.94 - 1040.50	870.00 - 2045.00	1103.00 - 1103.00	194.88 - 1103.00	587.00 - 2045.00
Range	150.00 - 2045.00	150.00 - 2045.00	194.88 - 1400.00	150.00 - 2045.00	194.88 - 1400.00	587.00 - 970.00	150.00 - 2045.00			150.00 - 1400.00	870.00 - 2045.00	1103.00 - 1103.00	150.00 - 1400.00	587.00 - 2045.00
95% CI	510.56 - 1243.42	232.71 - 1593.29	259.12 - 1408.43	232.71 - 1593.29	259.12 - 1408.43	193.63 - 1254.37	-28.45 - 1985.60	.-.	.-.	340.69 - 1066.53	- 6007.40 - 8922.40	.-.	207.60 - 1270.03	- 7946.82 - 10578.82
Test result after last dose of InO: CD4+ count.														
n	6	4	2	4	2	2	1	0	0	5	1	0	2	1
Mean	237.17	169.25	373.00	169.25	373.00	205.00	60.00			176.60	540.00		180.00	110.00
Standard deviation	170.35	106.41	236.17	106.41	236.17	134.35	.			93.60	.		169.71	.
Standard error of the mean	69.55	53.20	167.00	53.20	167.00	95.00	.	.	.	41.86	.	.	120.00	.
Median	206.50	158.50	373.00	158.50	373.00	205.00	60.00	.	.	206.00	540.00	.	180.00	110.00
Interquartile Range (IQR)	110.00 - 300.00	85.00 - 253.50	206.00 - 540.00	85.00 - 253.50	206.00 - 540.00	110.00 - 300.00	60.00 - 60.00	.-.	.-.	110.00 - 207.00	540.00 - 540.00	.-.	60.00 - 300.00	110.00 - 110.00
Range	60.00 - 540.00	60.00 - 300.00	206.00 - 540.00	60.00 - 300.00	206.00 - 540.00	110.00 - 300.00	60.00 - 60.00			60.00 - 300.00	540.00 - 540.00		60.00 - 300.00	110.00 - 110.00
95% CI	58.39 - 415.94	-0.07 - 338.57	1748.94 - 2494.94	-0.07 - 338.57	1748.94 - 2494.94	1002.09 - 1412.09		.-.	.-.	60.37 - 292.83	.-.	.-.	1344.74 - 1704.74	.-.
Test result after last dose of InO: CD8+ count.														
n	6	4	2	4	2	2	1	0	0	5	1	0	2	1
Mean	458.33	512.00	351.00	512.00	351.00	540.00	80.00			488.00	310.00		355.00	450.00
Standard deviation	277.02	339.49	57.98	339.49	57.98	127.28	.			298.87	.		388.91	.
Standard error of the mean	113.09	169.75	41.00	169.75	41.00	90.00	.	.	.	133.66	.	.	275.00	.
Median	421.00	540.00	351.00	540.00	351.00	540.00	80.00	.	.	450.00	310.00	.	355.00	450.00



Interquartile Range (IQR)	310.00 - 630.00	265.00 - 759.00	310.00 - 392.00	265.00 - 759.00	310.00 - 392.00	450.00 - 630.00	80.00 - 80.00	. - .	. - .	392.00 - 630.00	310.00 - 310.00	. - .	80.00 - 630.00	450.00 - 450.00
Range	80.00 - 888.00	80.00 - 888.00	310.00 - 392.00	80.00 - 888.00	310.00 - 392.00	450.00 - 630.00	80.00 - 80.00			80.00 - 888.00	310.00 - 310.00		80.00 - 630.00	450.00 - 450.00
95% CI	167.62 - 749.04	-28.21 - 1052.21	-169.95 - 871.95	-28.21 - 1052.21	-169.95 - 871.95	-603.56 - 1683.56				116.91 - 859.09			- 3139.21 - 3849.21	

Concomitant conditions at index (initiation of InO)														
n	84	37	27	35	28	26	35	3	6	34	22	15	29	34
Myocardial infarction	1 (1.19%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	1 (3.57%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	0 (0.00%)	0 (0.00%)	1 (3.45%)	0 (0.00%)
Congestive heart failure	1 (1.19%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Peripheral vascular disease	4 (4.76%)	1 (2.70%)	1 (3.70%)	2 (5.71%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.55%)	1 (6.67%)	1 (3.45%)	0 (0.00%)
Cerebrovascular disease	1 (1.19%)	1 (2.70%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	1 (3.85%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.67%)	1 (3.45%)	0 (0.00%)
Stroke	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dementia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Chronic pulmonary disease	1 (1.19%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	1 (3.57%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	1 (4.55%)	0 (0.00%)	1 (3.45%)	0 (0.00%)
Rheumatologic disease	1 (1.19%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Diabetes without chronic complications	6 (7.14%)	2 (5.41%)	1 (3.70%)	2 (5.71%)	2 (7.14%)	2 (7.69%)	2 (5.71%)	0 (0.00%)	0 (0.00%)	2 (5.88%)	0 (0.00%)	3 (20.00%)	3 (10.34%)	2 (5.88%)
Diabetes with chronic complications	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Connective tissue disease	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)



Peptic ulcer disease	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Renal disease	2 (2.38%)	0 (0.00%)	0 (0.00%)	2 (5.71%)	0 (0.00%)	1 (3.85%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	2 (13.33%)	1 (3.45%)	0 (0.00%)
Mild liver disease	5 (5.95%)	2 (5.41%)	2 (7.41%)	3 (8.57%)	1 (3.57%)	1 (3.85%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	0 (0.00%)	2 (13.33%)	2 (6.90%)	1 (2.94%)
Moderate or severe liver disease	2 (2.38%)	2 (5.41%)	0 (0.00%)	2 (5.71%)	0 (0.00%)	1 (3.85%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (5.88%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.94%)
Hemiplegia or paraplegia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Moderate-to-severe chronic kidney disease	1 (1.19%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Any malignancy, including leukaemia and lymphoma	27 (32.14%)	11 (29.73%)	10 (37.04%)	9 (25.71%)	11 (39.29%)	11 (42.31%)	13 (37.14%)	1 (33.33%)	1 (16.67%)	12 (35.29%)	11 (50.00%)	2 (13.33%)	13 (44.83%)	12 (35.29%)
Metastatic solid tumour	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
AIDS/HIV	1 (1.19%)	1 (2.70%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.85%)	0 (0.00%)	1 (33.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.94%)
Long term effects of COVID-19	1 (1.19%)	1 (2.70%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.55%)	0 (0.00%)	0 (0.00%)	1 (2.94%)
Hepatitis B	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hepatitis C	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Other	16 (19.05%)	7 (18.92%)	4 (14.81%)	7 (20.00%)	3 (10.71%)	5 (19.23%)	4 (11.43%)	0 (0.00%)	0 (0.00%)	6 (17.65%)	6 (27.27%)	2 (13.33%)	3 (10.34%)	7 (20.59%)
Not diagnosed with any concomitant conditions	32 (38.10%)	16 (43.24%)	10 (37.04%)	13 (37.14%)	11 (39.29%)	8 (30.77%)	17 (48.57%)	2 (66.67%)	3 (50.00%)	13 (38.24%)	9 (40.91%)	5 (33.33%)	9 (31.03%)	16 (47.06%)
3.20 What was the patient's														



WHO/ECOG score (performance status) at index?, n (%)														
n	84	37	27	35	28	26	35	3	6	34	22	15	29	34
0: Fully active, able to carry on all pre-disease performance without restriction	25 (29.76%)	9 (24.32%)	10 (37.04%)	9 (25.71%)	10 (35.71%)	3 (11.54%)	15 (42.86%)	0 (0.00%)	1 (16.67%)	12 (35.29%)	4 (18.18%)	5 (33.33%)	7 (24.14%)	12 (35.29%)
1: Restricted in physically strenuous activity but ambulatory and able to carry out light work	37 (44.05%)	21 (56.76%)	11 (40.74%)	20 (57.14%)	11 (39.29%)	15 (57.69%)	14 (40.00%)	1 (33.33%)	3 (50.00%)	17 (50.00%)	11 (50.00%)	7 (46.67%)	18 (62.07%)	11 (32.35%)
2: Ambulatory and capable of all self-care but unable to carry out work activities. Up more than 50% of waking hours	5 (5.95%)	3 (8.11%)	1 (3.70%)	3 (8.57%)	2 (7.14%)	2 (7.69%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	2 (5.88%)	3 (13.64%)	0 (0.00%)	1 (3.45%)	3 (8.82%)
3: Capable of only limited self-care, confined to bed or chair more than 50% of waking hours	2 (2.38%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	1 (3.57%)	0 (0.00%)	2 (5.71%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	1 (4.55%)	0 (0.00%)	0 (0.00%)	2 (5.88%)
Not assessed	12 (14.29%)	3 (8.11%)	4 (14.81%)	2 (5.71%)	3 (10.71%)	5 (19.23%)	2 (5.71%)	2 (66.67%)	1 (16.67%)	2 (5.88%)	2 (9.09%)	2 (13.33%)	2 (6.90%)	5 (14.71%)
unknown	3 (3.57%)	1 (2.70%)	0 (0.00%)	1 (2.86%)	1 (3.57%)	1 (3.85%)	1 (2.86%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	1 (4.55%)	1 (6.67%)	1 (3.45%)	1 (2.94%)

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3.21 Has the patient been diagnosed with veno-occlusive disease (VOD) at any time (up to and including point of data collection) during their ALL diagnosis and treatment?, n (%)														
n	84	37	27	35	28	26	35	3	6	34	22	15	29	34
Yes	6 (7.14%)	4 (10.81%)	1 (3.70%)	2 (5.71%)	2 (7.14%)	4 (15.38%)	1 (2.86%)	1 (33.33%)	1 (16.67%)	1 (2.94%)	2 (9.09%)	1 (6.67%)	2 (6.90%)	3 (8.82%)
No	74 (88.10%)	29 (78.38%)	26 (96.30%)	30 (85.71%)	25 (89.29%)	22 (84.62%)	32 (91.43%)	2 (66.67%)	5 (83.33%)	32 (94.12%)	18 (81.82%)	14 (93.33%)	25 (86.21%)	30 (88.24%)
Only suspected VOD	4 (4.76%)	4 (10.81%)	0 (0.00%)	3 (8.57%)	1 (3.57%)	0 (0.00%)	2 (5.71%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	2 (9.09%)	0 (0.00%)	2 (6.90%)	1 (2.94%)
How was the patient diagnosed with VOD?														
n	6	4	1	2	2	4	1	1	1	1	2	1	2	3
Liver biopsy	3 (50.00%)	2 (50.00%)	1 (100.00%)	2 (100.00%)	1 (50.00%)	3 (75.00%)	0 (0.00%)	0 (0.00%)	1 (100.00%)	1 (100.00%)	1 (50.00%)	1 (100.00%)	1 (50.00%)	2 (66.67%)
Ultrasound	3 (50.00%)	2 (50.00%)	0 (0.00%)	2 (100.00%)	0 (0.00%)	2 (50.00%)	1 (100.00%)	0 (0.00%)	1 (100.00%)	0 (0.00%)	2 (100.00%)	1 (100.00%)	2 (100.00%)	1 (33.33%)
Elevated biomarker levels (e.g., AST greater than 750 U/L)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Elevated bilirubin ≥ 2 mg/dL	2 (33.33%)	2 (50.00%)	0 (0.00%)	1 (50.00%)	0 (0.00%)	2 (50.00%)	0 (0.00%)	1 (100.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (100.00%)	1 (50.00%)	1 (33.33%)



Hepatomegal y (right upper quadrant pain)	2 (33.33%)	2 (50.00%)	0 (0.00%)	1 (50.00%)	0 (0.00%)	2 (50.00%)	0 (0.00%)	1 (100.00 %)	1 (100.00 %)	0 (0.00%)	1 (50.00%)	0 (0.00%)	0 (0.00%)	2 (66.67%)
Unexplained weight gain and fluid retention	2 (33.33%)	2 (50.00%)	0 (0.00%)	1 (50.00%)	0 (0.00%)	2 (50.00%)	0 (0.00%)	1 (100.00 %)	1 (100.00 %)	0 (0.00%)	1 (50.00%)	0 (0.00%)	0 (0.00%)	2 (66.67%)
Confirmed ascites	1 (16.67%)	1 (25.00%)	0 (0.00%)	1 (50.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	1 (100.00 %)	0 (0.00%)	1 (50.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)
Other	3 (50.00%)	1 (25.00%)	1 (100.00 %)	1 (50.00%)	1 (50.00%)	2 (50.00%)	1 (100.00 %)	0 (0.00%)	0 (0.00%)	1 (100.00 %)	1 (50.00%)	1 (100.00 %)	2 (100.00 %)	1 (33.33%)
None of the above	1 (16.67%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	1 (50.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
3.21 Did the patient receive defibrotide for treatment of their VOD (or suspected VOD) at any time (up to and including point of data collection) during their ALL diagnosis and treatment?, n (%)														
n	10	8	1	5	3	4	3	1	1	2	4	1	4	4
Yes	4 (40.00%)	4 (50.00%)	0 (0.00%)	2 (40.00%)	1 (33.33%)	2 (50.00%)	0 (0.00%)	1 (100.00 %)	1 (100.00 %)	0 (0.00%)	2 (50.00%)	0 (0.00%)	0 (0.00%)	3 (75.00%)
No	6 (60.00%)	4 (50.00%)	1 (100.00 %)	3 (60.00%)	2 (66.67%)	2 (50.00%)	3 (100.00 %)	0 (0.00%)	0 (0.00%)	2 (100.00 %)	2 (50.00%)	1 (100.00 %)	4 (100.00 %)	1 (25.00%)
3.21 What was the most severe grade of VOD the patient was														



diagnosed with at any time (up to and including data collection) during their ALL diagnosis and treatment?, n (%)														
n	10	8	1	5	3	4	3	1	1	2	4	1	4	4
Grade 1 - mild	4 (40.00%)	2 (25.00%)	1 (100.00%)	2 (40.00%)	1 (33.33%)	3 (75.00%)	1 (33.33%)	0 (0.00%)	1 (100.00%)	1 (50.00%)	2 (50.00%)	1 (100.00%)	2 (50.00%)	2 (50.00%)
No grading undertaken due to ongoing VOD or other reasons	5 (50.00%)	5 (62.50%)	0 (0.00%)	3 (60.00%)	1 (33.33%)	1 (25.00%)	2 (66.67%)	1 (100.00%)	0 (0.00%)	1 (50.00%)	2 (50.00%)	0 (0.00%)	2 (50.00%)	2 (50.00%)
Not known	1 (10.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	1 (33.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
3.21 Was bilirubin measured at the most severe VOD diagnosis?, n (%)														
n	6	4	1	2	2	4	1	1	1	1	2	1	2	3
Yes	6 (100.00%)	4 (100.00%)	1 (100.00%)	2 (100.00%)	2 (100.00%)	4 (100.00%)	1 (100.00%)	1 (100.00%)	1 (100.00%)	1 (100.00%)	2 (100.00%)	1 (100.00%)	2 (100.00%)	3 (100.00%)
3.21 What was the bilirubin level in the patient's blood at the most severe VOD diagnosis?, n (%)														
n	84	37	27	35	28	26	35	3	6	34	22	15	29	34



Not known	78 (92.86%)	33 (89.19%)	26 (96.30%)	33 (94.29%)	26 (92.86%)	22 (84.62%)	34 (97.14%)	2 (66.67%)	5 (83.33%)	33 (97.06%)	20 (90.91%)	14 (93.33%)	27 (93.10%)	31 (91.18%)
.1	1 (1.19%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.55%)	0 (0.00%)	1 (3.45%)	0 (0.00%)
.7	1 (1.19%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	1 (3.57%)	1 (3.85%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.94%)
1.87	1 (1.19%)	1 (2.70%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	1 (3.85%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	1 (4.55%)	0 (0.00%)	0 (0.00%)	1 (2.94%)
2.2	1 (1.19%)	1 (2.70%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	1 (3.85%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.67%)	1 (3.45%)	0 (0.00%)
25.65	1 (1.19%)	1 (2.70%)	0 (0.00%)	0 (0.00%)	1 (3.57%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
97	1 (1.19%)	1 (2.70%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.85%)	0 (0.00%)	1 (33.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.94%)
3.21 What was the bilirubin level in the patient's blood at the most severe VOD														
n	6	4	1	2	2	4	1	1	1	1	2	1	2	3
Mean	21.25	31.68	0.70	2.04	13.17	25.44	0.10	97.00	1.87	0.70	0.99	2.20	1.15	33.19
Standard deviation	38.38	44.95	.	0.23	17.64	47.71	.	.	.	.	1.25	.	1.48	55.26
Standard error of the mean	15.67	22.47	.	0.17	12.47	23.85	.	.	.	.	0.89	.	1.05	31.91
Median	2.04	13.92	0.70	2.04	13.17	2.04	0.10	97.00	1.87	0.70	0.99	2.20	1.15	1.87
Interquartile Range (IQR)	0.70 - 25.65	2.04 - 61.33	0.70 - 0.70	1.87 - 2.20	0.70 - 25.65	1.29 - 49.60	0.10 - 0.10	97.00 - 97.00	1.87 - 1.87	0.70 - 0.70	0.10 - 1.87	2.20 - 2.20	0.10 - 2.20	0.70 - 97.00
Range	0.10 - 97.00	1.87 - 97.00	0.70 - 0.70	1.87 - 2.20	0.70 - 25.65	0.70 - 97.00	0.10 - 0.10	97.00 - 97.00	1.87 - 1.87	0.70 - 0.70	0.10 - 1.87	2.20 - 2.20	0.10 - 2.20	0.70 - 97.00
95% CI	-19.03 - 61.53	-39.84 - 103.20	..	-0.06 - 4.13	-145.33 - 171.68	-50.47 - 101.36	..	..	..	..	-10.26 - 12.23	..	-12.19 - 14.49	-104.09 - 170.47
3.21 Was a platelet count test conducted at the most severe VOD diagnosis?, n (%)														

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n	6	4	1	2	2	4	1	1	1	1	2	1	2	3
	6 (100.00 %)	4 (100.00 %)	1 (100.00 %)	2 (100.00 %)	2 (100.00 %)	4 (100.00 %)	1 (100.00 %)	1 (100.00 %)	1 (100.00 %)	1 (100.00 %)	2 (100.00 %)	1 (100.00 %)	2 (100.00 %)	3 (100.00 %)
Yes														
3.21 Please enter the result of the platelet count test.														
n	5	4	1	2	2	4	0	1	1	1	1	1	1	3
Mean	57801.8 0	46502.2 5	1.0e+05	19504.5 0	1.2e+05	37252.2 5		7000.00	9.00	1.0e+05	9.00	39000.0 0	39000.0 0	36669.6 7
Standard deviation	61387.6 2	64601.7 6	.	27570.8 0	26162.9 5	47003.8 3		.	.	.	.	.	.	57550.0 1
Standard error of the mean	27453.3 8	32300.8 8	.	19495.5 0	18500.0 0	23501.9 1	.	.	.	.	.	.	.	33226.5 1
Median	39000.0 0	23000.0 0	1.0e+05	19504.5 0	1.2e+05	23000.0 0	.	7000.00	9.00	1.0e+05	9.00	39000.0 0	39000.0 0	7000.00
Interquartile Range (IQR)	7000.00 - 1.0e+05	3504.50 - 89500.0 0	1.0e+05 - 1.0e+05	9.00 - 39000.0 0	1.0e+05 - 1.4e+05	3504.50 - 71000.0 0	.	7000.00 - 7000.00	9.00 - 9.00	1.0e+05 - 1.0e+05	9.00 - 9.00	39000.0 0 - 39000.0 0	39000.0 0 - 39000.0 0	9.00 - 1.0e+05
Range	9.00 - 1.4e+05	9.00 - 1.4e+05	1.0e+05 - 1.0e+05	9.00 - 39000.0 0	1.0e+05 - 1.4e+05	9.00 - 1.0e+05		7000.00 - 7000.00	9.00 - 9.00	1.0e+05 - 1.0e+05	9.00 - 9.00	39000.0 0 - 39000.0 0	39000.0 0 - 39000.0 0	9.00 - 1.0e+05
95% CI	1.8e+04 - 1.3e+05	5.6e+04 - 1.5e+05	.	2.3e+05 - 2.7e+05	1.1e+05 - 3.6e+05	3.8e+04 - 1.1e+05	.	.	.	.	.	.	.	1.1e+05 - 1.8e+05
3.21 Please enter the result of the platelet count test., n (%)														
n	84 79	37 33	27 26	35 33	28 26	26 22	35 35	3 2	6 5	34 33	22 21	15 14	29 28	34 31
Not known	(94.05%)	(89.19%)	(96.30%)	(94.29%)	(92.86%)	(84.62%)	(100.00 %)	(66.67%)	(83.33%)	(97.06%)	(95.45%)	(93.33%)	(96.55%)	(91.18%)
103000	1 (1.19%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	1 (3.57%)	1 (3.85%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.94%)
140000	1 (1.19%)	1 (2.70%)	0 (0.00%)	0 (0.00%)	1 (3.57%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
39000	1 (1.19%)	1 (2.70%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	1 (3.85%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.67%)	1 (3.45%)	0 (0.00%)



7000	1 (1.19%)	1 (2.70%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.85%)	0 (0.00%)	1 (33.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.94%)
9	1 (1.19%)	1 (2.70%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	1 (3.85%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	1 (4.55%)	0 (0.00%)	0 (0.00%)	1 (2.94%)
3.24 Has the patient been diagnosed with neutropenic sepsis at any time (up to and including data collection) during their ALL diagnosis and treatment?, n (%)														
n	84	37	27	35	28	26	35	3	6	34	22	15	29	34
Yes	39 (46.43%)	23 (62.16%)	10 (37.04%)	24 (68.57%)	8 (28.57%)	12 (46.15%)	12 (34.29%)	1 (33.33%)	2 (33.33%)	15 (44.12%)	13 (59.09%)	5 (33.33%)	9 (31.03%)	16 (47.06%)
No	40 (47.62%)	12 (32.43%)	17 (62.96%)	9 (25.71%)	19 (67.86%)	12 (46.15%)	20 (57.14%)	1 (33.33%)	4 (66.67%)	16 (47.06%)	8 (36.36%)	9 (60.00%)	18 (62.07%)	15 (44.12%)
Not known	5 (5.95%)	2 (5.41%)	0 (0.00%)	2 (5.71%)	1 (3.57%)	2 (7.69%)	3 (8.57%)	1 (33.33%)	0 (0.00%)	3 (8.82%)	1 (4.55%)	1 (6.67%)	2 (6.90%)	3 (8.82%)

Overall, about a fifth of patients were diagnosed with extramedullary disease at their R/R ALL diagnosis (20.2%) (please see **Table 34** below). 25.0% of the patient's whose BMI at index was(in the range 25-30 had bulky extramedullary disease at their R/R ALL diagnosis (see **Table 34** below).

Table 34: Patient Extramedullary Disease Diagnosis, Bulky Extramedullary Disease, EMD Sites, CNS Disease Diagnosis and CNS Disease Status

	Overall	MRD status (1st cycle of InO)	MRD status (last cycle of InO)	MRD status (CAR-T infusion)	MRD status (prior to HPSC)	BMI at index (initiation of InO)	InO received:
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	Total	Positive	Negative	Positive	Negative	Positive	Negative	Positive	Negative	(18.5, 25)	(25, 30)	30+	Pre-apheresis	Post-apheresis
3.37 Was the patient diagnosed with extramedullary disease at their R/R ALL diagnosis?, n (%)														
n	84	37	27	35	28	26	35	3	6	34	22	15	29	34
Yes	17 (20.24%)	4 (10.81%)	5 (18.52%)	6 (17.14%)	6 (21.43%)	6 (23.08%)	7 (20.00%)	0 (0.00%)	1 (16.67%)	7 (20.59%)	4 (18.18%)	4 (26.67%)	5 (17.24%)	10 (29.41%)
No	67 (79.76%)	33 (89.19%)	22 (81.48%)	29 (82.86%)	22 (78.57%)	20 (76.92%)	28 (80.00%)	3 (100.00%)	5 (83.33%)	27 (79.41%)	18 (81.82%)	11 (73.33%)	24 (82.76%)	24 (70.59%)
3.37 Was the patient's extramedullary disease at their R/R ALL diagnosis bulky?, n (%)														
n	17	4	5	6	6	6	7	0	1	7	4	4	5	10
Yes	3 (17.65%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	1 (16.67%)	2 (28.57%)	0 (0.00%)	0 (0.00%)	2 (28.57%)	1 (25.00%)	0 (0.00%)	2 (40.00%)	1 (10.00%)
No	13 (76.47%)	4 (100.00%)	5 (100.00%)	6 (100.00%)	5 (83.33%)	4 (66.67%)	5 (71.43%)	0 (0.00%)	1 (100.00%)	5 (71.43%)	3 (75.00%)	4 (100.00%)	3 (60.00%)	8 (80.00%)
Not known	1 (5.88%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (10.00%)
EMD sites														
n	17	4	5	6	6	6	7	0	1	7	4	4	5	10
Skin	2 (11.76%)	1 (25.00%)	1 (20.00%)	1 (16.67%)	1 (16.67%)	0 (0.00%)	1 (14.29%)	0 (0.00%)	0 (0.00%)	2 (28.57%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (10.00%)
Oral	1 (5.88%)	1 (25.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	0 (0.00%)	1 (10.00%)



cns	3 (17.65 %)	1 (25.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	1 (16.67 %)	1 (14.29 %)	0 (.%)	0 (0.00%)	1 (14.29 %)	1 (25.00 %)	1 (25.00%)	0 (0.00%)	3 (30.00%)
Liver	1 (5.88%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	1 (16.67 %)	1 (16.67 %)	0 (0.00%)	0 (.%)	0 (0.00%)	1 (14.29 %)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (10.00%)
Spleen	3 (17.65 %)	0 (0.00%)	3 (60.00%)	0 (0.00%)	3 (50.00 %)	1 (16.67 %)	2 (28.57 %)	0 (.%)	0 (0.00%)	1 (14.29 %)	0 (0.00%)	1 (25.00%)	0 (0.00%)	3 (30.00%)
Testes	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (.%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lymph nodes	6 (35.29 %)	2 (50.00%)	2 (40.00%)	3 (50.00%)	2 (33.33 %)	3 (50.00 %)	1 (14.29 %)	0 (.%)	0 (0.00%)	3 (42.86 %)	1 (25.00 %)	2 (50.00%)	1 (20.00%)	4 (40.00%)
Other	8 (47.06 %)	1 (25.00%)	3 (60.00%)	2 (33.33%)	4 (66.67 %)	3 (50.00 %)	4 (57.14 %)	0 (.%)	1 (100.00 %)	4 (57.14 %)	2 (50.00 %)	1 (25.00%)	4 (80.00%)	3 (30.00%)
3.38]Was the patient diagnosed with CNS disease at their R/R ALL diagnosis?, n (%)														
n	84	37	27	35	28	26	35	3	6	34	22	15	29	34
Yes	12 (14.29 %)	3 (8.11%)	4 (14.81%)	4 (11.43%)	3 (10.71 %)	4 (15.38 %)	6 (17.14 %)	1 (33.33%)	1 (16.67%)	5 (14.71 %)	3 (13.64 %)	3 (20.00%)	4 (13.79%)	7 (20.59%)
No	72 (85.71 %)	34 (91.89%)	23 (85.19%)	31 (88.57%)	25 (89.29 %)	22 (84.62 %)	29 (82.86 %)	2 (66.67%)	5 (83.33%)	29 (85.29 %)	19 (86.36 %)	12 (80.00%)	25 (86.21%)	27 (79.41%)
3.38]What was the patient's CNS disease status at their R/R ALL diagnosis?, n (%)														
n	12	3	4	4	3	4	6	1	1	5	3	3	4	7
CNS 1	1 (8.33%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	1 (25.00 %)	0 (0.00%)	0 (0.00%)	1 (100.00 %)	0 (0.00%)	0 (0.00%)	1 (33.33%)	1 (25.00%)	0 (0.00%)



CNS 2	2 (16.67%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	1 (33.33%)	0 (0.00%)	2 (33.33%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	1 (33.33%)	0 (0.00%)	2 (50.00%)	0 (0.00%)
CNS 3	5 (41.67%)	2 (66.67%)	1 (25.00%)	2 (50.00%)	0 (0.00%)	3 (75.00%)	2 (33.33%)	1 (100.00%)	0 (0.00%)	3 (60.00%)	2 (66.67%)	0 (0.00%)	1 (25.00%)	4 (57.14%)
Not known	4 (33.33%)	1 (33.33%)	2 (50.00%)	1 (25.00%)	2 (66.67%)	0 (0.00%)	2 (33.33%)	0 (0.00%)	0 (0.00%)	1 (20.00%)	0 (0.00%)	2 (66.67%)	0 (0.00%)	3 (42.86%)

Overall, the majority of patients were not currently participating in a clinical trial other than the CD19 CAR-T trial (96.4%) (please see Table 35 below). Overall, half the patient sample was receiving daunorubicin and cyclophosphamide prior to bridging InO (50.0% respectively) (please see Table 35 below).

Table 35: Current Participation in Clinical Trial and Other Analyses Including Blinatumomab Analyses

	Overall	MRD status (1st cycle of InO)		MRD status (last cycle of InO)		MRD status (CAR-T infusion)		MRD status (prior to HPSCt)		BMI at index (initiation of InO)			InO received:	
	Total	Positive	Negative	Positive	Negative	Positive	Negative	Positive	Negative	(18.5, 25)	(25, 30)	30+	Pre-apheresis	Post-apheresis
4.1 Is the patient currently participating in a clinical trial other than a CD19 CAR-T trial?, n (%)														
n	84	37	27	35	28	26	35	3	6	34	22	15	29	34
Yes	3 (3.57%)	2 (5.41%)	1 (3.70%)	2 (5.71%)	1 (3.57%)	0 (0.00%)	2 (5.71%)	0 (0.00%)	0 (0.00%)	2 (5.88%)	1 (4.55%)	0 (0.00%)	0 (0.00%)	2 (5.88%)
No	81 (96.43%)	35 (94.59%)	26 (96.30%)	33 (94.29%)	27 (96.43%)	26 (100.00%)	33 (94.29%)	3 (100.00%)	6 (100.00%)	32 (94.12%)	21 (95.45%)	15 (100.00%)	29 (100.00%)	32 (94.12%)
Treatments received prior to bridging InO														
n	84	37	27	35	28	26	35	3	6	34	22	15	29	34



Vincristine	70 (83.33%))	31 (83.78%))	21 (77.78 %))	30 (85.71%))	23 (82.14 %))	23 (88.46%))	29 (82.86 %))	2 (66.67%))	6 (100.00 %))	28 (82.35%))	19 (86.36 %))	14 (93.33%))	24 (82.76%))	31 (91.18%))
Dexamethasone	58 (69.05%))	24 (64.86%))	19 (70.37 %))	24 (68.57%))	21 (75.00 %))	20 (76.92%))	26 (74.29 %))	2 (66.67%))	5 (83.33%))	21 (61.76%))	18 (81.82 %))	12 (80.00%))	22 (75.86%))	25 (73.53%))
Prednisolone	36 (42.86%))	16 (43.24%))	12 (44.44 %))	16 (45.71%))	12 (42.86 %))	10 (38.46%))	17 (48.57 %))	0 (0.00%))	2 (33.33%))	17 (50.00%))	11 (50.00 %))	5 (33.33%))	15 (51.72%))	14 (41.18%))
Methylprednisolone	9 (10.71%))	4 (10.81%))	3 (11.11 %))	4 (11.43%))	3 (10.71 %))	1 (3.85%))	3 (8.57%))	0 (0.00%))	1 (16.67%))	2 (5.88%))	5 (22.73 %))	1 (6.67%))	1 (3.45%))	4 (11.76%))
Hydrocortisone	7 (8.33%))	3 (8.11%))	1 (3.70%))	3 (8.57%))	1 (3.57%))	2 (7.69%))	3 (8.57%))	0 (0.00%))	1 (16.67%))	2 (5.88%))	4 (18.18 %))	1 (6.67%))	2 (6.90%))	5 (14.71%))
Doxorubicin	19 (22.62%))	12 (32.43%))	2 (7.41%))	12 (34.29%))	3 (10.71 %))	8 (30.77%))	7 (20.00 %))	2 (66.67%))	1 (16.67%))	5 (14.71%))	7 (31.82 %))	4 (26.67%))	6 (20.69%))	9 (26.47%))
Daunorubicin	42 (50.00%))	23 (62.16%))	13 (48.15 %))	21 (60.00%))	14 (50.00 %))	12 (46.15%))	18 (51.43 %))	1 (33.33%))	4 (66.67%))	15 (44.12%))	14 (63.64 %))	8 (53.33%))	11 (37.93%))	21 (61.76%))
Cyclophosphamide	42 (50.00%))	20 (54.05%))	13 (48.15 %))	18 (51.43%))	14 (50.00 %))	11 (42.31%))	20 (57.14 %))	3 (100.00 %))	2 (33.33%))	15 (44.12%))	11 (50.00 %))	10 (66.67%))	13 (44.83%))	19 (55.88%))
L-asparaginase	38 (45.24%))	23 (62.16%))	10 (37.04 %))	23 (65.71%))	10 (35.71 %))	14 (53.85%))	13 (37.14 %))	0 (0.00%))	4 (66.67%))	15 (44.12%))	13 (59.09 %))	7 (46.67%))	11 (37.93%))	18 (52.94%))
Methotrexate	56 (66.67%))	24 (64.86%))	18 (66.67 %))	25 (71.43%))	18 (64.29 %))	19 (73.08%))	22 (62.86 %))	2 (66.67%))	5 (83.33%))	22 (64.71%))	14 (63.64 %))	13 (86.67%))	17 (58.62%))	27 (79.41%))
Cytarabine	57 (67.86%))	25 (67.57%))	22 (81.48 %))	24 (68.57%))	22 (78.57 %))	17 (65.38%))	26 (74.29 %))	3 (100.00 %))	5 (83.33%))	24 (70.59%))	17 (77.27 %))	8 (53.33%))	20 (68.97%))	24 (70.59%))
Etoposide	2 (2.38%))	0 (0.00%))	1 (3.70%))	1 (2.86%))	1 (3.57%))	0 (0.00%))	1 (2.86%))	0 (0.00%))	0 (0.00%))	0 (0.00%))	0 (0.00%))	2 (13.33%))	0 (0.00%))	1 (2.94%))
Mercaptopurine	26 (30.95%))	13 (35.14%))	6 (22.22 %))	13 (37.14%))	6 (21.43 %))	12 (46.15%))	9 (25.71 %))	2 (66.67%))	3 (50.00%))	9 (26.47%))	9 (40.91 %))	5 (33.33%))	5 (17.24%))	17 (50.00%))
Intrathecal chemotherapy	56 (66.67%))	25 (67.57%))	22 (81.48 %))	25 (71.43%))	23 (82.14 %))	17 (65.38%))	27 (77.14 %))	1 (33.33%))	4 (66.67%))	25 (73.53%))	14 (63.64 %))	13 (86.67%))	22 (75.86%))	23 (67.65%))
Radiation therapy	9 (10.71%))	5 (13.51%))	2 (7.41%))	3 (8.57%))	4 (14.29 %))	2 (7.69%))	4 (11.43 %))	0 (0.00%))	0 (0.00%))	1 (2.94%))	6 (27.27 %))	0 (0.00%))	2 (6.90%))	5 (14.71%))



Imatinib	7 (8.33%)	2 (5.41%)	3 (11.11%)	2 (5.71%)	3 (10.71%)	1 (3.85%)	4 (11.43%)	1 (33.33%)	0 (0.00%)	4 (11.76%)	1 (4.55%)	2 (13.33%)	2 (6.90%)	3 (8.82%)
Dasatinib	10 (11.90%)	3 (8.11%)	4 (14.81%)	4 (11.43%)	3 (10.71%)	3 (11.54%)	4 (11.43%)	0 (0.00%)	0 (0.00%)	7 (20.59%)	1 (4.55%)	2 (13.33%)	4 (13.79%)	3 (8.82%)
Ponatinib	8 (9.52%)	2 (5.41%)	5 (18.52%)	1 (2.86%)	5 (17.86%)	4 (15.38%)	4 (11.43%)	2 (66.67%)	0 (0.00%)	5 (14.71%)	1 (4.55%)	1 (6.67%)	3 (10.34%)	5 (14.71%)
Nilotinib	1 (1.19%)	1 (2.70%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Rituximab	4 (4.76%)	2 (5.41%)	0 (0.00%)	2 (5.71%)	0 (0.00%)	1 (3.85%)	2 (5.71%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (9.09%)	1 (6.67%)	3 (10.34%)	0 (0.00%)
Blinatumomab	26 (30.95%)	12 (32.43%)	7 (25.93%)	12 (34.29%)	7 (25.00%)	10 (38.46%)	14 (40.00%)	1 (33.33%)	2 (33.33%)	9 (26.47%)	8 (36.36%)	8 (53.33%)	12 (41.38%)	12 (35.29%)
Bosutinib	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Asciminib	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Other TKI	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Inotuzumab ozogamicin (not including InO prescribed as bridge therapy to HPSCt o	4 (4.76%)	2 (5.41%)	0 (0.00%)	2 (5.71%)	0 (0.00%)	3 (11.54%)	0 (0.00%)	1 (33.33%)	0 (0.00%)	1 (2.94%)	1 (4.55%)	2 (13.33%)	0 (0.00%)	4 (11.76%)
Hematopoietic stem cell transplant (HPSCt)	30 (35.71%)	16 (43.24%)	8 (29.63%)	15 (42.86%)	10 (35.71%)	7 (26.92%)	15 (42.86%)	0 (0.00%)	1 (16.67%)	12 (35.29%)	11 (50.00%)	4 (26.67%)	12 (41.38%)	12 (35.29%)
Other	25 (29.76%)	13 (35.14%)	7 (25.93%)	11 (31.43%)	7 (25.00%)	9 (34.62%)	10 (28.57%)	1 (33.33%)	3 (50.00%)	10 (29.41%)	7 (31.82%)	3 (20.00%)	9 (31.03%)	12 (35.29%)
None of the above	2 (2.38%)	1 (2.70%)	1 (3.70%)	1 (2.86%)	1 (3.57%)	1 (3.85%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.55%)	1 (6.67%)	1 (3.45%)	0 (0.00%)
Days between initiation of Blinatumomab and index														



n	24	11	7	11	7	8	14	1	2	7	8	8	12	10
Mean	265.58	235.00	215.00	230.18	208.14	227.88	270.79	166.00	124.50	184.14	258.38	356.50	161.25	367.90
Standard deviation	298.73	254.79	110.30	258.01	116.89	222.21	333.33	.	53.03	244.20	191.07	433.63	117.06	396.63
Standard error of the mean	60.98	76.82	41.69	77.79	44.18	78.56	89.09	.	37.50	92.30	67.55	153.31	33.79	125.42
Median	164.00	94.00	229.00	75.00	229.00	164.00	182.00	166.00	124.50	75.00	243.00	199.50	125.50	250.50
Interquartile range (IQR)	81.00 - 311.00	55.00 - 442.00	119.00 - 285.00	45.00 - 442.00	94.00 - 285.00	57.00 - 339.50	94.00 - 285.00	166.00 - 166.00	87.00 - 162.00	40.00 - 229.00	101.50 - 311.00	96.50 - 424.00	81.00 - 225.50	119.00 - 406.00
Range	33.00 - 1367.00	33.00 - 715.00	87.00 - 406.00	33.00 - 715.00	87.00 - 406.00	33.00 - 669.00	55.00 - 1367.00	166.00 - 166.00	87.00 - 162.00	33.00 - 715.00	87.00 - 669.00	45.00 - 1367.00	33.00 - 442.00	40.00 - 1367.00
95% CI	139.44 - 391.73	63.83 - 406.17	112.99 - 317.01	56.85 - 403.52	100.04 - 316.24	42.10 - 413.65	78.32 - 463.25	.	-351.98 - 600.98	-41.71 - 409.99	98.63 - 418.12	-6.02 - 719.02	86.87 - 235.63	84.17 - 651.63
Date at which this patient initiated Blinatumomab prior to receiving InO as a bridge to CAR-T not known., n (%)														
n	2	1	0	1	0	2	0	0	0	2	0	0	0	2
Not known	2 (100.00 %)	1 (100.00 %)	0 (.)	1 (100.00 %)	0 (.)	2 (100.00 %)	0 (.)	0 (.)	0 (.)	2 (100.00 %)	0 (.)	0 (.)	0 (.)	2 (100.00 %)
4.2]What did the patient receive Blinatumomab for?, n (%)														
n	26	12	7	12	7	10	14	1	2	9	8	8	12	12
MRD conversion	7 (26.92 %)	2 (16.67 %)	3 (42.86 %)	3 (25.00 %)	3 (42.86 %)	4 (40.00 %)	3 (21.43 %)	0 (0.00 %)	1 (50.00 %)	1 (11.11 %)	2 (25.00 %)	4 (50.00 %)	3 (25.00 %)	4 (33.33 %)
R/R disease	17 (65.38 %)	9 (75.00 %)	4 (57.14 %)	7 (58.33 %)	4 (57.14 %)	5 (50.00 %)	11 (78.57 %)	1 (100.00 %)	1 (50.00 %)	7 (77.78 %)	6 (75.00 %)	3 (37.50 %)	9 (75.00 %)	7 (58.33 %)
Frontline treatment	1 (3.85 %)	0 (0.00 %)	0 (0.00 %)	1 (8.33 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (12.50 %)	0 (0.00 %)	0 (0.00 %)
Other	1 (3.85 %)	1 (8.33 %)	0 (0.00 %)	1 (8.33 %)	0 (0.00 %)	1 (10.00 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (11.11 %)	0 (0.00 %)	0 (0.00 %)	0 (0.00 %)	1 (8.33 %)
4.2]Was the patient														



refractory to Blinatumomab?, n (%)														
n	26	12	7	12	7	10	14	1	2	9	8	8	12	12
Yes	10 (38.46%)	6 (50.00%)	2 (28.57%)	5 (41.67%)	3 (42.86%)	5 (50.00%)	5 (35.71%)	1 (100.00%)	1 (50.00%)	3 (33.33%)	2 (25.00%)	4 (50.00%)	6 (50.00%)	4 (33.33%)
No	16 (61.54%)	6 (50.00%)	5 (71.43%)	7 (58.33%)	4 (57.14%)	5 (50.00%)	9 (64.29%)	0 (0.00%)	1 (50.00%)	6 (66.67%)	6 (75.00%)	4 (50.00%)	6 (50.00%)	8 (66.67%)
Days between initiation of InO prior to bridging InO and index														
n	4	2	0	2	0	3	0	1	0	1	1	2	0	4
Mean	198.25	358.50		358.50		249.33		31.00		667.00	31.00	47.50		198.25
Standard deviation	312.60	436.28		436.28		361.83		.		.	.	3.54		312.60
Standard error of the mean	156.30	308.50	.	308.50	.	208.91	.	.	.	.	.	2.50	.	156.30
Median	47.50	358.50	.	358.50	.	50.00	.	31.00	.	667.00	31.00	47.50	.	47.50
Interquartile range (IQR)	38.00 - 358.50	50.00 - 667.00	. - .	50.00 - 667.00	. - .	31.00 - 667.00	. - .	31.00 - 31.00	. - .	667.00 - 667.00	31.00 - 31.00	45.00 - 50.00	. - .	38.00 - 358.50
Range	31.00 - 667.00	50.00 - 667.00		50.00 - 667.00		31.00 - 667.00		31.00 - 31.00		667.00 - 667.00	31.00 - 31.00	45.00 - 50.00		31.00 - 667.00
95% CI	-299.17 - 695.67	3561.36 - 4278.36	. - .	3561.36 - 4278.36	. - .	-649.51 - 1148.18	. - .	. - .	. - .	. - .	. - .	15.73 - 79.27	. - .	-299.17 - 695.67
4.2]What was the total cumulative dose of Inotuzamab ozogamicin this patient rec														
n	4	2	0	2	0	3	0	1	0	1	1	2	0	4
Mean	1.83	2.25		2.25		1.67		0.50		3.30	0.50	1.77		1.83
Standard deviation	1.24	1.48		1.48		1.46		.		.	.	0.81		1.24
Standard error of the mean	0.62	1.05	.	1.05	.	0.84	.	.	.	.	.	0.57	.	0.62
Median	1.77	2.25	.	2.25	.	1.20	.	0.50	.	3.30	0.50	1.77	.	1.77
IQR	0.85 - 2.82	1.20 - 3.30	. - .	1.20 - 3.30	. - .	0.50 - 3.30	. - .	0.50 - 0.50	. - .	3.30 - 3.30	0.50 - 0.50	1.20 - 2.34	. - .	0.85 - 2.82
Range	0.50 - 3.30	1.20 - 3.30		1.20 - 3.30		0.50 - 3.30		0.50 - 0.50		3.30 - 3.30	0.50 - 0.50	1.20 - 2.34		0.50 - 3.30



95% CI	-0.13 - 3.80	-11.09 - 15.59	. . .	-11.09 - 15.59	. . .	-1.95 - 5.29	. . .	. . .	. . .	. . .	. . .	-5.47 - 9.01	. . .	-0.13 - 3.80
Days between initiation of HPSCT and index														
n	30	16	8	15	10	7	15	0	1	12	11	4	12	12
Mean	600.10	544.12	531.75	501.47	587.30	532.00	574.13		590.00	574.17	423.36	900.75	518.42	606.58
Standard deviation	447.21	287.18	387.73	239.10	402.25	219.76	498.31		.	324.95	315.59	629.12	382.10	439.32
Standard error of the mean	81.65	71.80	137.08	61.74	127.20	83.06	128.66	.	.	93.80	95.15	314.56	110.30	126.82
Median	546.50	546.50	487.50	542.00	512.50	542.00	427.00	.	590.00	556.00	385.00	715.50	431.00	561.50
Interquartile range (IQR)	229.00 - 759.00	307.50 - 753.50	181.00 - 764.50	243.00 - 748.00	189.00 - 874.00	372.00 - 759.00	173.00 - 874.00	. . .	590.00 - 590.00	311.00 - 799.00	158.00 - 572.00	482.00 - 1319.50	181.00 - 714.50	307.00 - 707.00
Range	125.00 - 1862.00	158.00 - 1184.00	148.00 - 1240.00	158.00 - 839.00	148.00 - 1240.00	195.00 - 839.00	125.00 - 1800.00		590.00 - 590.00	165.00 - 1240.00	125.00 - 1184.00	372.00 - 1800.00	148.00 - 1240.00	125.00 - 1800.00
95% CI	433.11 - 767.09	391.09 - 697.16	207.60 - 855.90	369.06 - 633.88	299.55 - 875.05	328.76 - 735.24	298.18 - 850.09	. . .	. . .	367.71 - 780.63	211.35 - 635.38	-100.32 - 1901.82	275.64 - 761.19	327.45 - 885.71
4.2]What was this patient's response to HPSCT prior to receiving InO as a bridge to CAR-T?, n (%)														
n	30	16	8	15	10	7	15	0	1	12	11	4	12	12
Complete remission (CR)	17 (56.67%)	8 (50.00%)	5 (62.50%)	7 (46.67%)	7 (70.00%)	4 (57.14%)	9 (60.00%)	0 (%)	1 (100.00%)	5 (41.67%)	6 (54.55%)	4 (100.00%)	8 (66.67%)	6 (50.00%)
Morphologic leukaemia-free state (MLFS)	3 (10.00%)	2 (12.50%)	0 (0.00%)	2 (13.33%)	0 (0.00%)	0 (0.00%)	1 (6.67%)	0 (%)	0 (0.00%)	1 (8.33%)	2 (18.18%)	0 (0.00%)	0 (0.00%)	2 (16.67%)
Progressive disease (PD)	1 (3.33%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	1 (10.00%)	0 (0.00%)	1 (6.67%)	0 (%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (8.33%)
Relapsed disease	8 (26.67%)	5 (31.25%)	2 (25.00%)	5 (33.33%)	2 (20.00%)	2 (28.57%)	4 (26.67%)	0 (%)	0 (0.00%)	4 (33.33%)	3 (27.27%)	0 (0.00%)	4 (33.33%)	2 (16.67%)
Uncertain response	1 (3.33%)	1 (6.25%)	0 (0.00%)	1 (6.67%)	0 (0.00%)	1 (14.29%)	0 (0.00%)	0 (%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (8.33%)



4.4 Did this patient receive InO as a bridge to HPSCT prior to using InO as a bridge to CAR-T?, n (%)														
n	2	1	0	1	0	1	0	0	0	1	0	1	0	2
No	2 (100.00%)	1 (100.00%)	0 (.%)	1 (100.00%)	0 (.%)	1 (100.00%)	0 (.%)	0 (.%)	0 (.%)	1 (100.00%)	0 (.%)	1 (100.00%)	0 (.%)	2 (100.00%)
4.5 Please enter the total number of cycles of InO treatment this patient has re														
n	84	37	27	35	28	26	35	3	6	34	22	15	29	34
Mean	1.31	1.27	1.22	1.23	1.21	1.23	1.31	1.67	1.17	1.24	1.27	1.27	1.52	1.06
Standard deviation	0.62	0.45	0.51	0.43	0.42	0.43	0.68	0.58	0.41	0.50	0.70	0.46	0.74	0.24
Standard error of the mean	0.07	0.07	0.10	0.07	0.08	0.08	0.11	0.33	0.17	0.09	0.15	0.12	0.14	0.04
Median	1.00	1.00	1.00	1.00	1.00	1.00	1.00	2.00	1.00	1.00	1.00	1.00	1.00	1.00
Interquartile range (IQR)	1.00 - 1.50	1.00 - 2.00	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00	1.00 - 2.00	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00	1.00 - 2.00	1.00 - 2.00	1.00 - 1.00
Range	1.00 - 4.00	1.00 - 2.00	1.00 - 3.00	1.00 - 2.00	1.00 - 2.00	1.00 - 2.00	1.00 - 4.00	1.00 - 2.00	1.00 - 2.00	1.00 - 3.00	1.00 - 4.00	1.00 - 2.00	1.00 - 4.00	1.00 - 2.00
95% CI	1.17 - 1.44	1.12 - 1.42	1.02 - 1.42	1.08 - 1.37	1.05 - 1.38	1.06 - 1.40	1.08 - 1.55	0.23 - 3.10	0.74 - 1.60	1.06 - 1.41	0.96 - 1.58	1.01 - 1.52	1.24 - 1.80	0.98 - 1.14
4.5 Please enter the total number of cycles of InO treatment this patient has received as a bridge to CAR-T., n (%)														
n	84	37	27	35	28	26	35	3	6	34	22	15	29	34
1	63 (75.00%)	27 (72.97%)	22 (81.48%)	27 (77.14%)	22 (78.57%)	20 (76.92%)	27 (77.14%)	1 (33.33%)	5 (83.33%)	27 (79.41%)	18 (81.82%)	11 (73.33%)	17 (58.62%)	32 (94.12%)
2	18 (21.43%)	10 (27.03%)	4 (14.81%)	8 (22.86%)	6 (21.43%)	6 (23.08%)	6 (17.14%)	2 (66.67%)	1 (16.67%)	6 (17.65%)	3 (13.64%)	4 (26.67%)	10 (34.48%)	2 (5.88%)
3	1 (1.19%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	0 (0.00%)	0 (0.00%)	1 (3.45%)	0 (0.00%)

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4	2 (2.38%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.55%)	0 (0.00%)	1 (3.45%)	0 (0.00%)
Bridging InO as an inpatient/outpatient														
n	84	37	27	35	28	26	35	3	6	34	22	15	29	34
Inpatient	37 (44.05%)	18 (48.65%)	9 (33.33%)	17 (48.57%)	10 (35.71%)	11 (42.31%)	13 (37.14%)	1 (33.33%)	4 (66.67%)	14 (41.18%)	11 (50.00%)	4 (26.67%)	13 (44.83%)	12 (35.29%)
Outpatient	52 (61.90%)	23 (62.16%)	19 (70.37%)	21 (60.00%)	20 (71.43%)	17 (65.38%)	24 (68.57%)	2 (66.67%)	3 (50.00%)	23 (67.65%)	12 (54.55%)	10 (66.67%)	21 (72.41%)	21 (61.76%)
Not known/Not recorded	5 (5.95%)	2 (5.41%)	2 (7.41%)	2 (5.71%)	2 (7.14%)	0 (0.00%)	3 (8.57%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	2 (9.09%)	2 (13.33%)	2 (6.90%)	1 (2.94%)

Overall, 84.5% of patients went on to receive CAR-T as the next step in treatment after InO was received as a bridge to CAR-T (please see **Table 36** below). Overall, the mean (SD) number of days between the final dose of InO and CAR-T (or the therapy given in its place) was 46.28 (42.41) (please see **Table 36** below).

Table 36: Next Step in Treatment Post-InO as a Bridge to CAR-T and Other Parameters including CAR-T Receipt as Part of a Clinical Trial, Next Treatment Ongoing or Discontinued, Time Between Final InO Dose and CAR-T and Number of Leukaphereses Needed.

	Overall	MRD status (1st cycle of InO)		MRD status (last cycle of InO)		MRD status (CAR-T infusion)		MRD status (prior to HPST)		BMI at index (initiation of InO)			InO received:	
	Total	Positive	Negative	Positive	Negative	Positive	Negative	Positive	Negative	(18.5, 25)	(25, 30)	30+	Pre-apheresis	Post-apheresis
5.1 Please indicate what the next step in treatment was after InO was received as a bridge to CAR-T?, n (%)														
n	84	37	27	35	28	26	35	3	6	34	22	15	29	34
Patient went on to receive CAR-T	71 (84.52%)	31 (83.78%)	25 (92.59%)	27 (77.14%)	27 (96.43%)	26 (100.00%)	35 (100.00%)	3 (100.00%)	6 (100.00%)	30 (88.24%)	20 (90.91%)	13 (86.67%)	29 (100.00%)	34 (100.00%)

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Patient received another therapy	9 (10.71%)	5 (13.51%)	1 (3.70%)	6 (17.14%)	1 (3.57%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (8.82%)	2 (9.09%)	2 (13.33%)	0 (0.00%)	0 (0.00%)
Patient went into palliative care	4 (4.76%)	1 (2.70%)	1 (3.70%)	2 (5.71%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
5.1 Did the patient receive CAR-T as part of a clinical trial?, n (%)														
n	71	31	25	27	27	26	35	3	6	30	20	13	29	34
Yes	9 (12.68%)	5 (16.13%)	1 (4.00%)	4 (14.81%)	2 (7.41%)	1 (3.85%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	4 (13.33%)	1 (5.00%)	1 (7.69%)	1 (3.45%)	1 (2.94%)
No	62 (87.32%)	26 (83.87%)	24 (96.00%)	23 (85.19%)	25 (92.59%)	25 (96.15%)	35 (100.00%)	3 (100.00%)	6 (100.00%)	26 (86.67%)	19 (95.00%)	12 (92.31%)	28 (96.55%)	33 (97.06%)
5.3 Please indicate if the next treatment is ongoing or if it has discontinued., n (%)														
n	73	32	25	30	26	26	35	3	6	30	22	14	29	34
Ongoing	23 (31.51%)	11 (34.38%)	7 (28.00%)	11 (36.67%)	8 (30.77%)	12 (46.15%)	8 (22.86%)	0 (0.00%)	0 (0.00%)	11 (36.67%)	4 (18.18%)	7 (50.00%)	9 (31.03%)	11 (32.35%)
Discontinued	34 (46.58%)	16 (50.00%)	8 (32.00%)	15 (50.00%)	7 (26.92%)	13 (50.00%)	12 (34.29%)	3 (100.00%)	3 (50.00%)	12 (40.00%)	14 (63.64%)	4 (28.57%)	9 (31.03%)	18 (52.94%)
Not known	16 (21.92%)	5 (15.62%)	10 (40.00%)	4 (13.33%)	11 (42.31%)	1 (3.85%)	15 (42.86%)	0 (0.00%)	3 (50.00%)	7 (23.33%)	4 (18.18%)	3 (21.43%)	11 (37.93%)	5 (14.71%)
Date of the final dose of InO not known., n (%)														
n	2	2	0	1	0	1	1	1	0	1	0	0	1	1
Not known	2 (100.00%)	2 (100.00%)	0 (.%)	1 (100.00%)	0 (.%)	1 (100.00%)	1 (100.00%)	1 (100.00%)	0 (.%)	1 (100.00%)	0 (.%)	0 (.%)	1 (100.00%)	1 (100.00%)
Days between final dose of InO and CAR-T (or the therapy														



given in its place)														
n	71	30	25	29	26	25	34	2	6	29	22	14	28	33
Mean	46.28	39.33	50.08	37.83	50.81	38.64	47.71	19.00	46.00	40.66	40.95	32.93	50.79	36.12
Standard deviation	42.41	36.68	23.70	37.06	23.53	52.35	23.45	7.07	36.50	22.67	24.34	20.22	23.62	45.88
Standard error of the mean	5.03	6.70	4.74	6.88	4.61	10.47	4.02	5.00	14.90	4.21	5.19	5.40	4.46	7.99
Median	35.00	31.50	50.00	29.00	50.50	24.00	46.00	19.00	39.00	35.00	34.00	27.00	51.50	27.00
Interquartile range (IQR)	22.00 - 57.00	21.00 - 45.00	28.00 - 58.00	14.00 - 43.00	28.00 - 66.00	13.00 - 43.00	28.00 - 66.00	14.00 - 24.00	12.00 - 82.00	24.00 - 55.00	23.00 - 51.00	17.00 - 51.00	34.00 - 68.50	20.00 - 39.00
Range	6.00 - 274.00	6.00 - 204.00	20.00 - 96.00	6.00 - 204.00	20.00 - 96.00	6.00 - 274.00	12.00 - 96.00	14.00 - 24.00	10.00 - 94.00	10.00 - 96.00	6.00 - 94.00	10.00 - 71.00	10.00 - 96.00	6.00 - 274.00
95% CI	36.24 - 56.32	25.64 - 53.03	40.30 - 59.86	23.73 - 51.93	41.30 - 60.31	17.03 - 60.25	39.52 - 55.89	-44.53 - 82.53	7.69 - 84.31	32.03 - 49.28	30.16 - 51.74	21.26 - 44.60	41.63 - 59.95	19.85 - 52.39
Days between final dose of InO and CAR-T infusion														
n	62	25	24	23	25	25	34	2	6	26	20	12	28	33
Mean	44.10	36.72	50.08	33.22	51.00	40.52	47.82	21.00	46.67	43.46	41.55	32.00	51.11	37.58
Standard deviation	37.22	19.80	24.21	18.13	24.13	51.86	23.55	4.24	35.74	22.44	24.74	18.66	23.43	45.60
Standard error of the mean	4.73	3.96	4.94	3.78	4.83	10.37	4.04	3.00	14.59	4.40	5.53	5.39	4.43	7.94
Median	34.50	34.00	49.00	29.00	51.00	27.00	46.00	21.00	39.00	41.00	34.00	27.00	51.50	27.00
Interquartile range (IQR)	22.00 - 56.00	23.00 - 50.00	27.50 - 63.00	15.00 - 45.00	28.00 - 70.00	15.00 - 43.00	28.00 - 68.00	18.00 - 24.00	14.00 - 82.00	28.00 - 57.00	22.50 - 57.00	15.50 - 50.50	34.00 - 69.50	20.00 - 42.00
Range	8.00 - 274.00	8.00 - 71.00	20.00 - 96.00	8.00 - 69.00	20.00 - 96.00	8.00 - 274.00	12.00 - 96.00	18.00 - 24.00	12.00 - 94.00	12.00 - 96.00	8.00 - 94.00	12.00 - 64.00	12.00 - 96.00	8.00 - 274.00
95% CI	34.64 - 53.55	28.55 - 44.89	39.86 - 60.31	25.38 - 41.06	41.04 - 60.96	19.11 - 61.93	39.60 - 56.04	-17.12 - 59.12	9.16 - 84.18	34.40 - 52.53	29.97 - 53.13	20.14 - 43.86	42.02 - 60.19	21.40 - 53.75
5.4 Please indicate the number of leukaphereses that were needed for this patient														
n	64	27	24	24	25	26	35	3	6	27	20	12	29	34
Mean	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00
Standard deviation	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Standard error of the mean	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Median	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00



Interquartile range (IQR)	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00
Range	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00
95% CI	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00
1.2 Please confirm if leukapheresis was successful., n (%)														
n	64	27	24	24	25	26	35	3	6	27	20	12	29	34
Leukapheresis was successful	64 (100.00 %)	27 (100.00 %)	24 (100.00 %)	24 (100.00 %)	25 (100.00 %)	26 (100.00 %)	35 (100.00 %)	3 (100.00 %)	6 (100.00 %)	27 (100.00 %)	20 (100.00 %)	12 (100.00 %)	29 (100.00 %)	34 (100.00 %)
5.4 Please enter the number of T-cells obtained.														
n	37	16	17	12	18	16	20	2	3	18	9	5	16	20
Mean	10.44	1.86	1.79	2.00	1.71	2.09	1.69	2.08	3.37	19.45	2.07	1.16	1.06	18.31
Standard deviation	52.17	1.32	2.44	1.43	2.39	1.52	2.26	0.74	2.60	74.79	2.20	0.80	1.46	70.81
Standard error of the mean	8.58	0.33	0.59	0.41	0.56	0.38	0.51	0.52	1.50	17.63	0.73	0.36	0.37	15.83
Median	1.49	1.89	0.40	2.00	0.40	2.00	0.49	2.08	4.49	1.00	0.58	1.00	0.40	2.00
Interquartile range (IQR)	0.40 - 2.50	0.40 - 2.55	0.40 - 2.00	0.40 - 2.83	0.40 - 2.00	0.40 - 2.88	0.40 - 1.89	1.56 - 2.61	0.40 - 5.22	0.40 - 2.50	0.40 - 3.15	0.40 - 2.00	0.40 - 0.75	1.25 - 3.55
Range	0.40 - 319.00	0.40 - 4.49	0.40 - 8.35	0.40 - 4.49	0.40 - 8.35	0.40 - 5.00	0.40 - 8.35	1.56 - 2.61	0.40 - 5.22	0.40 - 319.00	0.40 - 6.34	0.40 - 2.00	0.40 - 5.22	0.40 - 319.00
95% CI	-6.95 - 27.83	1.15 - 2.56	0.53 - 3.05	1.09 - 2.91	0.52 - 2.90	1.28 - 2.90	0.63 - 2.75	-4.59 - 8.76	-3.08 - 9.82	-17.74 - 56.64	0.38 - 3.76	0.16 - 2.16	0.28 - 1.84	-14.83 - 51.45
3.1 Number of T-cells obtained not known., n (%)														
n	34	15	8	15	9	10	15	1	3	12	11	8	13	14
Not known	34 (100.00 %)	15 (100.00 %)	8 (100.00 %)	15 (100.00 %)	9 (100.00 %)	10 (100.00 %)	15 (100.00 %)	1 (100.00 %)	3 (100.00 %)	12 (100.00 %)	11 (100.00 %)	8 (100.00 %)	13 (100.00 %)	14 (100.00 %)
5.4 Please enter the number of CAR-T cells administered in the infusion.														



n	42	18	18	15	18	16	24	2	2	19	14	5	21	20
Mean	16.57	14.18	1.15	16.68	1.15	15.95	1.24	2.05	1.85	22.68	18.18	0.68	1.13	33.46
Standard deviation	71.50	53.87	0.66	59.02	0.66	57.09	0.79	1.06	1.20	93.80	60.97	0.46	0.53	102.26
Standard error of the mean	11.03	12.70	0.16	15.24	0.16	14.27	0.16	0.75	0.85	21.52	16.30	0.21	0.12	22.87
Median	1.00	1.00	1.00	1.00	1.00	1.65	1.00	2.05	1.85	1.00	1.62	1.00	1.00	1.27
Interquartile range (IQR)	1.00 - 2.30	1.00 - 2.70	1.00 - 1.00	1.00 - 2.70	1.00 - 1.00	1.00 - 2.85	1.00 - 1.00	1.30 - 2.80	1.00 - 2.70	1.00 - 1.00	1.00 - 2.90	0.40 - 1.00	1.00 - 1.00	1.00 - 2.85
Range	0.00 - 410.00	0.00 - 230.00	0.00 - 3.00	0.00 - 230.00	0.00 - 3.00	0.00 - 230.00	0.00 - 3.80	1.30 - 2.80	1.00 - 2.70	0.00 - 410.00	1.00 - 230.00	0.00 - 1.00	0.40 - 3.00	0.00 - 410.00
95% CI	-5.71 - 38.85	-12.60 - 40.97	0.82 - 1.48	-16.00 - 49.36	0.82 - 1.48	-14.48 - 46.37	0.91 - 1.57	-7.48 - 11.58	-8.95 - 12.65	-22.52 - 67.89	-17.02 - 53.39	0.11 - 1.25	0.89 - 1.37	-14.39 - 81.32
Number of CAR-T cells administered in the infusion not known., n (%)														
n	22	9	6	9	7	10	11	1	4	8	6	7	8	14
Not known/Not recorded	22 (100.00 %)	9 (100.00 %)	6 (100.00 %)	9 (100.00 %)	7 (100.00 %)	10 (100.00 %)	11 (100.00 %)	1 (100.00 %)	4 (100.00 %)	8 (100.00 %)	6 (100.00 %)	7 (100.00 %)	8 (100.00 %)	14 (100.00 %)
5.4 Please enter the most recently measured bone marrow blast count at CAR-T inf														
n	58	26	23	24	24	24	33	2	6	25	19	10	28	29
Mean	9.42	15.77	3.39	14.54	3.25	18.30	3.24	37.00	9.75	9.76	6.39	11.65	4.55	14.23
Standard deviation	21.01	28.89	8.03	28.10	7.89	29.63	7.36	38.18	20.23	23.76	11.77	25.07	14.46	25.48
Standard error of the mean	2.76	5.67	1.67	5.74	1.61	6.05	1.28	27.00	8.26	4.75	2.70	7.93	2.73	4.73
Median	1.00	1.75	1.00	2.00	1.00	3.00	0.00	37.00	1.75	1.00	2.00	0.50	1.00	2.00
Interquartile range (IQR)	0.00 - 3.00	0.00 - 10.00	0.00 - 3.00	0.00 - 8.00	0.00 - 2.50	1.00 - 21.00	0.00 - 2.00	10.00 - 64.00	1.00 - 3.00	0.00 - 3.00	0.00 - 10.00	0.00 - 3.00	0.00 - 2.50	0.00 - 10.00
Range	0.00 - 86.00	0.00 - 86.00	0.00 - 35.00	0.00 - 86.00	0.00 - 35.00	0.00 - 86.00	0.00 - 35.00	10.00 - 64.00	0.00 - 51.00	0.00 - 86.00	0.00 - 51.00	0.00 - 76.00	0.00 - 76.00	0.00 - 86.00
95% CI	3.89 - 14.94	4.10 - 27.44	-0.08 - 6.86	2.67 - 26.41	-0.08 - 6.58	5.79 - 30.81	0.63 - 5.85	-306.07 - 380.07	-11.48 - 30.98	-0.05 - 19.57	0.72 - 12.07	-6.28 - 29.58	-1.05 - 10.16	4.54 - 23.92
Most recently measured bone marrow blast count at CAR-T														



infusion not known., n (%)														
n	6	1	1	0	1	2	2	1	0	2	1	2	1	5
Not known/Not recorded	6 (100.00%)	1 (100.00%)	1 (100.00%)	0 (0.00%)	1 (100.00%)	2 (100.00%)	2 (100.00%)	1 (100.00%)	0 (0.00%)	2 (100.00%)	1 (100.00%)	2 (100.00%)	1 (100.00%)	5 (100.00%)
5.4 Please indicate the MRD status at CAR-T infusion., n (%)														
n	64	27	24	24	25	26	35	3	6	27	20	12	29	34
Positive	26 (40.62%)	19 (70.37%)	2 (8.33%)	18 (75.00%)	2 (8.00%)	26 (100.00%)	0 (0.00%)	3 (100.00%)	3 (50.00%)	10 (37.04%)	7 (35.00%)	6 (50.00%)	7 (24.14%)	18 (52.94%)
Negative	35 (54.69%)	7 (25.93%)	22 (91.67%)	5 (20.83%)	23 (92.00%)	0 (0.00%)	35 (100.00%)	0 (0.00%)	3 (50.00%)	16 (59.26%)	12 (60.00%)	5 (41.67%)	22 (75.86%)	13 (38.24%)
Not known/Not recorded	3 (4.69%)	1 (3.70%)	0 (0.00%)	1 (4.17%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.70%)	1 (5.00%)	1 (8.33%)	0 (0.00%)	3 (8.82%)
5.4 Was the patient diagnosed with extramedullary disease at CAR-T infusion?, n (%)														
n	64	27	24	24	25	26	35	3	6	27	20	12	29	34
Yes	11 (17.19%)	4 (14.81%)	4 (16.67%)	4 (16.67%)	5 (20.00%)	6 (23.08%)	5 (14.29%)	0 (0.00%)	1 (16.67%)	7 (25.93%)	3 (15.00%)	0 (0.00%)	5 (17.24%)	6 (17.65%)
No	53 (82.81%)	23 (85.19%)	20 (83.33%)	20 (83.33%)	20 (80.00%)	20 (76.92%)	30 (85.71%)	3 (100.00%)	5 (83.33%)	20 (74.07%)	17 (85.00%)	12 (100.00%)	24 (82.76%)	28 (82.35%)
Location of EMD at CAR-T infusion														
n	11	4	4	4	5	6	5	0	1	7	3	0	5	6
Skin	1 (9.09%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (16.67%)
Oral	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
cns	2 (18.18%)	2 (50.00%)	0 (0.00%)	2 (50.00%)	0 (0.00%)	2 (33.33%)	0 (0.00%)	0 (0.00%)	1 (100.00%)	1 (14.29%)	1 (33.33%)	0 (0.00%)	0 (0.00%)	2 (33.33%)



Liver	4 (36.36%)	0 (0.00%)	2 (50.00%)	0 (0.00%)	3 (60.00%)	2 (33.33%)	2 (40.00%)	0 (.%)	0 (0.00%)	3 (42.86%)	0 (0.00%)	0 (.%)	1 (20.00%)	3 (50.00%)
Spleen	1 (9.09%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	1 (20.00%)	1 (16.67%)	0 (0.00%)	0 (.%)	0 (0.00%)	1 (14.29%)	0 (0.00%)	0 (.%)	0 (0.00%)	1 (16.67%)
Testes	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (.%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (.%)	0 (0.00%)	0 (0.00%)
Lymph nodes	3 (27.27%)	1 (25.00%)	2 (50.00%)	1 (25.00%)	2 (40.00%)	2 (33.33%)	1 (20.00%)	0 (.%)	0 (0.00%)	3 (42.86%)	0 (0.00%)	0 (.%)	1 (20.00%)	2 (33.33%)
Other	5 (45.45%)	1 (25.00%)	3 (75.00%)	1 (25.00%)	3 (60.00%)	2 (33.33%)	3 (60.00%)	0 (.%)	0 (0.00%)	3 (42.86%)	2 (66.67%)	0 (.%)	3 (60.00%)	2 (33.33%)
5.4 Please indicate the type of CAR-T prescribed., n (%)														
n	64	27	24	24	25	26	35	3	6	27	20	12	29	34
Kymriah	19 (29.69%)	13 (48.15%)	4 (16.67%)	10 (41.67%)	4 (16.00%)	11 (42.31%)	8 (22.86%)	2 (66.67%)	2 (33.33%)	8 (29.63%)	7 (35.00%)	0 (0.00%)	4 (13.79%)	14 (41.18%)
Tecartus	22 (34.38%)	7 (25.93%)	8 (33.33%)	8 (33.33%)	8 (32.00%)	8 (30.77%)	13 (37.14%)	1 (33.33%)	2 (33.33%)	9 (33.33%)	5 (25.00%)	8 (66.67%)	9 (31.03%)	13 (38.24%)
Other CD19-directed CAR T product	23 (35.94%)	7 (25.93%)	12 (50.00%)	6 (25.00%)	13 (52.00%)	7 (26.92%)	14 (40.00%)	0 (0.00%)	2 (33.33%)	10 (37.04%)	8 (40.00%)	4 (33.33%)	16 (55.17%)	7 (20.59%)
5.4 Please enter the most recently measured bone marrow blast count after the pa														
n	56	26	22	23	23	24	31	2	5	25	17	9	26	29
Mean	8.98	11.38	8.82	12.83	8.48	9.38	8.97	0.00	1.10	14.16	1.85	13.06	8.79	9.47
Standard deviation	24.08	28.34	22.98	29.90	22.51	26.51	22.84	0.00	1.02	30.84	3.33	29.15	21.72	26.74
Standard error of the mean	3.22	5.56	4.90	6.23	4.69	5.41	4.10	0.00	0.46	6.17	0.81	9.72	4.26	4.97
Median	1.00	0.50	1.50	1.00	1.00	0.00	1.00	0.00	1.50	1.00	1.00	1.00	1.00	0.00
Interquartile range (IQR)	0.00 - 2.00	0.00 - 1.50	0.00 - 3.00	0.00 - 2.00	0.00 - 3.00	0.00 - 1.75	0.00 - 3.00	0.00 - 0.00	0.00 - 2.00	0.00 - 3.00	0.00 - 2.00	0.00 - 3.00	0.00 - 2.00	0.00 - 1.50
Range	0.00 - 94.00	0.00 - 94.00	0.00 - 88.00	0.00 - 94.00	0.00 - 88.00	0.00 - 94.00	0.00 - 88.00	0.00 - 0.00	0.00 - 2.00	0.00 - 94.00	0.00 - 13.00	0.00 - 88.00	0.00 - 88.00	0.00 - 94.00

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95% CI	2.53 - 15.43	-0.06 - 22.83	-1.37 - 19.00	-0.10 - 25.75	-1.25 - 18.21	-1.82 - 20.57	0.59 - 17.35	0.00 - 0.00	-0.17 - 2.37	1.43 - 26.89	0.14 - 3.57	-9.35 - 35.46	0.02 - 17.56	-0.70 - 19.64
Most recently measured bone marrow blast count after the patient received CAR-T bridging therapy not known., n (%)														
n	8	1	2	1	2	2	4	1	1	2	3	3	3	5
Not known/Not recorded	8 (100.00 %)	1 (100.00 %)	2 (100.00 %)	1 (100.00 %)	2 (100.00 %)	2 (100.00 %)	4 (100.00 %)	1 (100.00 %)	1 (100.00 %)	2 (100.00 %)	3 (100.00 %)	3 (100.00 %)	3 (100.00 %)	5 (100.00 %)
6.1 Please enter the total number of treatment lines (i.e. number of salvage li														
n	62	26	24	23	25	24	35	3	6	27	19	12	29	33
Mean	0.68	0.81	0.75	0.61	0.68	0.58	0.80	3.00	1.50	0.48	0.84	0.33	0.93	0.45
Standard deviation	1.17	1.50	0.94	1.34	0.95	1.10	1.26	1.00	1.22	0.94	1.46	0.49	1.33	0.97
Standard error of the mean	0.15	0.29	0.19	0.28	0.19	0.22	0.21	0.58	0.50	0.18	0.34	0.14	0.25	0.17
Median	0.00	0.00	1.00	0.00	0.00	0.00	0.00	3.00	1.00	0.00	0.00	0.00	1.00	0.00
Interquartile range (IQR)	0.00 - 1.00	0.00 - 1.00	0.00 - 1.00	0.00 - 1.00	0.00 - 1.00	0.00 - 1.00	0.00 - 1.00	2.00 - 4.00	1.00 - 1.00	0.00 - 1.00	0.00 - 1.00	0.00 - 1.00	0.00 - 1.00	0.00 - 0.00
Range	0.00 - 5.00	0.00 - 5.00	0.00 - 4.00	0.00 - 5.00	0.00 - 4.00	0.00 - 4.00	0.00 - 5.00	2.00 - 4.00	1.00 - 4.00	0.00 - 4.00	0.00 - 5.00	0.00 - 1.00	0.00 - 5.00	0.00 - 4.00
95% CI	0.38 - 0.97	0.20 - 1.41	0.35 - 1.15	0.03 - 1.19	0.29 - 1.07	0.12 - 1.05	0.37 - 1.23	0.52 - 5.48	0.21 - 2.79	0.11 - 0.85	0.14 - 1.55	0.02 - 0.65	0.42 - 1.44	0.11 - 0.80
6.1 Please enter the total number of treatment lines (i.e. number of salvage lines) received for ALL after CAR-T bridging therapy., n (%)														
n	64	27	24	24	25	26	35	3	6	27	20	12	29	34
Not known	2 (3.12%)	1 (3.70%)	0 (0.00%)	1 (4.17%)	0 (0.00%)	2 (7.69%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.00%)	0 (0.00%)	0 (0.00%)	1 (2.94%)



0	39 (60.94%)	18 (66.67%)	11 (45.83%)	17 (70.83%)	13 (52.00%)	17 (65.38%)	19 (54.29%)	0 (0.00%)	0 (0.00%)	19 (70.37%)	12 (60.00%)	8 (66.67%)	14 (48.28%)	25 (73.53%)
1	14 (21.88%)	3 (11.11%)	10 (41.67%)	3 (12.50%)	9 (36.00%)	3 (11.54%)	11 (31.43%)	0 (0.00%)	5 (83.33%)	5 (18.52%)	3 (15.00%)	4 (33.33%)	10 (34.48%)	4 (11.76%)
2	4 (6.25%)	1 (3.70%)	2 (8.33%)	1 (4.17%)	2 (8.00%)	2 (7.69%)	2 (5.71%)	1 (33.33%)	0 (0.00%)	2 (7.41%)	2 (10.00%)	0 (0.00%)	2 (6.90%)	2 (5.88%)
3	1 (1.56%)	1 (3.70%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.85%)	0 (0.00%)	1 (33.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.94%)
4	3 (4.69%)	2 (7.41%)	1 (4.17%)	1 (4.17%)	1 (4.00%)	1 (3.85%)	2 (5.71%)	1 (33.33%)	1 (16.67%)	1 (3.70%)	1 (5.00%)	0 (0.00%)	2 (6.90%)	1 (2.94%)
5	1 (1.56%)	1 (3.70%)	0 (0.00%)	1 (4.17%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (5.00%)	0 (0.00%)	1 (3.45%)	0 (0.00%)
Treatments or procedures received for ALL after CAR- T therapy														
n	23	8	13	6	12	7	16	3	6	8	7	4	15	8
Vincristine	5 (21.74%)	2 (25.00%)	3 (23.08%)	1 (16.67%)	3 (25.00%)	1 (14.29%)	4 (25.00%)	1 (33.33%)	1 (16.67%)	0 (0.00%)	3 (42.86%)	0 (0.00%)	3 (20.00%)	2 (25.00%)
Dexamethason e	4 (17.39%)	2 (25.00%)	2 (15.38%)	1 (16.67%)	2 (16.67%)	1 (14.29%)	3 (18.75%)	1 (33.33%)	1 (16.67%)	0 (0.00%)	2 (28.57%)	0 (0.00%)	2 (13.33%)	2 (25.00%)
Prednisolone	4 (17.39%)	2 (25.00%)	2 (15.38%)	1 (16.67%)	2 (16.67%)	1 (14.29%)	3 (18.75%)	1 (33.33%)	0 (0.00%)	1 (12.50%)	2 (28.57%)	0 (0.00%)	3 (20.00%)	1 (12.50%)
Methylprednisol one	1 (4.35%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	1 (14.29%)	0 (0.00%)	1 (6.67%)	0 (0.00%)
Hydrocortisone	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Doxorubicin	1 (4.35%)	1 (12.50%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)	1 (6.67%)	0 (0.00%)
Daunorubicin	1 (4.35%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	1 (14.29%)	0 (0.00%)	1 (6.67%)	0 (0.00%)
Cyclophospham ide	6 (26.09%)	4 (50.00%)	2 (15.38%)	1 (16.67%)	2 (16.67%)	2 (28.57%)	4 (25.00%)	2 (66.67%)	1 (16.67%)	0 (0.00%)	3 (42.86%)	0 (0.00%)	4 (26.67%)	2 (25.00%)



L-asparaginase	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Methotrexate	6 (26.09%)	2 (25.00%)	3 (23.08%)	1 (16.67%)	3 (25.00%)	2 (28.57%)	4 (25.00%)	2 (66.67%)	1 (16.67%)	1 (12.50%)	3 (42.86%)	0 (0.00%)	3 (20.00%)	3 (37.50%)
Cytarabine	5 (21.74%)	1 (12.50%)	3 (23.08%)	1 (16.67%)	3 (25.00%)	1 (14.29%)	4 (25.00%)	1 (33.33%)	1 (16.67%)	1 (12.50%)	4 (57.14%)	0 (0.00%)	4 (26.67%)	1 (12.50%)
Etoposide	1 (4.35%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.25%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.67%)	0 (0.00%)
Mercaptopurine	3 (13.04%)	1 (12.50%)	2 (15.38%)	0 (0.00%)	2 (16.67%)	1 (14.29%)	2 (12.50%)	1 (33.33%)	1 (16.67%)	0 (0.00%)	1 (14.29%)	0 (0.00%)	1 (6.67%)	2 (25.00%)
Intrathecal chemotherapy	5 (21.74%)	2 (25.00%)	2 (15.38%)	1 (16.67%)	2 (16.67%)	2 (28.57%)	3 (18.75%)	2 (66.67%)	1 (16.67%)	1 (12.50%)	3 (42.86%)	0 (0.00%)	3 (20.00%)	2 (25.00%)
Radiation therapy	4 (17.39%)	3 (37.50%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	3 (42.86%)	1 (6.25%)	3 (100.00%)	0 (0.00%)	0 (0.00%)	2 (28.57%)	0 (0.00%)	1 (6.67%)	3 (37.50%)
Imatinib	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dasatinib	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Ponatinib	5 (21.74%)	1 (12.50%)	3 (23.08%)	1 (16.67%)	2 (16.67%)	2 (28.57%)	3 (18.75%)	1 (33.33%)	0 (0.00%)	3 (37.50%)	1 (14.29%)	1 (25.00%)	3 (20.00%)	2 (25.00%)
Nilotinib	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Rituximab	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blinatumomab	3 (13.04%)	2 (25.00%)	1 (7.69%)	2 (33.33%)	1 (8.33%)	1 (14.29%)	2 (12.50%)	0 (0.00%)	0 (0.00%)	1 (12.50%)	1 (14.29%)	1 (25.00%)	2 (13.33%)	1 (12.50%)
Bosutinib	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Asciminib	1 (4.35%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (14.29%)	0 (0.00%)	1 (33.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (12.50%)
Other TKI	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Inotuzumab ozogamicin (not including InO prescribed as bridge therapy to HPSC o	5 (21.74%)	1 (12.50%)	4 (30.77%)	1 (16.67%)	4 (33.33%)	1 (14.29%)	4 (25.00%)	0 (0.00%)	1 (16.67%)	3 (37.50%)	2 (28.57%)	0 (0.00%)	3 (20.00%)	2 (25.00%)



Hematopoietic stem cell transplant (HPSCT)	10 (43.48%)	5 (62.50%)	3 (23.08%)	4 (66.67%)	3 (25.00%)	6 (85.71%)	4 (25.00%)	3 (100.00%)	6 (100.00%)	2 (25.00%)	4 (57.14%)	2 (50.00%)	5 (33.33%)	5 (62.50%)
Other	6 (26.09%)	4 (50.00%)	2 (15.38%)	2 (33.33%)	2 (16.67%)	1 (14.29%)	5 (31.25%)	1 (33.33%)	1 (16.67%)	2 (25.00%)	2 (28.57%)	0 (0.00%)	5 (33.33%)	1 (12.50%)
None of the above	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Days between CAR-T infusion and start of next treatment														
n	23	8	13	6	12	7	16	3	6	8	7	4	15	8
Mean	194.74	187.38	203.46	195.67	218.33	150.43	214.12	155.00	177.83	197.12	204.71	193.75	210.47	165.25
Standard deviation	120.14	144.44	114.88	160.99	106.12	81.06	131.24	109.19	81.99	133.83	154.01	93.27	126.73	108.25
Standard error of the mean	25.05	51.07	31.86	65.72	30.63	30.64	32.81	63.04	33.47	47.31	58.21	46.64	32.72	38.27
Median	172.00	136.50	175.00	136.50	195.50	107.00	185.00	96.00	173.50	170.50	172.00	182.50	195.00	118.50
Interquartile range (IQR)	91.00 - 285.00	87.00 - 238.00	126.00 - 298.00	86.00 - 239.00	128.00 - 300.50	88.00 - 239.00	108.50 - 300.50	88.00 - 281.00	107.00 - 239.00	88.50 - 328.00	76.00 - 298.00	116.50 - 271.00	91.00 - 298.00	92.00 - 223.50
Range	25.00 - 500.00	76.00 - 500.00	25.00 - 378.00	76.00 - 500.00	75.00 - 378.00	76.00 - 281.00	25.00 - 500.00	88.00 - 281.00	76.00 - 298.00	25.00 - 378.00	75.00 - 500.00	107.00 - 303.00	25.00 - 500.00	76.00 - 378.00
95% CI	142.79 - 246.69	66.62 - 308.13	134.04 - 272.89	26.72 - 364.61	150.91 - 285.76	75.46 - 225.39	144.19 - 284.06	-116.25 - 426.25	91.79 - 263.88	85.24 - 309.01	62.28 - 347.15	45.33 - 342.17	140.29 - 280.65	74.75 - 255.75
6.1 Please enter the total number of HPSCs received after CAR-T bridging therap														
n	9	5	2	4	2	6	3	3	5	2	3	2	4	5
Mean	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00
Standard deviation	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Standard error of the mean	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Median	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00
Interquartile range (IQR)	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00
Range	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00
95% CI	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00	1.00 - 1.00



Total number of HPSCs received after CAR-T bridging therapy not known., n (%)														
n	1	0	1	0	1	0	1	0	1	0	1	0	1	0
Not known	1 (100.00%)	0 (0.00%)	1 (100.00%)	0 (0.00%)	1 (100.00%)	0 (0.00%)	1 (100.00%)	0 (0.00%)	1 (100.00%)	0 (0.00%)	1 (100.00%)	0 (0.00%)	1 (100.00%)	0 (0.00%)
1.2]Please indicate the method used to assess MRD prior to HPSC., n (%)														
n	9	4	3	3	3	6	3	3	6	1	4	2	4	5
Flow cytometry assays	4 (44.44%)	1 (25.00%)	3 (100.00%)	1 (33.33%)	3 (100.00%)	1 (16.67%)	3 (100.00%)	0 (0.00%)	4 (66.67%)	1 (100.00%)	3 (75.00%)	0 (0.00%)	3 (75.00%)	1 (20.00%)
Real-time quantitative polymerase chain reaction (RT-qPCR)	3 (33.33%)	1 (25.00%)	0 (0.00%)	1 (33.33%)	0 (0.00%)	3 (50.00%)	0 (0.00%)	2 (66.67%)	1 (16.67%)	0 (0.00%)	1 (25.00%)	1 (50.00%)	1 (25.00%)	2 (40.00%)
Next-generation sequencing (NGS)	2 (22.22%)	2 (50.00%)	0 (0.00%)	1 (33.33%)	0 (0.00%)	2 (33.33%)	0 (0.00%)	1 (33.33%)	1 (16.67%)	0 (0.00%)	0 (0.00%)	1 (50.00%)	0 (0.00%)	2 (40.00%)
Timing of the InO first dose, n (%)														
n	64	27	24	24	25	26	35	3	6	27	20	12	29	34
Before leukapheresis	29 (45.31%)	11 (40.74%)	14 (58.33%)	10 (41.67%)	15 (60.00%)	7 (26.92%)	22 (62.86%)	0 (0.00%)	4 (66.67%)	14 (51.85%)	9 (45.00%)	5 (41.67%)	29 (100.00%)	0 (0.00%)
Between leukapheresis and CAR-T infusion	35 (54.69%)	16 (59.26%)	10 (41.67%)	14 (58.33%)	10 (40.00%)	19 (73.08%)	13 (37.14%)	3 (100.00%)	2 (33.33%)	13 (48.15%)	11 (55.00%)	7 (58.33%)	0 (0.00%)	34 (100.00%)

Overall, over half of the patient sample (68.5%) had complete remission as the best response to next line of treatment after InO was received as a bridge to CAR-T (please see [Table 37](#) below). Of the n=64 patients, 85.9% were not diagnosed with CNS disease at CAR-T infusion (please see [Table 37](#) below).



Table 37: Patient's Best Response to Next Line of Treatment

	Overall	MRD status (1st cycle of InO)		MRD status (last cycle of InO)		MRD status (CAR-T infusion)		MRD status (prior to HPSCt)		BMI at index (initiation of InO)			InO received:	
	Total	Positive	Negative	Positive	Negative	Positive	Negative	Positive	Negative	(18.5, 25)	(25, 30)	30+	Pre-apheresis	Post-apheresis
5.3 What was the patient's best response to the next line of treatment after InO was received as a bridge to CAR-T., n (%)														
n	73	32	25	30	26	26	35	3	6	30	22	14	29	34
Complete remission (CR)	50 (68.49%)	23 (71.88%)	17 (68.00%)	21 (70.00%)	19 (73.08%)	20 (76.92%)	24 (68.57%)	2 (66.67%)	5 (83.33%)	18 (60.00%)	15 (68.18%)	11 (78.57%)	21 (72.41%)	23 (67.65%)
CR with partial hematologic recovery (CRh)	2 (2.74%)	1 (3.12%)	1 (4.00%)	1 (3.33%)	1 (3.85%)	1 (3.85%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	2 (6.67%)	0 (0.00%)	0 (0.00%)	2 (6.90%)	0 (0.00%)
CR with incomplete haematologic recovery (CRi)	4 (5.48%)	1 (3.12%)	3 (12.00%)	1 (3.33%)	2 (7.69%)	0 (0.00%)	4 (11.43%)	0 (0.00%)	0 (0.00%)	3 (10.00%)	1 (4.55%)	0 (0.00%)	2 (6.90%)	2 (5.88%)
Morphologic leukaemia-free state (MLFS)	3 (4.11%)	2 (6.25%)	0 (0.00%)	2 (6.67%)	0 (0.00%)	1 (3.85%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (9.09%)	1 (7.14%)	0 (0.00%)	3 (8.82%)
Aplastic marrow	1 (1.37%)	0 (0.00%)	1 (4.00%)	0 (0.00%)	1 (3.85%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	0 (0.00%)	1 (2.94%)
Refractory disease	5 (6.85%)	2 (6.25%)	0 (0.00%)	2 (6.67%)	0 (0.00%)	2 (7.69%)	1 (2.86%)	1 (33.33%)	0 (0.00%)	2 (6.67%)	2 (9.09%)	1 (7.14%)	2 (6.90%)	2 (5.88%)
Progressive	5 (6.85%)	3 (9.38%)	1 (4.00%)	3 (10.00%)	1 (3.85%)	1 (3.85%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	4 (13.33%)	1 (4.55%)	0 (0.00%)	0 (0.00%)	2 (5.88%)

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disease (PD)														
Relapsed disease	3 (4.11%)	0 (0.00%)	2 (8.00%)	0 (0.00%)	2 (7.69%)	1 (3.85%)	2 (5.71%)	0 (0.00%)	1 (16.67%)	1 (3.33%)	1 (4.55%)	0 (0.00%)	2 (6.90%)	1 (2.94%)
5.4 Was the patient diagnosed with CNS disease at CAR-T infusion?, n (%)														
n	64	27	24	24	25	26	35	3	6	27	20	12	29	34
Yes	8 (12.50%)	5 (18.52%)	0 (0.00%)	4 (16.67%)	0 (0.00%)	6 (23.08%)	2 (5.71%)	1 (33.33%)	1 (16.67%)	1 (3.70%)	3 (15.00%)	2 (16.67%)	2 (6.90%)	6 (17.65%)
No	55 (85.94%)	22 (81.48%)	23 (95.83%)	20 (83.33%)	24 (96.00%)	20 (76.92%)	32 (91.43%)	2 (66.67%)	5 (83.33%)	25 (92.59%)	17 (85.00%)	10 (83.33%)	27 (93.10%)	27 (79.41%)
Not known	1 (1.56%)	0 (0.00%)	1 (4.17%)	0 (0.00%)	1 (4.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	1 (3.70%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.94%)
5.4 Please indicate the disease status at CAR-T infusion., n (%)														
n	64	27	24	24	25	26	35	3	6	27	20	12	29	34
Salvage 1	22 (34.38%)	8 (29.63%)	8 (33.33%)	6 (25.00%)	8 (32.00%)	11 (42.31%)	10 (28.57%)	2 (66.67%)	1 (16.67%)	9 (33.33%)	6 (30.00%)	5 (41.67%)	8 (27.59%)	13 (38.24%)
Salvage 2	19 (29.69%)	10 (37.04%)	5 (20.83%)	9 (37.50%)	4 (16.00%)	8 (30.77%)	9 (25.71%)	1 (33.33%)	1 (16.67%)	6 (22.22%)	8 (40.00%)	2 (16.67%)	8 (27.59%)	11 (32.35%)
Salvage 3 or later	17 (26.56%)	8 (29.63%)	6 (25.00%)	8 (33.33%)	8 (32.00%)	7 (26.92%)	10 (28.57%)	0 (0.00%)	2 (33.33%)	10 (37.04%)	3 (15.00%)	4 (33.33%)	10 (34.48%)	7 (20.59%)
Not known	6 (9.38%)	1 (3.70%)	5 (20.83%)	1 (4.17%)	5 (20.00%)	0 (0.00%)	6 (17.14%)	0 (0.00%)	2 (33.33%)	2 (7.41%)	3 (15.00%)	1 (8.33%)	3 (10.34%)	3 (8.82%)
5.4 Did this patient experience B-cell recovery														



after CAR-T infusion?, n (%)														
n	64	27	24	24	25	26	35	3	6	27	20	12	29	34
Yes	23 (35.94%)	8 (29.63%)	10 (41.67%)	7 (29.17%)	10 (40.00%)	10 (38.46%)	12 (34.29%)	2 (66.67%)	2 (33.33%)	9 (33.33%)	6 (30.00%)	5 (41.67%)	7 (24.14%)	16 (47.06%)
No	32 (50.00%)	15 (55.56%)	9 (37.50%)	13 (54.17%)	11 (44.00%)	15 (57.69%)	15 (42.86%)	1 (33.33%)	3 (50.00%)	11 (40.74%)	12 (60.00%)	7 (58.33%)	14 (48.28%)	17 (50.00%)
Not known	9 (14.06%)	4 (14.81%)	5 (20.83%)	4 (16.67%)	4 (16.00%)	1 (3.85%)	8 (22.86%)	0 (0.00%)	1 (16.67%)	7 (25.93%)	2 (10.00%)	0 (0.00%)	8 (27.59%)	1 (2.94%)
5.4 Is B-cell recovery still ongoing for this patient?, n (%)														
n	23	8	10	7	10	10	12	2	2	9	6	5	7	16
Yes	14 (60.87%)	3 (37.50%)	7 (70.00%)	3 (42.86%)	7 (70.00%)	3 (30.00%)	10 (83.33%)	0 (0.00%)	1 (50.00%)	6 (66.67%)	5 (83.33%)	1 (20.00%)	5 (71.43%)	9 (56.25%)
No	4 (17.39%)	2 (25.00%)	2 (20.00%)	2 (28.57%)	2 (20.00%)	3 (30.00%)	1 (8.33%)	0 (0.00%)	0 (0.00%)	2 (22.22%)	0 (0.00%)	2 (40.00%)	1 (14.29%)	3 (18.75%)
Not known	5 (21.74%)	3 (37.50%)	1 (10.00%)	2 (28.57%)	1 (10.00%)	4 (40.00%)	1 (8.33%)	2 (100.00%)	1 (50.00%)	1 (11.11%)	1 (16.67%)	2 (40.00%)	1 (14.29%)	4 (25.00%)
B-cell recovery time (days)														
n	4	2	2	2	2	3	1	0	0	2	0	2	1	3
Mean	121.75	129.50	114.00	129.50	114.00	95.33	201.00			143.50		100.00	201.00	95.33
Standard deviation	79.92	61.52	123.04	61.52	123.04	73.45	.			81.32		103.24	.	73.45
Standard error of the mean	39.96	43.50	87.00	43.50	87.00	42.40	.	.	.	57.50	.	73.00	.	42.40
Median	129.50	129.50	114.00	129.50	114.00	86.00	201.00	.	.	143.50	.	100.00	201.00	86.00
Interquartile Range (IQR)	56.50 - 187.00	86.00 - 173.00	27.00 - 201.00	86.00 - 173.00	27.00 - 201.00	27.00 - 173.00	201.00 - 201.00	.	.	86.00 - 201.00	.	27.00 - 173.00	201.00 - 201.00	27.00 - 173.00
Range	27.00 - 201.00	86.00 - 173.00	27.00 - 201.00	86.00 - 173.00	27.00 - 201.00	27.00 - 173.00	201.00 - 201.00			86.00 - 201.00		27.00 - 173.00	201.00 - 201.00	27.00 - 173.00



95% CI	-5.42 - 248.92	-423.22 - 682.22	-991.44 - 1219.44	-423.22 - 682.22	-991.44 - 1219.44	-87.12 - 277.78	. . .	. . .	. . .	-587.11 - 874.11	. . .	-827.55 - 1027.55	. . .	-87.12 - 277.78
Date it was determined this patient had entered B-cell recovery not known., n (%)														
n	1	0	1	0	1	0	1	0	0	0	0	1	1	0
Not known	1 (100.00 %)	0 (.%)	1 (100.00 %)	0 (.%)	1 (100.00 %)	0 (.%)	1 (100.00 %)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	1 (100.00 %)	1 (100.00 %)	0 (.%)

The mean (SD) number of total salvage treatment lines received for ALL after CAR-T bridging therapy was 0.68 (1.17) (please see **Table 38** below). Over a quarter of patients received methotrexate (26.1%) for ALL after CAR-T therapy (please see **Table 38** below).

Table 38: Number of Treatment Lines Received for ALL after CAR-T Bridging Therapy

	Overall	MRD status (1st cycle of InO)		MRD status (last cycle of InO)		MRD status (CAR-T infusion)		MRD status (prior to HPST)		BMI at index (initiation of InO)			InO received:	
	Total	Positive	Negative	Positive	Negative	Positive	Negative	Positive	Negative	(18.5, 25)	(25, 30)	30+	Pre- apheres is	Post- apheres is
6.1 Please enter the total number of treatment lines (i.e. number of salvage lines) received for ALL after CAR- T bridging therapy														
n	62.00	26.00	24.00	23.00	25.00	24.00	35.00	3.00	6.00	27.00	19.00	12.00	29.00	33.00
Mean	0.68	0.81	0.75	0.61	0.68	0.58	0.80	3.00	1.50	0.48	0.84	0.33	0.93	0.45
Standard deviation	1.17	1.50	0.94	1.34	0.95	1.10	1.26	1.00	1.22	0.94	1.46	0.49	1.33	0.97
Standard error of the mean	0.15	0.29	0.19	0.28	0.19	0.22	0.21	0.58	0.50	0.18	0.34	0.14	0.25	0.17
Median	0.00	0.00	1.00	0.00	0.00	0.00	0.00	3.00	1.00	0.00	0.00	0.00	1.00	0.00



Interquartile Range (IQR)	0.00 - 1.00	0.00 - 1.00	0.00 - 1.00	0.00 - 1.00	0.00 - 1.00	0.00 - 1.00	0.00 - 1.00	2.00 - 4.00	1.00 - 1.00	0.00 - 1.00	0.00 - 1.00	0.00 - 1.00	0.00 - 1.00	0.00 - 0.00
Range	0.00 - 5.00	0.00 - 5.00	0.00 - 4.00	0.00 - 5.00	0.00 - 4.00	0.00 - 4.00	0.00 - 5.00	2.00 - 4.00	1.00 - 4.00	0.00 - 4.00	0.00 - 5.00	0.00 - 1.00	0.00 - 5.00	0.00 - 4.00
95% CI	0.38 - 0.97	0.20 - 1.41	0.35 - 1.15	0.03 - 1.19	0.29 - 1.07	0.12 - 1.05	0.37 - 1.23	0.52 - 5.48	0.21 - 2.79	0.11 - 0.85	0.14 - 1.55	0.02 - 0.65	0.42 - 1.44	0.11 - 0.80
6.1 Please enter the total number of treatment lines (i.e. number of salvage lines) received for ALL after CAR-T bridging therapy.. n (%)														
n	64.00	27.00	24.00	24.00	25.00	26.00	35.00	3.00	6.00	27.00	20.00	12.00	29.00	34.00
Not known	2.00 (3.12%)	1.00 (3.70%)	0.00 (0.00%)	1.00 (4.17%)	0.00 (0.00%)	2.00 (7.69%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (5.00%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (2.94%)
0	39.00 (60.94%)	18.00 (66.67%)	11.00 (45.83%)	17.00 (70.83%)	13.00 (52.00%)	17.00 (65.38%)	19.00 (54.29%)	0.00 (0.00%)	0.00 (0.00%)	19.00 (70.37%)	12.00 (60.00%)	8.00 (66.67%)	14.00 (48.28%)	25.00 (73.53%)
1	14.00 (21.88%)	3.00 (11.11%)	10.00 (41.67%)	3.00 (12.50%)	9.00 (36.00%)	3.00 (11.54%)	11.00 (31.43%)	0.00 (0.00%)	5.00 (83.33%)	5.00 (18.52%)	3.00 (15.00%)	4.00 (33.33%)	10.00 (34.48%)	4.00 (11.76%)
2	4.00 (6.25%)	1.00 (3.70%)	2.00 (8.33%)	1.00 (4.17%)	2.00 (8.00%)	2.00 (7.69%)	2.00 (5.71%)	1.00 (33.33%)	0.00 (0.00%)	2.00 (7.41%)	2.00 (10.00%)	0.00 (0.00%)	2.00 (6.90%)	2.00 (5.88%)
3	1.00 (1.56%)	1.00 (3.70%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (3.85%)	0.00 (0.00%)	1.00 (33.33%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (2.94%)
4	3.00 (4.69%)	2.00 (7.41%)	1.00 (4.17%)	1.00 (4.17%)	1.00 (4.00%)	1.00 (3.85%)	2.00 (5.71%)	1.00 (33.33%)	1.00 (16.67%)	1.00 (3.70%)	1.00 (5.00%)	0.00 (0.00%)	2.00 (6.90%)	1.00 (2.94%)
5	1.00 (1.56%)	1.00 (3.70%)	0.00 (0.00%)	1.00 (4.17%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (2.86%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (5.00%)	0.00 (0.00%)	1.00 (3.45%)	0.00 (0.00%)
Treatments or procedures received for ALL after CAR-T therapy														
n	23.00	8.00	13.00	6.00	12.00	7.00	16.00	3.00	6.00	8.00	7.00	4.00	15.00	8.00
Vincristine	5.00 (21.74%)	2.00 (25.00%)	3.00 (23.08%)	1.00 (16.67%)	3.00 (25.00%)	1.00 (14.29%)	4.00 (25.00%)	1.00 (33.33%)	1.00 (16.67%)	0.00 (0.00%)	3.00 (42.86%)	0.00 (0.00%)	3.00 (20.00%)	2.00 (25.00%)



Dexamethasone	4.00 (17.39%)	2.00 (25.00%)	2.00 (15.38%)	1.00 (16.67%)	2.00 (16.67%)	1.00 (14.29%)	3.00 (18.75%)	1.00 (33.33%)	1.00 (16.67%)	0.00 (0.00%)	2.00 (28.57%)	0.00 (0.00%)	2.00 (13.33%)	2.00 (25.00%)
Prednisolone	4.00 (17.39%)	2.00 (25.00%)	2.00 (15.38%)	1.00 (16.67%)	2.00 (16.67%)	1.00 (14.29%)	3.00 (18.75%)	1.00 (33.33%)	0.00 (0.00%)	1.00 (12.50%)	2.00 (28.57%)	0.00 (0.00%)	3.00 (20.00%)	1.00 (12.50%)
Methylprednisolone	1.00 (4.35%)	0.00 (0.00%)	1.00 (7.69%)	0.00 (0.00%)	1.00 (8.33%)	0.00 (0.00%)	1.00 (6.25%)	0.00 (0.00%)	1.00 (16.67%)	0.00 (0.00%)	1.00 (14.29%)	0.00 (0.00%)	1.00 (6.67%)	0.00 (0.00%)
Hydrocortisone	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)
Doxorubicin	1.00 (4.35%)	1.00 (12.50%)	0.00 (0.00%)	1.00 (16.67%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (6.25%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (14.29%)	0.00 (0.00%)	1.00 (6.67%)	0.00 (0.00%)
Daunorubicin	1.00 (4.35%)	0.00 (0.00%)	1.00 (7.69%)	0.00 (0.00%)	1.00 (8.33%)	0.00 (0.00%)	1.00 (6.25%)	0.00 (0.00%)	1.00 (16.67%)	0.00 (0.00%)	1.00 (14.29%)	0.00 (0.00%)	1.00 (6.67%)	0.00 (0.00%)
Cyclophosphamide	6.00 (26.09%)	4.00 (50.00%)	2.00 (15.38%)	1.00 (16.67%)	2.00 (16.67%)	2.00 (28.57%)	4.00 (25.00%)	2.00 (66.67%)	1.00 (16.67%)	0.00 (0.00%)	3.00 (42.86%)	0.00 (0.00%)	4.00 (26.67%)	2.00 (25.00%)
L-asparaginase	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)
Methotrexate	6.00 (26.09%)	2.00 (25.00%)	3.00 (23.08%)	1.00 (16.67%)	3.00 (25.00%)	2.00 (28.57%)	4.00 (25.00%)	2.00 (66.67%)	1.00 (16.67%)	1.00 (12.50%)	3.00 (42.86%)	0.00 (0.00%)	3.00 (20.00%)	3.00 (37.50%)
Cytarabine	5.00 (21.74%)	1.00 (12.50%)	3.00 (23.08%)	1.00 (16.67%)	3.00 (25.00%)	1.00 (14.29%)	4.00 (25.00%)	1.00 (33.33%)	1.00 (16.67%)	1.00 (12.50%)	4.00 (57.14%)	0.00 (0.00%)	4.00 (26.67%)	1.00 (12.50%)
Etoposide	1.00 (4.35%)	1.00 (12.50%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (6.25%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (6.67%)	0.00 (0.00%)
Mercaptopurine	3.00 (13.04%)	1.00 (12.50%)	2.00 (15.38%)	0.00 (0.00%)	2.00 (16.67%)	1.00 (14.29%)	2.00 (12.50%)	1.00 (33.33%)	1.00 (16.67%)	0.00 (0.00%)	1.00 (14.29%)	0.00 (0.00%)	1.00 (6.67%)	2.00 (25.00%)
Intrathecal chemotherapy	5.00 (21.74%)	2.00 (25.00%)	2.00 (15.38%)	1.00 (16.67%)	2.00 (16.67%)	2.00 (28.57%)	3.00 (18.75%)	2.00 (66.67%)	1.00 (16.67%)	1.00 (12.50%)	3.00 (42.86%)	0.00 (0.00%)	3.00 (20.00%)	2.00 (25.00%)
Radiation therapy	4.00 (17.39%)	3.00 (37.50%)	0.00 (0.00%)	1.00 (16.67%)	0.00 (0.00%)	3.00 (42.86%)	1.00 (6.25%)	3.00 (100.00%)	0.00 (0.00%)	0.00 (0.00%)	2.00 (28.57%)	0.00 (0.00%)	1.00 (6.67%)	3.00 (37.50%)
Imatinib	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)
Dasatinib	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)
Ponatinib	5.00 (21.74%)	1.00 (12.50%)	3.00 (23.08%)	1.00 (16.67%)	2.00 (16.67%)	2.00 (28.57%)	3.00 (18.75%)	1.00 (33.33%)	0.00 (0.00%)	3.00 (37.50%)	1.00 (14.29%)	1.00 (25.00%)	3.00 (20.00%)	2.00 (25.00%)

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Nilotinib	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)
Rituximab	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)
Blinatumomab	3.00 (13.04%)	2.00 (25.00%)	1.00 (7.69%)	2.00 (33.33%)	1.00 (8.33%)	1.00 (14.29%)	2.00 (12.50%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (12.50%)	1.00 (14.29%)	1.00 (25.00%)	2.00 (13.33%)	1.00 (12.50%)
Bosutinib	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)
Asciminib	1.00 (4.35%)	1.00 (12.50%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (14.29%)	0.00 (0.00%)	1.00 (33.33%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (12.50%)
Other TKI	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)
Inotuzumab ozogamicin (not including InO prescribed as bridge therapy to HPSCT o	5.00 (21.74%)	1.00 (12.50%)	4.00 (30.77%)	1.00 (16.67%)	4.00 (33.33%)	1.00 (14.29%)	4.00 (25.00%)	0.00 (0.00%)	1.00 (16.67%)	3.00 (37.50%)	2.00 (28.57%)	0.00 (0.00%)	3.00 (20.00%)	2.00 (25.00%)
Hematopoietic stem cell transplant (HPSCT)	10.00 (43.48%)	5.00 (62.50%)	3.00 (23.08%)	4.00 (66.67%)	3.00 (25.00%)	6.00 (85.71%)	4.00 (25.00%)	3.00 (100.00%)	6.00 (100.00%)	2.00 (25.00%)	4.00 (57.14%)	2.00 (50.00%)	5.00 (33.33%)	5.00 (62.50%)
Other	6.00 (26.09%)	4.00 (50.00%)	2.00 (15.38%)	2.00 (33.33%)	2.00 (16.67%)	1.00 (14.29%)	5.00 (31.25%)	1.00 (33.33%)	1.00 (16.67%)	2.00 (25.00%)	2.00 (28.57%)	0.00 (0.00%)	5.00 (33.33%)	1.00 (12.50%)
None of the above	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)
1.2 Was MRD assessed before this round of HPSCT after CAR-T bridging therapy., n (%)														
n	10.00	5.00	3.00	4.00	3.00	6.00	4.00	3.00	6.00	2.00	4.00	2.00	5.00	5.00
Yes	9.00 (90.00%)	4.00 (80.00%)	3.00 (100.00%)	3.00 (75.00%)	3.00 (100.00%)	6.00 (100.00%)	3.00 (75.00%)	3.00 (100.00%)	6.00 (100.00%)	1.00 (50.00%)	4.00 (100.00%)	2.00 (100.00%)	4.00 (80.00%)	5.00 (100.00%)
No	1.00 (10.00%)	1.00 (20.00%)	0.00 (0.00%)	1.00 (25.00%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (25.00%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (50.00%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (20.00%)	0.00 (0.00%)
1.2 Please indicate the result of the MRD analysis														



prior to HPSCT., n (%)														
n	9.00	4.00	3.00	3.00	3.00	6.00	3.00	3.00	6.00	1.00	4.00	2.00	4.00	5.00
Positive	3.00 (33.33%)	2.00 (50.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	3.00 (50.00%)	0.00 (0.00%)	3.00 (100.00%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (25.00%)	0.00 (0.00%)	0.00 (0.00%)	3.00 (60.00%)
Negative	6.00 (66.67%)	2.00 (50.00%)	3.00 (100.00%)	3.00 (100.00%)	3.00 (100.00%)	3.00 (50.00%)	3.00 (100.00%)	0.00 (0.00%)	6.00 (100.00%)	1.00 (100.00%)	3.00 (75.00%)	2.00 (100.00%)	4.00 (100.00%)	2.00 (40.00%)
1.3]What was the patient's response to HPSCT?, n (%)														
n	10.00	5.00	3.00	4.00	3.00	6.00	4.00	3.00	6.00	2.00	4.00	2.00	5.00	5.00
Complete remission (CR)	8.00 (80.00%)	4.00 (80.00%)	3.00 (100.00%)	3.00 (75.00%)	3.00 (100.00%)	4.00 (66.67%)	4.00 (100.00%)	2.00 (66.67%)	5.00 (83.33%)	2.00 (100.00%)	4.00 (100.00%)	1.00 (50.00%)	4.00 (80.00%)	4.00 (80.00%)
CR with partial hematologic recovery (CRh)	1.00 (10.00%)	1.00 (20.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (16.67%)	0.00 (0.00%)	1.00 (33.33%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (20.00%)
Relapsed disease	1.00 (10.00%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (25.00%)	0.00 (0.00%)	1.00 (16.67%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (16.67%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (50.00%)	1.00 (20.00%)	0.00 (0.00%)
6.1]Was the patient diagnosed with graft-versus-host disease (GvHD) following any of their HPSCT(s) received after CAR-T bridging therapy?, n (%)														
n	10.00	5.00	3.00	4.00	3.00	6.00	4.00	3.00	6.00	2.00	4.00	2.00	5.00	5.00
Yes	6.00 (60.00%)	3.00 (60.00%)	1.00 (33.33%)	4.00 (100.00%)	1.00 (33.33%)	4.00 (66.67%)	2.00 (50.00%)	1.00 (33.33%)	4.00 (66.67%)	2.00 (100.00%)	2.00 (50.00%)	2.00 (100.00%)	3.00 (60.00%)	3.00 (60.00%)
No	4.00 (40.00%)	2.00 (40.00%)	2.00 (66.67%)	0.00 (0.00%)	2.00 (66.67%)	2.00 (33.33%)	2.00 (50.00%)	2.00 (66.67%)	2.00 (33.33%)	0.00 (0.00%)	2.00 (50.00%)	0.00 (0.00%)	2.00 (40.00%)	2.00 (40.00%)
Type of GvHD the patient diagnosed with following any of their HSCT(s)														



received after CAR-T therapy														
n	6.00	3.00	1.00	4.00	1.00	4.00	2.00	1.00	4.00	2.00	2.00	2.00	3.00	3.00
Acute	6.00 (100.00%)	3.00 (100.00%)	1.00 (100.00%)	4.00 (100.00%)	1.00 (100.00%)	4.00 (100.00%)	2.00 (100.00%)	1.00 (100.00%)	4.00 (100.00%)	2.00 (100.00%)	2.00 (100.00%)	2.00 (100.00%)	3.00 (100.00%)	3.00 (100.00%)
Chronic	2.00 (33.33%)	1.00 (33.33%)	1.00 (100.00%)	1.00 (25.00%)	1.00 (100.00%)	1.00 (25.00%)	1.00 (50.00%)	0.00 (0.00%)	2.00 (50.00%)	1.00 (50.00%)	0.00 (0.00%)	1.00 (50.00%)	1.00 (33.33%)	1.00 (33.33%)

The median overall survival from index for those with positive MRD after the first cycle of InO was 17.13 (please see **Table 39** below). The median overall survival from index for those with BMI at index over 30+ was 27.09 (please see **Table 39** below).

Table 39: Overall Survival (from Index)

	MRD status (1st cycle of InO)		MRD status (last cycle of InO)		MRD status (CAR-T infusion)		MRD status (prior to HPSCt)		BMI at index (initiation of InO)			InO received:	
	Positive	Negative	Positive	Negative	Positive	Negative	Positive	Negative	[18.5, 25)	[25, 30)	30+	Pre-apheresis	Post-apheresis
Number of observations	37	27	35	28	26	35	3	6	34	22	15	29	34
Number of events	20	6	18	6	9	10	2	2	14	6	5	11	9
Number censored	17	21	17	22	17	25	1	4	20	16	10	18	25
Median	17.13	.	17.13	.	33.17	.	33.17	.	.	.	27.09	.	33.17
Time points													
6	80.5%	96.2%	76.4%	100.0%	96.6%	97.1%	.	.	78.6%	95.2%	93.3%	93.1%	96.9%
12	61.6%	87.0%	59.4%	91.3%	71.8%	82.6%	.	100.0%	64.7%	78.8%	77.8%	81.5%	72.0%
18	46.7%	81.2%	45.5%	80.6%	57.6%	69.3%	66.7%	80.0%	55.7%	71.0%	62.2%	61.4%	67.2%
24	46.7%	69.6%	45.5%	69.8%	57.6%	60.0%	66.7%	60.0%	51.1%	63.1%	62.2%	51.1%	67.2%
30	33.4%	69.6%	27.3%	69.8%	57.6%	60.0%	66.7%	60.0%	51.1%	63.1%	31.1%	51.1%	67.2%
36	26.7%	69.6%	27.3%	69.8%	28.8%	60.0%	0.0%	60.0%	51.1%	63.1%	31.1%	51.1%	33.6%

The median overall survival from CAR-T infusion for those with positive MRD after the first cycle of InO was 31.86 (please see **Table 40** below). The median overall survival from CAR-T infusion for those with BMI at index over 30+ was 14.24 (please see **Table 40** below).



Table 40: Overall Survival (from CAR-T Infusion)

	MRD status (1st cycle of InO)		MRD status (last cycle of InO)		MRD status (CAR-T infusion)		MRD status (prior to HPSCt)		BMI at index (initiation of InO)			InO received:	
	Positive	Negative	Positive	Negative	Positive	Negative	Positive	Negative	[18.5, 25)	[25, 30)	30+	Pre-apheresis	Post-apheresis
Number of observations	27	24	24	25	26	35	3	6	27	20	12	29	34
Number of events	11	5	9	5	9	10	2	2	8	5	4	11	9
Number censored	16	19	15	20	17	25	1	4	19	15	8	18	25
Median	31.86	.	15.78	.	31.86	.	31.86	.	.	.	14.24	.	31.86
Time points													
6	92.1%	90.4%	91.0%	90.9%	91.8%	86.7%	.	.	91.8%	81.7%	82.5%	85.5%	89.1%
12	56.6%	90.4%	61.5%	90.9%	62.8%	78.8%	66.7%	100.0%	71.9%	81.7%	70.7%	76.2%	67.1%
18	50.3%	69.6%	46.1%	71.4%	54.9%	60.2%	66.7%	60.0%	59.9%	64.4%	47.1%	50.8%	67.1%
24	50.3%	69.6%	46.1%	71.4%	54.9%	60.2%	66.7%	60.0%	59.9%	64.4%	47.1%	50.8%	67.1%
30	50.3%	69.6%	46.1%	71.4%	54.9%	60.2%	66.7%	60.0%	59.9%	64.4%	47.1%	50.8%	67.1%
36	37.7%	69.6%	46.1%	71.4%	27.5%	60.2%	0.0%	60.0%	59.9%	64.4%	47.1%	50.8%	33.6%

The median time to next salvage treatment for those with negative MRD after the first cycle of InO was 9.96 months (please see **Table 41** below). The median time to next salvage treatment for those who received InO pre-apheresis was 9.96 (please see **Table 41** below).

Table 41: Time to Next Salvage Treatment

	MRD status (1st cycle of InO)		MRD status (last cycle of InO)		MRD status (CAR-T infusion)		MRD status (prior to HPSCt)		BMI at index (initiation of InO)			InO received:	
	Positive	Negative	Positive	Negative	Positive	Negative	Positive	Negative	[18.5, 25)	[25, 30)	30+	Pre-apheresis	Post-apheresis
Number of observations	27	24	24	25	26	35	3	6	27	20	12	29	34
Number of events	8	13	6	12	7	16	3	6	8	7	4	15	8



Number censored	19	11	18	13	19	19	0	0	19	13	8	14	26
Median	.	9.96	.	12.2	.	12.43	3.16	5.75	.	.	.	9.96	.
Time points													
6	0.8	0.7	0.8	0.7	0.8	0.8	0.3	0.3	0.8	0.8	0.8	0.7	0.8
12	0.7	0.4	0.7	0.5	0.7	0.6	0.0	0.0	0.8	0.6	0.6	0.5	0.8
18	0.6	0.3	0.6	0.4	0.7	0.4	0.0	0.0	0.6	0.5	0.6	0.4	0.7
24	0.6	0.3	0.6	0.4	0.7	0.4	0.0	0.0	0.6	0.5	0.6	0.4	0.7
30	0.6	0.3	0.6	0.4	0.7	0.4	0.0	0.0	0.6	0.5	0.6	0.4	0.7
36	0.6	0.3	0.6	0.4	0.7	0.4	0.0	0.0	0.6	0.5	0.6	0.4	0.7

For patients with positive MRD at first cycle of InO, 13.5% had age greater than 60 as a risk factor for VOD at index (please see **Table 42** below). For patients with negative MRD prior to HPSCT, 16.67% had age greater than 60 as a risk factor for VOD at index (please see **Table 42** below).

Table 42: Risk Factors for VOD at Index

	MRD status (1st cycle of InO)		MRD status (last cycle of InO)		MRD status (CAR-T infusion)		MRD status (prior to HPSCT)		BMI at index (initiation of InO)			InO received:	
	Positive	Negative	Positive	Negative	Positive	Negative	Positive	Negative	(18.5, 25)	(25, 30)	30+	Pre-apheresis	Post-apheresis
Risk factors for VOD at times:													
n	37.00	27.00	35.00	28.00	26.00	35.00	3.00	6.00	34.00	22.00	15.00	29.00	34.00
Age greater than 60	5.00 (13.51%)	6.00 (22.22%)	6.00 (17.14%)	6.00 (21.43%)	6.00 (23.08%)	6.00 (17.14%)	0.00 (0.00%)	1.00 (16.67%)	10.00 (29.41%)	2.00 (9.09%)	2.00 (13.33%)	9.00 (31.03%)	4.00 (11.76%)
Poor performance status (Karnovsky <90%)	2.00 (5.41%)	0.00 (0.00%)	2.00 (5.71%)	1.00 (3.57%)	2.00 (7.69%)	1.00 (2.86%)	0.00 (0.00%)	0.00 (0.00%)	2.00 (5.88%)	1.00 (4.55%)	1.00 (6.67%)	1.00 (3.45%)	3.00 (8.82%)
Female receiving norethisterone	1.00 (2.70%)	0.00 (0.00%)	1.00 (2.86%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (6.67%)	0.00 (0.00%)	0.00 (0.00%)
Underlying haemoglobinopathy	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)

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(thalassaemia or sickle-cell disease)													
Diagnosis of primary haemophagocytic lymphohistiocytosis, adrenoleucodystrophy	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)
Prior abdominal or hepatic irradiation	2.00 (5.41%)	0.00 (0.00%)	2.00 (5.71%)	1.00 (3.57%)	2.00 (7.69%)	2.00 (5.71%)	0.00 (0.00%)	0.00 (0.00%)	2.00 (5.88%)	2.00 (9.09%)	0.00 (0.00%)	1.00 (3.45%)	4.00 (11.76%)
Pre-existing liver disease including cirrhosis	1.00 (2.70%)	0.00 (0.00%)	1.00 (2.86%)	0.00 (0.00%)	1.00 (3.85%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (2.94%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (2.94%)
Elevated AST (>2.5 upper limit of normal) or bilirubin (>1.5 upper limit of norm	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (2.86%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (2.94%)	1.00 (4.55%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (2.94%)
Active viral hepatitis B or C	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)
Pre-existing hepatic fibrosis or elevated serum ferritin	7.00 (18.92%)	9.00 (33.33%)	6.00 (17.14%)	10.00 (35.71%)	7.00 (26.92%)	10.00 (28.57%)	0.00 (0.00%)	0.00 (0.00%)	9.00 (26.47%)	5.00 (22.73%)	3.00 (20.00%)	12.00 (41.38%)	5.00 (14.71%)
Prior autologous or allogeneic transplant	16.00 (43.24%)	9.00 (33.33%)	16.00 (45.71%)	10.00 (35.71%)	8.00 (30.77%)	16.00 (45.71%)	0.00 (0.00%)	1.00 (16.67%)	12.00 (35.29%)	12.00 (54.55%)	4.00 (26.67%)	14.00 (48.28%)	12.00 (35.29%)
Prior treatment with either Gemtuzumab ozogamicin or Inotuzumab ozogamicin	2.00 (5.41%)	0.00 (0.00%)	2.00 (5.71%)	0.00 (0.00%)	2.00 (7.69%)	0.00 (0.00%)	1.00 (33.33%)	0.00 (0.00%)	2.00 (5.88%)	1.00 (4.55%)	1.00 (6.67%)	0.00 (0.00%)	3.00 (8.82%)
Hepatotoxic drug use	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (6.67%)	0.00 (0.00%)	1.00 (2.94%)
Metabolic syndrome	1.00 (2.70%)	1.00 (3.70%)	1.00 (2.86%)	1.00 (3.57%)	1.00 (3.85%)	1.00 (2.86%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	2.00 (13.33%)	2.00 (6.90%)	0.00 (0.00%)
Genetic factors	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)
Haematopoietic progenitor source	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)
Donor-recipient HLA disparity	6.00 (16.22%)	2.00 (7.41%)	5.00 (14.29%)	3.00 (10.71%)	4.00 (15.38%)	3.00 (8.57%)	0.00 (0.00%)	0.00 (0.00%)	4.00 (11.76%)	3.00 (13.64%)	1.00 (6.67%)	4.00 (13.79%)	3.00 (8.82%)
Graft-versus-host disease (GvHD) prophylaxis with sirolimus and tacrolimus	3.00 (8.11%)	0.00 (0.00%)	3.00 (8.57%)	0.00 (0.00%)	1.00 (3.85%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	2.00 (5.88%)	0.00 (0.00%)	2.00 (13.33%)	0.00 (0.00%)	2.00 (5.88%)



None of the above	15.00 (40.54%)	12.00 (44.44%)	12.00 (34.29%)	13.00 (46.43%)	10.00 (38.46%)	13.00 (37.14%)	2.00 (66.67%)	4.00 (66.67%)	12.00 (35.29%)	7.00 (31.82%)	6.00 (40.00%)	7.00 (24.14%)	15.00 (44.12%)
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For patients with a negative MRD at first cycle of InO, 33.3% had pre-existing hepatic fibrosis or elevated serum ferritin as a risk factor for VOD at last dose of InO (please see **Table 43** below). For patients with positive MRD at first cycle of InO, 40.5% had prior autologous or allogenic transplant as a risk factor for VOD at last dose of InO (please see **Table 43** below).

Table 43: Risk Factors for VOD at Last Dose of InO

	MRD status (1st cycle of InO)		MRD status (last cycle of InO)		MRD status (CAR-T infusion)		MRD status (prior to HPST)		BMI at index (initiation of InO)			InO received:	
	Positive	Negative	Positive	Negative	Positive	Negative	Positive	Negative	(18.5, 25)	(25, 30)	30+	Pre-apheresis	Post-apheresis
Risk factors for VOD at times:													
n	37.00	27.00	35.00	28.00	26.00	35.00	3.00	6.00	34.00	22.00	15.00	29.00	34.00
Age greater than 60	5.00 (13.51%)	6.00 (22.22%)	6.00 (17.14%)	6.00 (21.43%)	6.00 (23.08%)	6.00 (17.14%)	0.00 (0.00%)	1.00 (16.67%)	10.00 (29.41%)	2.00 (9.09%)	2.00 (13.33%)	9.00 (31.03%)	4.00 (11.76%)
Poor performance status (Karnovsky <90%)	1.00 (2.70%)	0.00 (0.00%)	2.00 (5.71%)	1.00 (3.57%)	1.00 (3.85%)	1.00 (2.86%)	0.00 (0.00%)	0.00 (0.00%)	2.00 (5.88%)	1.00 (4.55%)	1.00 (6.67%)	1.00 (3.45%)	2.00 (5.88%)
Female receiving norethisterone	1.00 (2.70%)	0.00 (0.00%)	1.00 (2.86%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (6.67%)	0.00 (0.00%)	0.00 (0.00%)
Underlying haemoglobinopathy (thalassaemia or sickle-cell disease)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)
Diagnosis of primary haemophagocytic lymphohistiocytosis, adrenoleucodystrophy	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)
Prior abdominal or hepatic irradiation	2.00 (5.41%)	0.00 (0.00%)	2.00 (5.71%)	1.00 (3.57%)	2.00 (7.69%)	2.00 (5.71%)	0.00 (0.00%)	0.00 (0.00%)	2.00 (5.88%)	2.00 (9.09%)	0.00 (0.00%)	1.00 (3.45%)	4.00 (11.76%)
Pre-existing liver disease including cirrhosis	1.00 (2.70%)	0.00 (0.00%)	1.00 (2.86%)	0.00 (0.00%)	1.00 (3.85%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (2.94%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (2.94%)



Elevated AST (>2.5 upper limit of normal) or bilirubin (>1.5 upper limit of norm)	2.00 (5.41%)	0.00 (0.00%)	2.00 (5.71%)	0.00 (0.00%)	2.00 (7.69%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (2.94%)	0.00 (0.00%)	1.00 (6.67%)	1.00 (3.45%)	1.00 (2.94%)
Active viral hepatitis B or C	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)
Pre-existing hepatic fibrosis or elevated serum ferritin	7.00 (18.92%)	9.00 (33.33%)	6.00 (17.14%)	10.00 (35.71%)	7.00 (26.92%)	10.00 (28.57%)	0.00 (0.00%)	0.00 (0.00%)	9.00 (26.47%)	5.00 (22.73%)	3.00 (20.00%)	12.00 (41.38%)	5.00 (14.71%)
Prior autologous or allogenic transplant	15.00 (40.54%)	11.00 (40.74%)	15.00 (42.86%)	12.00 (42.86%)	8.00 (30.77%)	17.00 (48.57%)	0.00 (0.00%)	1.00 (16.67%)	14.00 (41.18%)	12.00 (54.55%)	4.00 (26.67%)	14.00 (48.28%)	13.00 (38.24%)
Prior treatment with either Gemtuzumab ozogamicin or Inotuzumab ozogamicin	7.00 (18.92%)	1.00 (3.70%)	7.00 (20.00%)	1.00 (3.57%)	4.00 (15.38%)	0.00 (0.00%)	1.00 (33.33%)	0.00 (0.00%)	5.00 (14.71%)	2.00 (9.09%)	3.00 (20.00%)	0.00 (0.00%)	5.00 (14.71%)
Hepatotoxic drug use	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)
Metabolic syndrome	1.00 (2.70%)	1.00 (3.70%)	1.00 (2.86%)	1.00 (3.57%)	1.00 (3.85%)	1.00 (2.86%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	2.00 (13.33%)	2.00 (6.90%)	0.00 (0.00%)
Genetic factors	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)
Haematopoietic progenitor source	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)
Donor-recipient HLA disparity	6.00 (16.22%)	2.00 (7.41%)	5.00 (14.29%)	3.00 (10.71%)	4.00 (15.38%)	3.00 (8.57%)	0.00 (0.00%)	0.00 (0.00%)	4.00 (11.76%)	3.00 (13.64%)	1.00 (6.67%)	4.00 (13.79%)	3.00 (8.82%)
Graft-versus-host disease (GvHD) prophylaxis with sirolimus and tacrolimus	4.00 (10.81%)	0.00 (0.00%)	4.00 (11.43%)	0.00 (0.00%)	2.00 (7.69%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	3.00 (8.82%)	0.00 (0.00%)	1.00 (6.67%)	1.00 (3.45%)	1.00 (2.94%)
None of the above	12.00 (32.43%)	9.00 (33.33%)	8.00 (22.86%)	10.00 (35.71%)	8.00 (30.77%)	12.00 (34.29%)	2.00 (66.67%)	4.00 (66.67%)	8.00 (23.53%)	6.00 (27.27%)	5.00 (33.33%)	6.00 (20.69%)	13.00 (38.24%)

For patients with a BMI at index (in the range 18.5-25, 33.3% had an age greater than 60 as a risk factor for VOD at CAR-T apheresis (please see [Table 44](#) below).



Table 44: Risk Factors for VOD at CAR-T Apheresis

	MRD status (1st cycle of InO)		MRD status (last cycle of InO)		MRD status (CAR-T infusion)		MRD status (prior to HPST)		BMI at index (initiation of InO)			InO received:	
	Positive	Negative	Positive	Negative	Positive	Negative	Positive	Negative	(18.5, 25)	(25, 30)	30+	Pre-apheresis	Post-apheresis
Risk factors for VOD at times:													
n	31.00	25.00	27.00	27.00	26.00	35.00	3.00	6.00	30.00	20.00	13.00	29.00	34.00
Age greater than 60	4.00 (12.90%)	6.00 (24.00%)	5.00 (18.52%)	6.00 (22.22%)	6.00 (23.08%)	6.00 (17.14%)	0.00 (0.00%)	1.00 (16.67%)	10.00 (33.33%)	2.00 (10.00%)	2.00 (15.38%)	9.00 (31.03%)	4.00 (11.76%)
Poor performance status (Karnovsky <90%)	2.00 (6.45%)	0.00 (0.00%)	2.00 (7.41%)	1.00 (3.70%)	2.00 (7.69%)	1.00 (2.86%)	0.00 (0.00%)	0.00 (0.00%)	2.00 (6.67%)	1.00 (5.00%)	1.00 (7.69%)	1.00 (3.45%)	3.00 (8.82%)
Female receiving norethisterone	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)
Underlying haemoglobinopathy (thalassaemia or sickle-cell disease)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)
Diagnosis of primary haemophagocytic lymphohistiocytosis, adrenoleucodystrophy	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)
Prior abdominal or hepatic irradiation	2.00 (6.45%)	0.00 (0.00%)	2.00 (7.41%)	1.00 (3.70%)	2.00 (7.69%)	2.00 (5.71%)	0.00 (0.00%)	0.00 (0.00%)	2.00 (6.67%)	2.00 (10.00%)	0.00 (0.00%)	1.00 (3.45%)	4.00 (11.76%)
Pre-existing liver disease including cirrhosis	1.00 (3.23%)	0.00 (0.00%)	1.00 (3.70%)	0.00 (0.00%)	1.00 (3.85%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (3.33%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (2.94%)
Elevated AST (>2.5 upper limit of normal) or bilirubin (>1.5 upper limit of norm)	2.00 (6.45%)	1.00 (4.00%)	2.00 (7.41%)	1.00 (3.70%)	2.00 (7.69%)	1.00 (2.86%)	0.00 (0.00%)	0.00 (0.00%)	2.00 (6.67%)	0.00 (0.00%)	1.00 (7.69%)	1.00 (3.45%)	2.00 (5.88%)
Active viral hepatitis B or C	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)
Pre-existing hepatic fibrosis or elevated serum ferritin	7.00 (22.58%)	9.00 (36.00%)	6.00 (22.22%)	10.00 (37.04%)	7.00 (26.92%)	10.00 (28.57%)	0.00 (0.00%)	0.00 (0.00%)	9.00 (30.00%)	5.00 (25.00%)	3.00 (23.08%)	12.00 (41.38%)	5.00 (14.71%)
Prior autologous or allogeneic transplant	13.00 (41.94%)	10.00 (40.00%)	12.00 (44.44%)	12.00 (44.44%)	8.00 (30.77%)	16.00 (45.71%)	0.00 (0.00%)	1.00 (16.67%)	13.00 (43.33%)	11.00 (55.00%)	4.00 (30.77%)	13.00 (44.83%)	13.00 (38.24%)



Prior treatment with either Gemtuzumab ozogamicin or Inotuzumab ozogamicin	12.00 (38.71%)	3.00 (12.00%)	12.00 (44.44%)	3.00 (11.11%)	9.00 (34.62%)	4.00 (11.43%)	1.00 (33.33%)	1.00 (16.67%)	9.00 (30.00%)	5.00 (25.00%)	4.00 (30.77%)	4.00 (13.79%)	9.00 (26.47%)
Hepatotoxic drug use	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (7.69%)	0.00 (0.00%)	1.00 (2.94%)
Metabolic syndrome	1.00 (3.23%)	1.00 (4.00%)	1.00 (3.70%)	1.00 (3.70%)	1.00 (3.85%)	1.00 (2.86%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	2.00 (15.38%)	2.00 (6.90%)	0.00 (0.00%)
Genetic factors	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)
Haematopoietic progenitor source	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)
Donor-recipient HLA disparity	4.00 (12.90%)	2.00 (8.00%)	3.00 (11.11%)	3.00 (11.11%)	3.00 (11.54%)	3.00 (8.57%)	0.00 (0.00%)	0.00 (0.00%)	2.00 (6.67%)	3.00 (15.00%)	1.00 (7.69%)	4.00 (13.79%)	2.00 (5.88%)
Graft-versus-host disease (GvHD) prophylaxis with sirolimus and tacrolimus	1.00 (3.23%)	0.00 (0.00%)	1.00 (3.70%)	0.00 (0.00%)	1.00 (3.85%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (3.33%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (2.94%)
None of the above	8.00 (25.81%)	8.00 (32.00%)	4.00 (14.81%)	9.00 (33.33%)	6.00 (23.08%)	11.00 (31.43%)	2.00 (6.67%)	3.00 (16.67%)	5.00 (16.67%)	4.00 (20.00%)	4.00 (30.77%)	6.00 (20.69%)	11.00 (32.35%)

For patients with a negative MRD at CAR-T infusion, 20.0% had age greater than 60 as a risk factor for VOD at CAR-T induction (please see **Table 45** below). For patients with negative MRD at first cycle of InO, 24.0% had age greater than 60 as a risk factor for VOD at CAR-T induction (please see **Table 45** below).

Table 45: Risk Factor for VOD at CAR-T Induction

	MRD status (1st cycle of InO)		MRD status (last cycle of InO)		MRD status (CAR-T infusion)		MRD status (prior to HPSCt)		BMI at index (initiation of InO)			InO received:	
	Positive	Negative	Positive	Negative	Positive	Negative	Positive	Negative	(18.5, 25)	(25, 30)	30+	Pre-apheresis	Post-apheresis
Risk factors for VOD at times:													
n	31.00	25.00	27.00	27.00	26.00	35.00	3.00	6.00	30.00	20.00	13.00	29.00	34.00
Age greater than 60	4.00 (12.90%)	6.00 (24.00%)	5.00 (18.52%)	6.00 (22.22%)	6.00 (23.08%)	7.00 (20.00%)	0.00 (0.00%)	1.00 (16.67%)	10.00 (33.33%)	3.00 (15.00%)	2.00 (15.38%)	10.00 (34.48%)	4.00 (11.76%)

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Poor performance status (Karnovsky <90%)	2.00 (6.45%)	0.00 (0.00%)	2.00 (7.41%)	1.00 (3.70%)	2.00 (7.69%)	1.00 (2.86%)	0.00 (0.00%)	0.00 (0.00%)	2.00 (6.67%)	1.00 (5.00%)	1.00 (7.69%)	1.00 (3.45%)	3.00 (8.82%)
Female receiving norethisterone	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)
Underlying haemoglobinopathy (thalassaemia or sickle-cell disease)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)
Diagnosis of primary haemophagocytic lymphohistiocytosis, adrenoleucodystrophy	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)
Prior abdominal or hepatic irradiation	2.00 (6.45%)	0.00 (0.00%)	2.00 (7.41%)	1.00 (3.70%)	2.00 (7.69%)	2.00 (5.71%)	0.00 (0.00%)	0.00 (0.00%)	2.00 (6.67%)	2.00 (10.00%)	0.00 (0.00%)	1.00 (3.45%)	4.00 (11.76%)
Pre-existing liver disease including cirrhosis	1.00 (3.23%)	0.00 (0.00%)	1.00 (3.70%)	0.00 (0.00%)	1.00 (3.85%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (3.33%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (2.94%)
Elevated AST (>2.5 upper limit of normal) or bilirubin (>1.5 upper limit of norm)	3.00 (9.68%)	0.00 (0.00%)	3.00 (11.11%)	0.00 (0.00%)	3.00 (11.54%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (3.33%)	1.00 (5.00%)	1.00 (7.69%)	1.00 (3.45%)	2.00 (5.88%)
Active viral hepatitis B or C	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)
Pre-existing hepatic fibrosis or elevated serum ferritin	7.00 (22.58%)	9.00 (36.00%)	6.00 (22.22%)	10.00 (37.04%)	7.00 (26.92%)	10.00 (28.57%)	0.00 (0.00%)	0.00 (0.00%)	9.00 (30.00%)	5.00 (25.00%)	3.00 (23.08%)	12.00 (41.38%)	5.00 (14.71%)
Prior autologous or allogenic transplant	13.00 (41.94%)	10.00 (40.00%)	12.00 (44.44%)	12.00 (44.44%)	8.00 (30.77%)	17.00 (48.57%)	0.00 (0.00%)	1.00 (16.67%)	13.00 (43.33%)	12.00 (60.00%)	4.00 (30.77%)	14.00 (48.28%)	13.00 (38.24%)
Prior treatment with either Gemtuzumab ozogamicin or Inotuzumab ozogamicin	13.00 (41.94%)	4.00 (16.00%)	13.00 (48.15%)	4.00 (14.81%)	10.00 (38.46%)	7.00 (20.00%)	1.00 (33.33%)	1.00 (16.67%)	9.00 (30.00%)	8.00 (40.00%)	5.00 (38.46%)	5.00 (17.24%)	13.00 (38.24%)
Hepatotoxic drug use	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (7.69%)	0.00 (0.00%)	1.00 (2.94%)
Metabolic syndrome	1.00 (3.23%)	1.00 (4.00%)	1.00 (3.70%)	1.00 (3.70%)	1.00 (3.85%)	1.00 (2.86%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	2.00 (15.38%)	2.00 (6.90%)	0.00 (0.00%)
Genetic factors	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)
Haematopoietic progenitor source	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)



Donor-recipient HLA disparity	5.00 (16.13%)	2.00 (8.00%)	4.00 (14.81%)	3.00 (11.11%)	4.00 (15.38%)	3.00 (8.57%)	0.00 (0.00%)	0.00 (0.00%)	3.00 (10.00%)	3.00 (15.00%)	1.00 (7.69%)	4.00 (13.79%)	3.00 (8.82%)
Graft-versus-host disease (GvHD) prophylaxis with sirolimus and tacrolimus	1.00 (3.23%)	0.00 (0.00%)	1.00 (3.70%)	0.00 (0.00%)	1.00 (3.85%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (3.33%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (2.94%)
None of the above	8.00 (25.81%)	7.00 (28.00%)	4.00 (14.81%)	8.00 (29.63%)	6.00 (23.08%)	9.00 (25.71%)	2.00 (66.67%)	3.00 (50.00%)	5.00 (16.67%)	3.00 (15.00%)	3.00 (23.08%)	5.00 (17.24%)	10.00 (29.41%)

For patients with a positive MRD in the first cycle of InO, the mean (SD) number of doses of InO in cycle 1 was 2.49 (0.74) (please see **Table 46** below). For patients with a BMI at index of 30+, the mean (SD) number of doses of InO in cycle 1 was 2.53 (0.64) (please see **Table 46** below).

Table 46: Number of InO Doses per Cycle (Cycle 1)

	MRD status (1st cycle of InO)		MRD status (last cycle of InO)		MRD status (CAR-T infusion)		MRD status (prior to HPSCT)		BMI at index (initiation of InO)			InO received:	
	Positive	Negative	Positive	Negative	Positive	Negative	Positive	Negative	(18.5, 25)	(25, 30)	30+	Pre-apheresis	Post-apheresis
Number of doses													
n	35	27	34	28	25	33	2	6	33	21	15	27	33
Mean	2.49	2.78	2.50	2.86	2.28	2.67	1.50	2.67	2.45	2.57	2.53	2.70	2.24
Standard deviation	0.74	0.58	0.71	0.45	0.79	0.74	0.71	0.52	0.75	0.75	0.64	0.72	0.79
Standard error of the mean	0.13	0.11	0.12	0.08	0.16	0.13	0.50	0.21	0.13	0.16	0.17	0.14	0.14
Median	3.00	3.00	3.00	3.00	2.00	3.00	1.50	3.00	3.00	3.00	3.00	3.00	2.00
Interquartile Range (IQR)	2.00 - 3.00	3.00 - 3.00	2.00 - 3.00	3.00 - 3.00	2.00 - 3.00	3.00 - 3.00	1.00 - 2.00	2.00 - 3.00	2.00 - 3.00	2.00 - 3.00	2.00 - 3.00	3.00 - 3.00	2.00 - 3.00
Range	1.00 - 3.00	1.00 - 3.00	1.00 - 3.00	1.00 - 3.00	1.00 - 3.00	1.00 - 3.00	1.00 - 2.00	2.00 - 3.00	1.00 - 3.00	1.00 - 3.00	1.00 - 3.00	1.00 - 3.00	1.00 - 3.00
95% CI	2.23 - 2.74	2.55 - 3.01	2.25 - 2.75	2.68 - 3.03	1.95 - 2.61	2.41 - 2.93	-4.85 - 7.85	2.12 - 3.21	2.19 - 2.72	2.23 - 2.91	2.18 - 2.89	2.42 - 2.99	1.96 - 2.52
Number of doses, n (%)													
n	37	27	35	28	26	35	3	6	34	22	15	29	34



.	2 (5.41%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	1 (3.85%)	2 (5.71%)	1 (33.33%)	0 (0.00%)	1 (2.94%)	1 (4.55%)	0 (0.00%)	2 (6.90%)	1 (2.94%)
1	5 (13.51%)	2 (7.41%)	4 (11.43%)	1 (3.57%)	5 (19.23%)	5 (14.29%)	1 (33.33%)	0 (0.00%)	5 (14.71%)	3 (13.64%)	1 (6.67%)	4 (13.79%)	7 (20.59%)
2	8 (21.62%)	2 (7.41%)	9 (25.71%)	2 (7.14%)	8 (30.77%)	1 (2.86%)	1 (33.33%)	2 (33.33%)	8 (23.53%)	3 (13.64%)	5 (33.33%)	0 (0.00%)	11 (32.35%)
3	22 (59.46%)	23 (85.19%)	21 (60.00%)	25 (89.29%)	12 (46.15%)	27 (77.14%)	0 (0.00%)	4 (66.67%)	20 (58.82%)	15 (68.18%)	9 (60.00%)	23 (79.31%)	15 (44.12%)
Unknown, n (%)													
n	2	0	1	0	1	2	1	0	1	1	0	2	1
Unknown	2 (100.00%)	0 (0.00%)	1 (100.00%)	0 (0.00%)	1 (100.00%)	2 (100.00%)	1 (100.00%)	0 (0.00%)	1 (100.00%)	1 (100.00%)	0 (0.00%)	2 (100.00%)	1 (100.00%)

For the patients with a positive MRD at first cycle of InO, the mean (SD) number of InO doses in cycle 2 was 2.45 (0.82) (please see **Table 47** below). For the patients with positive MRD at last cycle of InO, the mean (SD) number of InO doses in cycle 2 was 2.44 (0.73) (please see **Table 47** below).

Table 47: Number of InO Doses per Cycle (Cycle 2)

	MRD status (1st cycle of InO)		MRD status (last cycle of InO)		MRD status (CAR-T infusion)		MRD status (prior to HPSCT)		BMI at index (initiation of InO)			InO received:	
	Positive	Negative	Positive	Negative	Positive	Negative	Positive	Negative	(18.5, 25)	(25, 30)	30+	Pre-apheresis	Post-apheresis
Number of doses													
n	11	5	9	6	6	8	2	1	8	3	4	11	3
Mean	2.45	2.80	2.44	2.83	2.33	2.62	2.00	3.00	2.38	2.67	2.50	2.55	2.33
Standard deviation	0.82	0.45	0.73	0.41	0.82	0.52	1.41	.	0.74	0.58	0.58	0.52	1.15
Standard error of the mean	0.25	0.20	0.24	0.17	0.33	0.18	1.00	.	0.26	0.33	0.29	0.16	0.67
Median	3.00	3.00	3.00	3.00	2.50	3.00	2.00	3.00	2.50	3.00	2.50	3.00	3.00
Interquartile Range (IQR)	2.00 - 3.00	3.00 - 3.00	2.00 - 3.00	3.00 - 3.00	2.00 - 3.00	2.00 - 3.00	1.00 - 3.00	3.00 - 3.00	2.00 - 3.00	2.00 - 3.00	2.00 - 3.00	2.00 - 3.00	1.00 - 3.00
Range	1.00 - 3.00	2.00 - 3.00	1.00 - 3.00	2.00 - 3.00	1.00 - 3.00	2.00 - 3.00	1.00 - 3.00	3.00 - 3.00	1.00 - 3.00	2.00 - 3.00	2.00 - 3.00	2.00 - 3.00	1.00 - 3.00
95% CI	1.90 - 3.01	2.24 - 3.36	1.89 - 3.00	2.40 - 3.26	1.48 - 3.19	2.19 - 3.06	-10.71 - 14.71	. - .	1.75 - 3.00	1.23 - 4.10	1.58 - 3.42	2.19 - 2.90	-0.54 - 5.20



Number of doses, n (%)													
n	11	5	9	6	6	9	2	1	8	4	4	12	3
.	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (25.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)
1	2 (18.18%)	0 (0.00%)	1 (11.11%)	0 (0.00%)	1 (16.67%)	0 (0.00%)	1 (50.00%)	0 (0.00%)	1 (12.50%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (33.33%)
2	2 (18.18%)	1 (20.00%)	3 (33.33%)	1 (16.67%)	2 (33.33%)	3 (33.33%)	0 (0.00%)	0 (0.00%)	3 (37.50%)	1 (25.00%)	2 (50.00%)	5 (41.67%)	0 (0.00%)
3	7 (63.64%)	4 (80.00%)	5 (55.56%)	5 (83.33%)	3 (50.00%)	5 (55.56%)	1 (50.00%)	1 (100.00%)	4 (50.00%)	2 (50.00%)	2 (50.00%)	6 (50.00%)	2 (66.67%)
Unknown, n (%)													
n	0	0	0	0	0	1	0	0	0	1	0	1	0
Unknown	0 (.)	0 (.)	0 (.)	0 (.)	0 (.)	1 (100.00%)	0 (.)	0 (.)	0 (.)	1 (100.00%)	0 (.)	1 (100.00%)	0 (.)

For the patients with positive MRD at first cycle of InO in dose 1 across all cycles, the mean (SD) was 0.79 (0.30) (please see **Table 48** below). For the patients with positive MRD at last cycle of InO in dose 1 across all cycles, the mean (SD) was 0.75 (0.29) (please see **Table 48** below).

Table 48: Dose of InO Treatment (All Cycles, Dose 1)

	MRD status (1st cycle of InO)		MRD status (last cycle of InO)		MRD status (CAR-T infusion)		MRD status (prior to HPSCt)		BMI at index (initiation of InO)			InO received:	
	Positive	Negative	Positive	Negative	Positive	Negative	Positive	Negative	(18.5, 25)	(25, 30)	30+	Pre-apheresis	Post-apheresis
Dose of InO treatment (mg/m ²)													
n	42	30	40	31	28	39	3	7	39	23	16	37	32
Mean	0.79	0.82	0.75	0.84	0.74	0.81	0.60	0.76	0.72	0.76	0.75	0.71	0.83
Standard deviation	0.30	0.34	0.29	0.32	0.26	0.32	0.17	0.11	0.28	0.24	0.31	0.19	0.37
Standard error of the mean	0.046	0.061	0.045	0.058	0.048	0.051	0.100	0.043	0.045	0.051	0.077	0.032	0.066
Median	0.8	0.8	0.8	0.8	0.8	0.8	0.5	0.8	0.8	0.8	0.8	0.8	0.8
Interquartile Range (IQR)	0.5 - 0.8	0.8 - 0.8	0.5 - 0.8	0.8 - 0.8	0.5 - 0.8	0.5 - 0.8	0.5 - 0.8	0.8 - 0.8	0.5 - 0.8	0.5 - 0.8	0.6 - 0.8	0.5 - 0.8	0.5 - 0.8
Range	0.4 - 1.7	0.3 - 1.8	0.4 - 1.7	0.5 - 1.8	0.4 - 1.8	0.3 - 1.8	0.5 - 0.8	0.5 - 0.8	0.3 - 1.8	0.5 - 1.7	0.5 - 1.8	0.3 - 1.2	0.4 - 1.8
95% CI	0.7 - 0.9	0.7 - 0.9	0.7 - 0.8	0.7 - 1.0	0.6 - 0.8	0.7 - 0.9	0.2 - 1.0	0.7 - 0.9	0.6 - 0.8	0.7 - 0.9	0.6 - 0.9	0.6 - 0.8	0.7 - 1.0

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Dose unknown, n (%)													
n	4	3	3	3	3	3	1	0	3	1	3	2	4
Unknown	4 (100.0%)	3 (100.0%)	3 (100.0%)	3 (100.0%)	3 (100.0%)	3 (100.0%)	1 (100.0%)	0 (.%)	3 (100.0%)	1 (100.0%)	3 (100.0%)	2 (100.0%)	4 (100.0%)

For the patients with positive MRD in last cycle of InO in dose 2 across all cycles, the mean (SD) was 0.56 (0.16) (please see **Table 49** below). For the patients who received InO in pre-apheresis, the mean (SD) in dose 2 across all cycles was 0.51 (0.08) (please see **Table 49** below).

Table 49: Dose of InO Treatment (All Cycles, Dose 2)

	MRD status (1st cycle of InO)		MRD status (last cycle of InO)		MRD status (CAR-T infusion)		MRD status (prior to HPST)		BMI at index (initiation of InO)			InO received:	
	Positive	Negative	Positive	Negative	Positive	Negative	Positive	Negative	(18.5, 25)	(25, 30)	30+	Pre-apheresis	Post-apheresis
Dose of InO treatment (mg/m2)													
n	36	27	36	30	23	33	1	7	33	20	15	33	24
Mean	0.56	0.59	0.56	0.57	0.53	0.59	0.50	0.50	0.56	0.53	0.54	0.51	0.64
Standard deviation	0.15	0.29	0.16	0.26	0.13	0.27	.	0.00	0.25	0.11	0.17	0.08	0.31
Standard error of the mean	0.025	0.056	0.027	0.047	0.026	0.046	.	0.000	0.044	0.025	0.043	0.014	0.064
Median	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
Interquartile Range (IQR)	0.5 - 0.5	0.5 - 0.5	0.5 - 0.5	0.5 - 0.5	0.5 - 0.5	0.5 - 0.5	0.5 - 0.5	0.5 - 0.5	0.5 - 0.5	0.5 - 0.5	0.5 - 0.5	0.5 - 0.5	0.5 - 0.5
Range	0.3 - 1.0	0.3 - 1.8	0.3 - 1.0	0.5 - 1.8	0.5 - 1.1	0.3 - 1.8	0.5 - 0.5	0.5 - 0.5	0.3 - 1.8	0.5 - 1.0	0.3 - 1.1	0.3 - 0.8	0.5 - 1.8
95% CI	0.5 - 0.6	0.5 - 0.7	0.5 - 0.6	0.5 - 0.7	0.5 - 0.6	0.5 - 0.7	. - .	0.5 - 0.5	0.5 - 0.6	0.5 - 0.6	0.4 - 0.6	0.5 - 0.5	0.5 - 0.8
Dose unknown, n (%)													
n	3	3	2	3	2	3	1	0	2	1	3	1	4
Unknown	3 (100.0%)	3 (100.0%)	2 (100.0%)	3 (100.0%)	2 (100.0%)	3 (100.0%)	1 (100.0%)	0 (.%)	2 (100.0%)	1 (100.0%)	3 (100.0%)	1 (100.0%)	4 (100.0%)



For the patients with positive MRD in first cycle of InO in dose 3 across all cycles, the mean (SD) was 0.58 (0.18) (please see **Table 50** below). For the patients who received InO pre-apheresis in dose 3 across all cycles, the mean (SD) was 0.51 (0.09) (please see **Table 50** below).

Table 50: Dose of InO Treatment (All Cycles, Dose 3)

	MRD status (1st cycle of InO)		MRD status (last cycle of InO)		MRD status (CAR-T infusion)		MRD status (prior to HPSCt)		BMI at index (initiation of InO)			InO received:	
	Positive	Negative	Positive	Negative	Positive	Negative	Positive	Negative	(18.5, 25)	(25, 30)	30+	Pre-apheresis	Post-apheresis
Dose of InO treatment (mg/m2)													
n	26	24	24	27	13	29	0	5	22	16	8	28	13
Mean	0.58	0.56	0.58	0.53	0.53	0.57		0.50	0.54	0.52	0.57	0.51	0.65
Standard deviation	0.18	0.16	0.19	0.12	0.18	0.16		0.00	0.13	0.14	0.21	0.09	0.24
Standard error of the mean	0.034	0.033	0.039	0.023	0.050	0.029	.	0.000	0.028	0.034	0.075	0.017	0.068
Median	0.5	0.5	0.5	0.5	0.5	0.5	.	0.5	0.5	0.5	0.5	0.5	0.5
Interquartile Range (IQR)	0.5 - 0.5	0.5 - 0.5	0.5 - 0.5	0.5 - 0.5	0.5 - 0.5	0.5 - 0.5	. - .	0.5 - 0.5	0.5 - 0.5	0.5 - 0.5	0.5 - 0.5	0.5 - 0.5	0.5 - 0.9
Range	0.3 - 1.0	0.5 - 1.1	0.3 - 1.0	0.5 - 1.1	0.3 - 1.1	0.5 - 1.0		0.5 - 0.5	0.5 - 1.0	0.3 - 1.0	0.5 - 1.1	0.3 - 0.8	0.5 - 1.1
95% CI	0.5 - 0.6	0.5 - 0.6	0.5 - 0.7	0.5 - 0.6	0.4 - 0.6	0.5 - 0.6	. - .	0.5 - 0.5	0.5 - 0.6	0.4 - 0.6	0.4 - 0.8	0.5 - 0.5	0.5 - 0.8
Dose unknown, n (%)													
n	3	3	2	3	2	3	1	0	2	1	3	1	4
Unknown	3 (100.0%)	3 (100.0%)	2 (100.0%)	3 (100.0%)	2 (100.0%)	3 (100.0%)	1 (100.0%)	0 (%)	2 (100.0%)	1 (100.0%)	3 (100.0%)	1 (100.0%)	4 (100.0%)

For patients with positive MRD in the last cycle of InO, the mean (SD) in dose 1 of cycle 1 was 0.80 (0.30) (please see **Table 51** below). For patients with positive MRD in the first cycle of InO, the mean (SD) in dose 1 of cycle 1 was 0.81 (0.28) (please see **Table 51** below).

Table 51: Dose of InO per Dose (Cycle 1, dose 1)

	MRD status (1st cycle of InO)	MRD status (last cycle of InO)	MRD status (CAR-T infusion)	MRD status (prior to HPSCt)	BMI at index (initiation of InO)	InO received:
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	Positive	Negative	Positive	Negative	Positive	Negative	Positive	Negative	(18.5, 25)	(25, 30)	30+	Pre-apheresis	Post-apheresis
Dose of InO treatment (mg/m ²)													
n	32	24	31	25	23	30	2	6	30	20	12	25	30
Mean	0.81	0.89	0.80	0.87	0.79	0.85	0.65	0.80	0.78	0.77	0.83	0.77	0.84
Standard deviation	0.28	0.33	0.30	0.30	0.25	0.32	0.21	0.00	0.29	0.26	0.33	0.14	0.38
Standard error of the mean	0.050	0.067	0.054	0.061	0.053	0.058	0.150	0.000	0.052	0.057	0.094	0.029	0.069
Median	0.8	0.8	0.8	0.8	0.8	0.8	0.7	0.8	0.8	0.8	0.8	0.8	0.8
Interquartile Range (IQR)	0.7 - 0.8	0.8 - 0.8	0.6 - 0.8	0.8 - 0.8	0.8 - 0.8	0.8 - 0.8	0.5 - 0.8	0.8 - 0.8	0.6 - 0.8	0.7 - 0.8	0.7 - 0.8	0.8 - 0.8	0.5 - 0.8
Range	0.4 - 1.7	0.5 - 1.8	0.4 - 1.7	0.5 - 1.8	0.4 - 1.8	0.5 - 1.8	0.5 - 0.8	0.8 - 0.8	0.4 - 1.8	0.5 - 1.7	0.5 - 1.8	0.5 - 1.2	0.4 - 1.8
95% CI	0.7 - 0.9	0.7 - 1.0	0.7 - 0.9	0.7 - 1.0	0.7 - 0.9	0.7 - 1.0	-1.3 - 2.6	0.8 - 0.8	0.7 - 0.9	0.7 - 0.9	0.6 - 1.0	0.7 - 0.8	0.7 - 1.0
Dose unknown, n (%)													
n	3	3	3	3	2	3	0	0	3	1	3	2	3
Unknown	3 (100.0%)	3 (100.0%)	3 (100.0%)	3 (100.0%)	2 (100.0%)	3 (100.0%)	0 (%)	0 (%)	3 (100.0%)	1 (100.0%)	3 (100.0%)	2 (100.0%)	3 (100.0%)

For patients with BMI in the range 18.5-25 at index(, the mean (SD) for the dose of InO in cycle 1 dose 2 was 0.57 (0.27) (please see **Table 52** below). For patients with negative MRD at CAR-T infusion, the mean (SD) of InO in cycle 1 dose 2 was 0.60 (0.29) (please see **Table 52** below).

Table 52: Dose of InO per Dose (Cycle 1, Dose 2)

	MRD status (1st cycle of InO)		MRD status (last cycle of InO)		MRD status (CAR-T infusion)		MRD status (prior to HPST)		BMI at index (initiation of InO)			InO received:	
	Positive	Negative	Positive	Negative	Positive	Negative	Positive	Negative	(18.5, 25)	(25, 30)	30+	Pre-apheresis	Post-apheresis
Dose of InO treatment (mg/m ²)													
n	28	22	28	24	19	25	1	6	26	17	11	22	23
Mean	0.55	0.60	0.55	0.59	0.53	0.60	0.50	0.50	0.57	0.53	0.55	0.51	0.63
Standard deviation	0.15	0.31	0.16	0.29	0.14	0.29	.	0.00	0.27	0.12	0.20	0.06	0.32

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Standard error of the mean	0.028	0.065	0.029	0.059	0.032	0.058	.	0.000	0.053	0.029	0.059	0.014	0.066
Median	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
Interquartile Range (IQR)	0.5 - 0.5	0.5 - 0.5	0.5 - 0.5	0.5 - 0.5	0.5 - 0.5	0.5 - 0.5	0.5 - 0.5	0.5 - 0.5	0.5 - 0.5	0.5 - 0.5	0.5 - 0.5	0.5 - 0.5	0.5 - 0.5
Range	0.3 - 1.0	0.5 - 1.8	0.3 - 1.0	0.5 - 1.8	0.5 - 1.1	0.5 - 1.8	0.5 - 0.5	0.5 - 0.5	0.5 - 1.8	0.5 - 1.0	0.3 - 1.1	0.5 - 0.8	0.5 - 1.8
95% CI	0.5 - 0.6	0.5 - 0.7	0.5 - 0.6	0.5 - 0.7	0.5 - 0.6	0.5 - 0.7	. - .	0.5 - 0.5	0.5 - 0.7	0.5 - 0.6	0.4 - 0.7	0.5 - 0.5	0.5 - 0.8
Dose unknown, n (%)													
n	2	3	2	3	1	3	0	0	2	1	3	1	3
Unknown	2 (100.0%)	3 (100.0%)	2 (100.0%)	3 (100.0%)	1 (100.0%)	3 (100.0%)	0 (%)	0 (%)	2 (100.0%)	1 (100.0%)	3 (100.0%)	1 (100.0%)	3 (100.0%)

For patients who received InO pre-apheresis, the mean (SD) for dose of InO in cycle 1 dose 3 was 0.50 (0.08) (please see **Table 53** below). For patients who had negative MRD at CAR-T infusion, the mean (SD) for dose of InO in cycle 1 dose 3 was 0.55 (0.15) (please see **Table 53** below).

Table 53: Dose of InO per Dose (Cycle 1, Dose 3)

	MRD status (1st cycle of InO)		MRD status (last cycle of InO)		MRD status (CAR-T infusion)		MRD status (prior to HPSCT)	BMI at index (initiation of InO)			InO received:	
	Positive	Negative	Positive	Negative	Positive	Negative	Negative	(18.5, 25)	(25, 30)	30+	Pre-apheresis	Post-apheresis
Dose of InO treatment (mg/m2)												
n	20	20	19	22	11	24	4	18	14	6	22	12
Mean	0.57	0.55	0.56	0.54	0.54	0.55	0.50	0.53	0.52	0.60	0.50	0.63
Standard deviation	0.18	0.16	0.19	0.13	0.20	0.15	0.00	0.12	0.15	0.24	0.08	0.24
Standard error of the mean	0.039	0.035	0.043	0.028	0.059	0.031	0.000	0.028	0.039	0.100	0.017	0.070
Median	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
Interquartile Range (IQR)	0.5 - 0.5	0.5 - 0.5	0.5 - 0.5	0.5 - 0.5	0.5 - 0.5	0.5 - 0.5	0.5 - 0.5	0.5 - 0.5	0.5 - 0.5	0.5 - 0.5	0.5 - 0.5	0.5 - 0.8
Range	0.3 - 1.0	0.5 - 1.1	0.3 - 1.0	0.5 - 1.1	0.3 - 1.1	0.5 - 1.0	0.5 - 0.5	0.5 - 1.0	0.3 - 1.0	0.5 - 1.1	0.3 - 0.8	0.5 - 1.1
95% CI	0.5 - 0.6	0.5 - 0.6	0.5 - 0.7	0.5 - 0.6	0.4 - 0.7	0.5 - 0.6	0.5 - 0.5	0.5 - 0.6	0.4 - 0.6	0.3 - 0.9	0.5 - 0.5	0.5 - 0.8
Dose unknown, n (%)												
n	2	3	2	3	1	3	0	2	1	3	1	3



Unknown	2 (100.0%)	3 (100.0%)	2 (100.0%)	3 (100.0%)	1 (100.0%)	3 (100.0%)	0 (%)	2 (100.0%)	1 (100.0%)	3 (100.0%)	1 (100.0%)	3 (100.0%)
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For patients who had a positive MRD at first cycle of InO, the mean (SD) of InO in cycle 2 dose 1 was 0.74 (0.36) (please see **Table 54** below). For patients who received InO pre-apheresis, the mean (SD) of InO in cycle 2 dose 1 was 0.62 (0.23) (please see **Table 54** below).

Table 54: Dose of InO per Dose (Cycle 2, Dose 1)

	MRD status (1st cycle of InO)		MRD status (last cycle of InO)		MRD status (CAR-T infusion)		MRD status (prior to HPSCt)		BMI at index (initiation of InO)			InO received:	
	Positive	Negative	Positive	Negative	Positive	Negative	Positive	Negative	(18.5, 25)	(25, 30)	30+	Pre-apheresis	Post-apheresis
Dose of InO treatment (mg/m ²)													
n	10	5	9	6	5	8	1	1	8	3	4	11	2
Mean	0.74	0.58	0.60	0.72	0.50	0.71	0.50	0.50	0.55	0.70	0.53	0.62	0.70
Standard deviation	0.36	0.18	0.17	0.40	0.00	0.26	.	.	0.14	0.17	0.05	0.23	0.28
Standard error of the mean	0.114	0.080	0.058	0.164	0.000	0.091	.	.	0.050	0.100	0.025	0.069	0.200
Median	0.5	0.5	0.5	0.5	0.5	0.7	0.5	0.5	0.5	0.8	0.5	0.5	0.7
Interquartile Range (IQR)	0.5 - 0.9	0.5 - 0.5	0.5 - 0.6	0.5 - 0.8	0.5 - 0.5	0.5 - 0.9	0.5 - 0.5	0.5 - 0.5	0.5 - 0.5	0.5 - 0.8	0.5 - 0.6	0.5 - 0.8	0.5 - 0.9
Range	0.5 - 1.5	0.5 - 0.9	0.5 - 0.9	0.5 - 1.5	0.5 - 0.5	0.5 - 1.2	0.5 - 0.5	0.5 - 0.5	0.5 - 0.9	0.5 - 0.8	0.5 - 0.6	0.5 - 1.2	0.5 - 0.9
95% CI	0.5 - 1.0	0.4 - 0.8	0.5 - 0.7	0.3 - 1.1	0.5 - 0.5	0.5 - 0.9	. - .	. - .	0.4 - 0.7	0.3 - 1.1	0.4 - 0.6	0.5 - 0.8	-1.8 - 3.2
Dose unknown, n (%)													
n	1	0	0	0	1	0	1	0	0	0	0	0	1
Unknown	1 (100.0%)	0 (%)	0 (%)	0 (%)	1 (100.0%)	0 (%)	1 (100.0%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (100.0%)

For patients who had a negative MRD at CAR-T infusion, the mean (SD) of InO in cycle 2 dose 2 was 0.56 (0.19) (please see **Table 55** below). For patients who received InO pre-apheresis , the mean (SD) of InO in cycle 2 dose 2 was 0.51 (0.11) (please see **Table 55** below).



Table 55: Dose of InO per Dose (Cycle 2, Dose 2)

	MRD status (1st cycle of InO)		MRD status (last cycle of InO)		MRD status (CAR-T infusion)		MRD status (prior to HPST)		BMI at index (initiation of InO)			InO received:	
	Positive	Negative	Positive	Negative	Positive	Negative	Positive	Negative	(18.5, 25)	(25, 30)	30+	Pre-apheresis	Post-apheresis
Dose of InO treatment (mg/m2)													
n	8	5	8	6	4	8	0	1	7	3	4	11	1
Mean	0.59	0.54	0.61	0.50	0.50	0.56		0.50	0.53	0.50	0.53	0.51	0.90
Standard deviation	0.16	0.22	0.18	0.00	0.00	0.19		.	0.18	0.00	0.05	0.11	.
Standard error of the mean	0.058	0.098	0.064	0.000	0.000	0.068	.	.	0.068	0.000	0.025	0.034	.
Median	0.5	0.5	0.5	0.5	0.5	0.5	.	0.5	0.5	0.5	0.5	0.5	0.9
Interquartile Range (IQR)	0.5 - 0.7	0.5 - 0.5	0.5 - 0.8	0.5 - 0.5	0.5 - 0.5	0.5 - 0.7	. - .	0.5 - 0.5	0.5 - 0.5	0.5 - 0.5	0.5 - 0.6	0.5 - 0.5	0.9 - 0.9
Range	0.5 - 0.9	0.3 - 0.9	0.5 - 0.9	0.5 - 0.5	0.5 - 0.5	0.3 - 0.9		0.5 - 0.5	0.3 - 0.9	0.5 - 0.5	0.5 - 0.6	0.3 - 0.8	0.9 - 0.9
95% CI	0.5 - 0.7	0.3 - 0.8	0.5 - 0.8	0.5 - 0.5	0.5 - 0.5	0.4 - 0.7	. - .	. - .	0.4 - 0.7	0.5 - 0.5	0.4 - 0.6	0.4 - 0.6	. - .
Dose unknown, n (%)													
n	1	0	0	0	1	0	1	0	0	0	0	0	1
Unknown	1 (100.0%)	0 (.%)	0 (.%)	0 (.%)	1 (100.0%)	0 (.%)	1 (100.0%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	1 (100.0%)

For patients who had positive MRD at first cycle of InO, the mean (SD) for InO in cycle 2 dose 3 was 0.62 (0.18) (please see Table 56 below). For patients who received InO pre-apheresis, the mean (SD) for InO in cycle 2 dose 3 was 0.55 (0.12) (please see Table 56 below).

Table 56: Dose of InO per Dose (Cycle 2, Dose 3)

	MRD status (1st cycle of InO)		MRD status (last cycle of InO)		MRD status (CAR-T infusion)		MRD status (prior to HPST)		BMI at index (initiation of InO)			InO received:	
	Positive	Negative	Positive	Negative	Positive	Negative	Positive	Negative	(18.5, 25)	(25, 30)	30+	Pre-apheresis	Post-apheresis
Dose of InO treatment (mg/m2)													
n	6	4	5	5	2	5	0	1	4	2	2	6	1

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Mean	0.62	0.60	0.66	0.50	0.50	0.64		0.50	0.60	0.50	0.50	0.55	0.90
Standard deviation	0.18	0.20	0.22	0.00	0.00	0.19		.	0.20	0.00	0.00	0.12	.
Standard error of the mean	0.075	0.100	0.098	0.000	0.000	0.087	.	.	0.100	0.000	0.000	0.050	.
Median	0.5	0.5	0.5	0.5	0.5	0.5	.	0.5	0.5	0.5	0.5	0.5	0.9
Interquartile Range (IQR)	0.5 - 0.8	0.5 - 0.7	0.5 - 0.9	0.5 - 0.5	0.5 - 0.5	0.5 - 0.8	. - .	0.5 - 0.5	0.5 - 0.7	0.5 - 0.5	0.5 - 0.5	0.5 - 0.5	0.9 - 0.9
Range	0.5 - 0.9	0.5 - 0.9	0.5 - 0.9	0.5 - 0.5	0.5 - 0.5	0.5 - 0.9		0.5 - 0.5	0.5 - 0.9	0.5 - 0.5	0.5 - 0.5	0.5 - 0.8	0.9 - 0.9
95% CI	0.4 - 0.8	0.3 - 0.9	0.4 - 0.9	0.5 - 0.5	0.5 - 0.5	0.4 - 0.9	. - .	. - .	0.3 - 0.9	0.5 - 0.5	0.5 - 0.5	0.4 - 0.7	. - .
Dose unknown, n (%)													
n	1	0	0	0	1	0	1	0	0	0	0	0	1
Unknown	1 (100.0%)	0 (.%)	0 (.%)	0 (.%)	1 (100.0%)	0 (.%)	1 (100.0%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	0 (.%)	1 (100.0%)

For patients who had a negative MRD at CAR-T infusion, 85.7% had MRD assessed (please see Table 57 below). For the patients who had positive MRD at last cycle of InO, 90.9% had their MRD assessed using flow cytometry assays (please see **Table 57** below).

Table 57: MRD Assessment, Including Method Used

	Overall	MRD status (1st cycle of InO)		MRD status (last cycle of InO)		MRD status (CAR-T infusion)		MRD status (prior to HPSCt)		BMI at index (initiation of InO)			InO received:	
	Total	Positive	Negative	Positive	Negative	Positive	Negative	Positive	Negative	(18.5, 25)	(25, 30)	30+	Pre-apheresis	Post-apheresis
Was MRD assessed?, n (%)														
n	84	37	27	35	28	26	35	3	6	34	22	15	29	34
Yes	65 (77.4%)	37 (100.0%)	27 (100.0%)	33 (94.3%)	27 (96.4%)	21 (80.8%)	30 (85.7%)	2 (66.7%)	5 (83.3%)	29 (85.3%)	16 (72.7%)	12 (80.0%)	25 (86.2%)	26 (76.5%)
No	18 (21.4%)	0 (0.0%)	0 (0.0%)	2 (5.7%)	1 (3.6%)	5 (19.2%)	5 (14.3%)	1 (33.3%)	1 (16.7%)	5 (14.7%)	6 (27.3%)	2 (13.3%)	4 (13.8%)	7 (20.6%)
3	1 (1.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (6.7%)	0 (0.0%)	1 (2.9%)
Method used to assess MRD														
n	65	37	27	33	27	21	30	2	5	29	16	12	25	26

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Flow cytometry assays	57 (87.7%)	32 (86.5%)	25 (92.6%)	30 (90.9%)	25 (92.6%)	18 (85.7%)	26 (86.7%)	0 (0.0%)	5 (100.0%)	28 (96.6%)	14 (87.5%)	10 (83.3%)	25 (100.0%)	18 (69.2%)
Real-time quantitative polymerase chain reaction (RT-qPCR) assays	10 (15.4%)	3 (8.1%)	7 (25.9%)	3 (9.1%)	6 (22.2%)	2 (9.5%)	7 (23.3%)	0 (0.0%)	0 (0.0%)	5 (17.2%)	1 (6.2%)	3 (25.0%)	4 (16.0%)	5 (19.2%)
Next-generation sequencing (NGS)	1 (1.5%)	1 (2.7%)	0 (0.0%)	1 (3.0%)	0 (0.0%)	1 (4.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (6.2%)	0 (0.0%)	1 (4.0%)	0 (0.0%)
Other	1 (1.5%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (4.8%)	0 (0.0%)	1 (50.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.8%)
InO prescribed as:, n (%)														
n	84	37	27	35	28	26	35	3	6	34	22	15	29	34
Monotherapy	63 (75.0%)	28 (75.7%)	19 (70.4%)	27 (77.1%)	20 (71.4%)	19 (73.1%)	24 (68.6%)	1 (33.3%)	6 (100.0%)	23 (67.6%)	17 (77.3%)	13 (86.7%)	23 (79.3%)	21 (61.8%)
Combination with chemotherapy and/or another agent	21 (25.0%)	9 (24.3%)	8 (29.6%)	8 (22.9%)	8 (28.6%)	7 (26.9%)	11 (31.4%)	2 (66.7%)	0 (0.0%)	11 (32.4%)	5 (22.7%)	2 (13.3%)	6 (20.7%)	13 (38.2%)

Overall, 19.1% of patients (n=21) had cyclophosphamide prescribed in combination with InO at first cycle of bridging InO (please see **Table 58** below). Of the patients who had a negative MRD at CAR-T infusion, 18.2% had cytarabine prescribed in combination with InO at first cycle of InO as a bridge to CAR-T (please see **Table 58** below).

Table 58: Treatment Prescribed in Combination with InO at First Cycle of InO as a Bridge to CAR-T

	Overall	MRD status (1st cycle of InO)		MRD status (last cycle of InO)		MRD status (CAR-T infusion)		MRD status (prior to HPSCt)		BMI at index (initiation of InO)			InO received:	
	Total	Positive	Negative	Positive	Negative	Positive	Negative	Positive	Negative	(18.5, 25)	(25, 30)	30+	Pre-apheresis	Post-apheresis
Treatment in combination with InO treatment														
n	21.00	9.00	8.00	8.00	8.00	7.00	11.00	2.00	0.00	11.00	5.00	2.00	6.00	13.00



Vincristine	3.00 (14.29 %)	2.00 (22.22 %)	0.00 (0.00%)	3.00 (37.50 %)	0.00 (0.00%)	1.00 (14.29 %)	0.00 (0.00%)	0.00 (0.00%)	0.00 (.%)	0.00 (0.00%)	2.00 (40.00 %)	1.00 (50.00 %)	0.00 (0.00%)	2.00 (15.38%)
Dexamethasone	1.00 (4.76%)	1.00 (11.11 %)	0.00 (0.00%)	1.00 (12.50 %)	0.00 (0.00%)	1.00 (14.29 %)	0.00 (0.00%)	0.00 (0.00%)	0.00 (.%)	0.00 (0.00%)	1.00 (20.00 %)	0.00 (0.00%)	0.00 (0.00%)	1.00 (7.69%)
Prednisolone	1.00 (4.76%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (12.50 %)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (.%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (50.00 %)	0.00 (0.00%)	0.00 (0.00%)
Methylprednisolone	1.00 (4.76%)	0.00 (0.00%)	1.00 (12.50 %)	0.00 (0.00%)	1.00 (12.50 %)	0.00 (0.00%)	1.00 (9.09%)	0.00 (0.00%)	0.00 (.%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (7.69%)
Hydrocortisone	2.00 (9.52%)	1.00 (11.11 %)	0.00 (0.00%)	1.00 (12.50 %)	0.00 (0.00%)	1.00 (14.29 %)	1.00 (9.09%)	0.00 (0.00%)	0.00 (.%)	0.00 (0.00%)	2.00 (40.00 %)	0.00 (0.00%)	0.00 (0.00%)	2.00 (15.38%)
Doxorubicin	2.00 (9.52%)	1.00 (11.11 %)	0.00 (0.00%)	2.00 (25.00 %)	0.00 (0.00%)	1.00 (14.29 %)	0.00 (0.00%)	0.00 (0.00%)	0.00 (.%)	1.00 (9.09%)	0.00 (0.00%)	1.00 (50.00 %)	1.00 (16.67%)	0.00 (0.00%)
Daunorubicin	2.00 (9.52%)	2.00 (22.22 %)	0.00 (0.00%)	2.00 (25.00 %)	0.00 (0.00%)	1.00 (14.29 %)	0.00 (0.00%)	0.00 (0.00%)	0.00 (.%)	0.00 (0.00%)	2.00 (40.00 %)	0.00 (0.00%)	0.00 (0.00%)	2.00 (15.38%)
Cyclophosphamide	4.00 (19.05 %)	1.00 (11.11 %)	2.00 (25.00 %)	2.00 (25.00 %)	1.00 (12.50 %)	0.00 (0.00%)	3.00 (27.27 %)	0.00 (0.00%)	0.00 (.%)	3.00 (27.27 %)	0.00 (0.00%)	1.00 (50.00 %)	2.00 (33.33%)	1.00 (7.69%)
L-asparaginase	1.00 (4.76%)	1.00 (11.11 %)	0.00 (0.00%)	1.00 (12.50 %)	0.00 (0.00%)	1.00 (14.29 %)	0.00 (0.00%)	0.00 (0.00%)	0.00 (.%)	0.00 (0.00%)	1.00 (20.00 %)	0.00 (0.00%)	0.00 (0.00%)	1.00 (7.69%)
Methotrexate	3.00 (14.29 %)	1.00 (11.11 %)	0.00 (0.00%)	1.00 (12.50 %)	0.00 (0.00%)	0.00 (0.00%)	2.00 (18.18 %)	0.00 (0.00%)	0.00 (.%)	0.00 (0.00%)	3.00 (60.00 %)	0.00 (0.00%)	1.00 (16.67%)	2.00 (15.38%)
Cytarabine	4.00 (19.05 %)	2.00 (22.22 %)	0.00 (0.00%)	2.00 (25.00 %)	0.00 (0.00%)	2.00 (28.57 %)	2.00 (18.18 %)	0.00 (0.00%)	0.00 (.%)	1.00 (9.09%)	3.00 (60.00 %)	0.00 (0.00%)	1.00 (16.67%)	3.00 (23.08%)
Etoposide	1.00 (4.76%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (12.50 %)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (.%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (50.00 %)	0.00 (0.00%)	0.00 (0.00%)
Mercaptopurine	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (.%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)
Imatinib	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (.%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)
Dasatinib	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (.%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)
Ponatinib	6.00 (28.57 %)	2.00 (22.22 %)	3.00 (37.50 %)	1.00 (12.50 %)	3.00 (37.50 %)	4.00 (57.14 %)	2.00 (18.18 %)	2.00 (100.00 %)	0.00 (.%)	4.00 (36.36 %)	1.00 (20.00 %)	0.00 (0.00%)	2.00 (33.33%)	4.00 (30.77%)
Nilotinib	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (.%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)

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Rituximab	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (.%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)
Blinatumomab	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (.%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)
Bosutinib	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (.%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)
Asciminib	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (.%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)
Other TKI	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (.%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)
Inotuzumab ozogamicin (not including InO prescribed as bridge therapy to HPSC o	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (.%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)
Hematopoietic stem cell transplant (HPSC T)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (.%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)
Other	1.00 (4.76%)	0.00 (0.00%)	1.00 (12.50 %)	0.00 (0.00%)	1.00 (12.50 %)	0.00 (0.00%)	1.00 (9.09%)	0.00 (0.00%)	0.00 (.%)	1.00 (9.09%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (7.69%)
None of the above	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (.%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)
Not known	3.00 (14.29 %)	2.00 (22.22 %)	1.00 (12.50 %)	1.00 (12.50 %)	2.00 (25.00 %)	0.00 (0.00%)	2.00 (18.18 %)	0.00 (0.00%)	0.00 (.%)	1.00 (9.09%)	0.00 (0.00%)	1.00 (50.00 %)	0.00 (0.00%)	2.00 (15.38%)

Of the patients who had positive MRD in last cycle of InO, 33.3% were prescribed vincristine in combination with InO at last cycle of InO as a bridge to CAR-T (please see **Table 59** below). Of the patients who had a BMI in the range of 25-30 at index(, 33.3% were prescribed dexamethasone in combination with InO at last cycle of InO as a bridge to CAR-T (please see **Table 59** below).

Table 59: Treatment Prescribed in Combination with InO at Last Cycle of InO as a Bridge to CAR-T

	Overall	MRD status (1st cycle of InO)		MRD status (last cycle of InO)		MRD status (CAR- T infusion)		MRD status (prior to HPSC T)		BMI at index (initiation of InO)			InO received:	
	Total	Positive	Negativ e	Positive	Negativ e	Positive	Negativ e	Positive	Negativ e	(18.5, 25)	(25, 30)	30+	Pre- apheresi s	Post- apheresi s



Treatment in combination with InO treatment														
n	22.00	9.00	9.00	9.00	8.00	8.00	11.00	2.00	0.00	12.00	6.00	2.00	7.00	13.00
Vincristine	5.00 (22.73%)	2.00 (22.22%)	1.00 (11.11%)	3.00 (33.33%)	1.00 (12.50%)	1.00 (12.50%)	1.00 (9.09%)	0.00 (0.00%)	0.00 (.%)	0.00 (0.00%)	4.00 (66.67%)	1.00 (50.00%)	1.00 (14.29%)	2.00 (15.38%)
Dexamethasone	2.00 (9.09%)	1.00 (11.11%)	0.00 (0.00%)	1.00 (11.11%)	0.00 (0.00%)	1.00 (12.50%)	1.00 (9.09%)	0.00 (0.00%)	0.00 (.%)	0.00 (0.00%)	2.00 (33.33%)	0.00 (0.00%)	1.00 (14.29%)	1.00 (7.69%)
Prednisolone	1.00 (4.55%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (11.11%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (.%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (50.00%)	0.00 (0.00%)	0.00 (0.00%)
Methylprednisolone	1.00 (4.55%)	0.00 (0.00%)	1.00 (11.11%)	0.00 (0.00%)	1.00 (12.50%)	0.00 (0.00%)	1.00 (9.09%)	0.00 (0.00%)	0.00 (.%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (7.69%)
Hydrocortisone	2.00 (9.09%)	1.00 (11.11%)	0.00 (0.00%)	1.00 (11.11%)	0.00 (0.00%)	1.00 (12.50%)	1.00 (9.09%)	0.00 (0.00%)	0.00 (.%)	0.00 (0.00%)	2.00 (33.33%)	0.00 (0.00%)	0.00 (0.00%)	2.00 (15.38%)
Doxorubicin	2.00 (9.09%)	1.00 (11.11%)	0.00 (0.00%)	2.00 (22.22%)	0.00 (0.00%)	1.00 (12.50%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (.%)	1.00 (8.33%)	0.00 (0.00%)	1.00 (50.00%)	1.00 (14.29%)	0.00 (0.00%)
Daunorubicin	2.00 (9.09%)	2.00 (22.22%)	0.00 (0.00%)	2.00 (22.22%)	0.00 (0.00%)	1.00 (12.50%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (.%)	0.00 (0.00%)	2.00 (33.33%)	0.00 (0.00%)	0.00 (0.00%)	2.00 (15.38%)
Cyclophosphamide	5.00 (22.73%)	1.00 (11.11%)	2.00 (22.22%)	2.00 (22.22%)	1.00 (12.50%)	0.00 (0.00%)	4.00 (36.36%)	0.00 (0.00%)	0.00 (.%)	3.00 (25.00%)	1.00 (16.67%)	1.00 (50.00%)	3.00 (42.86%)	1.00 (7.69%)
L-asparaginase	1.00 (4.55%)	1.00 (11.11%)	0.00 (0.00%)	1.00 (11.11%)	0.00 (0.00%)	1.00 (12.50%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (.%)	0.00 (0.00%)	1.00 (16.67%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (7.69%)
Methotrexate	2.00 (9.09%)	1.00 (11.11%)	0.00 (0.00%)	1.00 (11.11%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (9.09%)	0.00 (0.00%)	0.00 (.%)	0.00 (0.00%)	2.00 (33.33%)	0.00 (0.00%)	0.00 (0.00%)	2.00 (15.38%)
Cytarabine	3.00 (13.64%)	2.00 (22.22%)	0.00 (0.00%)	2.00 (22.22%)	0.00 (0.00%)	2.00 (25.00%)	1.00 (9.09%)	0.00 (0.00%)	0.00 (.%)	1.00 (8.33%)	2.00 (33.33%)	0.00 (0.00%)	0.00 (0.00%)	3.00 (23.08%)
Etoposide	1.00 (4.55%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (11.11%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (.%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (50.00%)	0.00 (0.00%)	0.00 (0.00%)
Mercaptopurine	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (.%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)
Imatinib	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (.%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)
Dasatinib	1.00 (4.55%)	1.00 (11.11%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (12.50%)	0.00 (0.00%)	1.00 (50.00%)	0.00 (.%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (7.69%)

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Ponatinib	5.00 (22.73%)	1.00 (11.11%)	3.00 (33.33%)	1.00 (11.11%)	3.00 (37.50%)	3.00 (37.50%)	2.00 (18.18%)	1.00 (50.00%)	0.00 (.%)	4.00 (33.33%)	1.00 (16.67%)	0.00 (0.00%)	2.00 (28.57%)	3.00 (23.08%)
Nilotinib	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (.%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)
Rituximab	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (.%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)
Blinatumomab	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (.%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)
Bosutinib	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (.%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)
Asciminib	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (.%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)
Other TKI	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (.%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)
Inotuzumab ozogamicin (not including InO prescribed as bridge therapy to HPSC o	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (.%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)
Hematopoietic stem cell transplant (HPSC T)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (.%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)
Other	3.00 (13.64%)	1.00 (11.11%)	1.00 (11.11%)	1.00 (11.11%)	1.00 (12.50%)	1.00 (12.50%)	2.00 (18.18%)	0.00 (0.00%)	0.00 (.%)	2.00 (16.67%)	1.00 (16.67%)	0.00 (0.00%)	2.00 (28.57%)	1.00 (7.69%)
None of the above	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (.%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)
Not known	2.00 (9.09%)	1.00 (11.11%)	1.00 (11.11%)	1.00 (11.11%)	1.00 (12.50%)	0.00 (0.00%)	2.00 (18.18%)	0.00 (0.00%)	0.00 (.%)	1.00 (8.33%)	0.00 (0.00%)	1.00 (50.00%)	0.00 (0.00%)	2.00 (15.38%)

Overall, n=65 patients (83.3%) received a 30mg dose of ponatinib after first cycle of InO (please see **Table 60** below). 100% of patients who had a negative MRD at last cycle of InO (n=3) received a 30 mg dose of ponatinib after first cycle of InO (please see **Table 60** below).

Table 60: Ponatinib Dose after First Cycle of InO

	Overall	MRD status (1st cycle of InO)	MRD status (last cycle of InO)	MRD status (CAR-T infusion)	MRD status (prior to HPSC T)	BMI at index (initiation of InO)	InO received:
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	Total	Positive	Negative	Positive	Negative	Positive	Negative	Positive	(18.5, 25)	(25, 30)	Pre- apheresis	Post- apheresis
Dose, n (%)												
n	6	2	3	1	3	4	2	2	4	1	2	4
30mg	5 (83.3%)	1 (50.0%)	3 (100.0%)	1 (100.0%)	3 (100.0%)	3 (75.0%)	2 (100.0%)	1 (50.0%)	4 (100.0%)	1 (100.0%)	2 (100.0% el)	3 (75.0%)
45mg	1 (16.7%)	1 (50.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (25.0%)	0 (0.0%)	1 (50.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (25.0%)

Overall, n=6 patients (100%) received a 30mg dose of ponatinib after last cycle of InO (please see **Table 61** below). 100% of patients who had a negative MRD at last cycle of InO (n=4) received a 30mg dose of ponatinib after last cycle of InO (please see **Table 61** below).

Table 61: Ponatinib Dose after Last Cycle of InO

	Overall	MRD status (1st cycle of InO)		MRD status (last cycle of InO)		MRD status (CAR-T infusion)		MRD status (prior to HPSC)	BMI at index (initiation of InO)		InO received:	
	Total	Positive	Negative	Positive	Negative	Positive	Negative	Positive	(18.5, 25)	(25, 30)	Pre- apheresis	Post- apheresis
Dose, n (%)												
n	6	1	4	1	4	3	3	1	5	1	3	3
30mg	6 (100.0%)	1 (100.0%)	4 (100.0%)	1 (100.0%)	4 (100.0%)	3 (100.0%)	3 (100.0%)	1 (100.0%)	5 (100.0%)	1 (100.0%)	3 (100.0%)	3 (100.0%)

Of the patients who had a negative MRD at first cycle of InO, 62.96% had complete remission as the best response to first dose of InO (please see **Table 62** below). Of the patients who had a negative MRD prior to HPSC, 50.0% had complete remission as the best response to first dose of InO (please see **Table 62** below).

Table 62: Patient's Best Response (First Dose)

	Overall	MRD status (1st cycle of InO)	MRD status (last cycle of InO)	MRD status (CAR-T infusion)	MRD status (prior to HPSC)	BMI at index (initiation of InO)	InO received:
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	Total	Positive	Negative	Positive	Negative	Positive	Negative	Positive	Negative	(18.5, 25)	(25, 30)	30+	Pre-apheresis	Post-apheresis
Best Response, n (%)														
n	84	37	27	35	28	26	35	3	6	34	22	15	29	34
Complete remission (CR)	26 (30.95%)	6 (16.22%)	17 (62.96%)	7 (20.00%)	16 (57.14%)	5 (19.23%)	17 (48.57%)	0 (0.00%)	3 (50.00%)	10 (29.41%)	7 (31.82%)	7 (46.67%)	11 (37.93%)	11 (32.35%)
CR with partial hematologic recovery (CRh)	3 (3.57%)	1 (2.70%)	2 (7.41%)	1 (2.86%)	2 (7.14%)	0 (0.00%)	2 (5.71%)	0 (0.00%)	0 (0.00%)	2 (5.88%)	0 (0.00%)	1 (6.67%)	2 (6.90%)	0 (0.00%)
CR with incomplete haematologic recovery (CRI)	7 (8.33%)	3 (8.11%)	3 (11.11%)	3 (8.57%)	3 (10.71%)	2 (7.69%)	3 (8.57%)	0 (0.00%)	0 (0.00%)	3 (8.82%)	2 (9.09%)	1 (6.67%)	3 (10.34%)	2 (5.88%)
Morphologic leukaemia-free state (MLFS)	4 (4.76%)	3 (8.11%)	0 (0.00%)	3 (8.57%)	0 (0.00%)	3 (11.54%)	1 (2.86%)	0 (0.00%)	1 (16.67%)	2 (5.88%)	1 (4.55%)	1 (6.67%)	1 (3.45%)	3 (8.82%)
Refractory disease	23 (27.38%)	17 (45.95%)	0 (0.00%)	14 (40.00%)	1 (3.57%)	10 (38.46%)	4 (11.43%)	2 (66.67%)	1 (16.67%)	8 (23.53%)	6 (27.27%)	3 (20.00%)	4 (13.79%)	10 (29.41%)
Progressive disease (PD)	6 (7.14%)	2 (5.41%)	2 (7.41%)	3 (8.57%)	2 (7.14%)	2 (7.69%)	2 (5.71%)	0 (0.00%)	1 (16.67%)	5 (14.71%)	0 (0.00%)	1 (6.67%)	1 (3.45%)	3 (8.82%)
Relapsed disease	4 (4.76%)	3 (8.11%)	0 (0.00%)	1 (2.86%)	1 (3.57%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (4.55%)	0 (0.00%)	1 (3.45%)	1 (2.94%)
Uncertain response	4 (4.76%)	0 (0.00%)	1 (3.70%)	1 (2.86%)	1 (3.57%)	1 (3.85%)	2 (5.71%)	1 (33.33%)	0 (0.00%)	1 (2.94%)	2 (9.09%)	0 (0.00%)	1 (3.45%)	2 (5.88%)
Not applicable	6 (7.14%)	2 (5.41%)	2 (7.41%)	2 (5.71%)	2 (7.14%)	3 (11.54%)	3 (8.57%)	0 (0.00%)	0 (0.00%)	3 (8.82%)	3 (13.64%)	0 (0.00%)	5 (17.24%)	1 (2.94%)
unknown	1 (1.19%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.67%)	0 (0.00%)	1 (2.94%)
ECOG, n (%)														
n	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Was MRD assessed?, n (%)														



n	84	37	27	35	28	26	35	3	6	34	22	15	29	34
Yes	65 (77.38%)	37 (100.00%)	27 (100.00%)	33 (94.29%)	27 (96.43%)	21 (80.77%)	30 (85.71%)	2 (66.67%)	5 (83.33%)	29 (85.29%)	16 (72.73%)	12 (80.00%)	25 (86.21%)	26 (76.47%)
No	18 (21.43%)	0 (0.00%)	0 (0.00%)	2 (5.71%)	1 (3.57%)	5 (19.23%)	5 (14.29%)	1 (33.33%)	1 (16.67%)	5 (14.71%)	6 (27.27%)	2 (13.33%)	4 (13.79%)	7 (20.59%)
3	1 (1.19%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.67%)	0 (0.00%)	1 (2.94%)
MRD result, n (%)														
n	65	37	27	33	27	21	30	2	5	29	16	12	25	26
Positive	37 (56.92%)	37 (100.00%)	0 (0.00%)	32 (96.97%)	2 (7.41%)	19 (90.48%)	7 (23.33%)	2 (100.00%)	2 (40.00%)	15 (51.72%)	10 (62.50%)	6 (50.00%)	11 (44.00%)	15 (57.69%)
Negative	27 (41.54%)	0 (0.00%)	27 (100.00%)	1 (3.03%)	25 (92.59%)	2 (9.52%)	22 (73.33%)	0 (0.00%)	3 (60.00%)	14 (48.28%)	6 (37.50%)	5 (41.67%)	14 (56.00%)	10 (38.46%)
Not known/Not recorded	1 (1.54%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (8.33%)	0 (0.00%)	1 (3.85%)

Of the patients who had negative MRD at last cycle of InO, 64.3% had complete remission as the best response at last dose of InO (please see **Table 63** below). Of the patients who had a negative MRD status at CAR-T infusion, 51.4% had complete remission as the best response at last dose of InO (please see **Table 63** below).

Table 63: Patient's best response (last dose)

	Overall	MRD status (1st cycle of InO)		MRD status (last cycle of InO)		MRD status (CAR-T infusion)		MRD status (prior to HPSCt)		BMI at index (initiation of InO)			InO received:	
	Total	Positive	Negative	Positive	Negative	Positive	Negative	Positive	Negative	(18.5, 25)	(25, 30)	30+	Pre-apheresis	Post-apheresis
Best Response, n (%)														
n	84	37	27	35	28	26	35	3	6	34	22	15	29	34
Complete remission (CR)	29 (34.52%)	8 (21.62%)	16 (59.26%)	7 (20.00%)	18 (64.29%)	5 (19.23%)	18 (51.43%)	0 (0.00%)	3 (50.00%)	9 (26.47%)	9 (40.91%)	7 (46.67%)	12 (41.38%)	11 (32.35%)
CR with partial hematologic	5 (5.95%)	3 (8.11%)	2 (7.41%)	3 (8.57%)	2 (7.14%)	2 (7.69%)	2 (5.71%)	0 (0.00%)	0 (0.00%)	4 (11.76%)	0 (0.00%)	1 (6.67%)	4 (13.79%)	0 (0.00%)



recovery (CRh)														
CR with incomplete haematologic recovery (CRi)	5 (5.95%)	2 (5.41%)	3 (11.11%)	2 (5.71%)	3 (10.71%)	2 (7.69%)	3 (8.57%)	0 (0.00%)	0 (0.00%)	2 (5.88%)	2 (9.09%)	1 (6.67%)	3 (10.34%)	2 (5.88%)
Morphologic leukaemia-free state (MLFS)	4 (4.76%)	3 (8.11%)	0 (0.00%)	3 (8.57%)	0 (0.00%)	3 (11.54%)	1 (2.86%)	0 (0.00%)	1 (16.67%)	2 (5.88%)	1 (4.55%)	1 (6.67%)	1 (3.45%)	3 (8.82%)
Refractory disease	22 (26.19%)	15 (40.54%)	0 (0.00%)	13 (37.14%)	0 (0.00%)	10 (38.46%)	4 (11.43%)	2 (6.67%)	1 (16.67%)	7 (20.59%)	6 (27.27%)	3 (20.00%)	4 (13.79%)	10 (29.41%)
Progressive disease (PD)	8 (9.52%)	3 (8.11%)	3 (11.11%)	5 (14.29%)	2 (7.14%)	2 (7.69%)	2 (5.71%)	0 (0.00%)	1 (16.67%)	6 (17.65%)	0 (0.00%)	1 (6.67%)	1 (3.45%)	3 (8.82%)
Relapsed disease	3 (3.57%)	2 (5.41%)	0 (0.00%)	2 (5.71%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.94%)	1 (4.55%)	0 (0.00%)	0 (0.00%)	1 (2.94%)
Uncertain response	3 (3.57%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.57%)	1 (3.85%)	2 (5.71%)	1 (33.33%)	0 (0.00%)	1 (2.94%)	2 (9.09%)	0 (0.00%)	1 (3.45%)	2 (5.88%)
Not applicable	3 (3.57%)	0 (0.00%)	3 (11.11%)	0 (0.00%)	2 (7.14%)	1 (3.85%)	2 (5.71%)	0 (0.00%)	0 (0.00%)	2 (5.88%)	1 (4.55%)	0 (0.00%)	2 (6.90%)	1 (2.94%)
unknown	1 (1.19%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.67%)	0 (0.00%)	1 (2.94%)
Not known/Not recorded	1 (1.19%)	1 (2.70%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.45%)	0 (0.00%)
ECOG, n (%)														
n	84	37	27	35	28	26	35	3	6	34	22	15	29	34
0: Fully active, able to carry on all pre-disease performance without restriction	29 (34.52%)	9 (24.32%)	14 (51.85%)	9 (25.71%)	14 (50.00%)	4 (15.38%)	18 (51.43%)	0 (0.00%)	2 (33.33%)	15 (44.12%)	5 (22.73%)	6 (40.00%)	10 (34.48%)	13 (38.24%)
1: Restricted in physically strenuous activity but	35 (41.67%)	18 (48.65%)	9 (33.33%)	18 (51.43%)	9 (32.14%)	13 (50.00%)	12 (34.29%)	1 (33.33%)	3 (50.00%)	13 (38.24%)	12 (54.55%)	7 (46.67%)	15 (51.72%)	10 (29.41%)

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ambulatory and able to carry out light work														
2: Ambulatory and capable of all self-care but unable to carry out work activities. Up and about GT 50% of waking hours	9 (10.71%)	5 (13.51%)	2 (7.41%)	5 (14.29%)	3 (10.71%)	4 (15.38%)	3 (8.57%)	0 (0.00%)	0 (0.00%)	4 (11.76%)	4 (18.18%)	1 (6.67%)	2 (6.90%)	6 (17.65%)
3: Capable of only limited self-care, confined to bed or chair GT 50% of waking hours	1 (1.19%)	0 (0.00%)	1 (3.70%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Not assessed	10 (11.90%)	5 (13.51%)	1 (3.70%)	2 (5.71%)	2 (7.14%)	5 (19.23%)	2 (5.71%)	2 (6.67%)	1 (16.67%)	2 (5.88%)	1 (4.55%)	1 (6.67%)	2 (6.90%)	5 (14.71%)
Was MRD assessed?, n (%)														
n	84	37	27	35	28	26	35	3	6	34	22	15	29	34
Yes	65 (77.38%)	35 (94.59%)	26 (96.30%)	35 (100.00%)	28 (100.00%)	20 (76.92%)	30 (85.71%)	0 (0.00%)	6 (100.00%)	29 (85.29%)	16 (72.73%)	14 (93.33%)	26 (89.66%)	24 (70.59%)
No	18 (21.43%)	2 (5.41%)	1 (3.70%)	0 (0.00%)	0 (0.00%)	6 (23.08%)	5 (14.29%)	3 (100.00%)	0 (0.00%)	5 (14.71%)	6 (27.27%)	0 (0.00%)	3 (10.34%)	9 (26.47%)
3	1 (1.19%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.67%)	0 (0.00%)	1 (2.94%)
MRD result, n (%)														
n	65	35	26	35	28	20	30	0	6	29	16	14	26	24



Positive	35 (53.85%)	32 (91.43%)	1 (3.85%)	35 (100.00%)	0 (0.00%)	18 (90.00%)	5 (16.67%)	0 (.%)	3 (50.00%)	15 (51.72%)	9 (56.25%)	8 (57.14%)	10 (38.46%)	13 (54.17%)
Negative	28 (43.08%)	2 (5.71%)	25 (96.15%)	0 (0.00%)	28 (100.00%)	2 (10.00%)	23 (76.67%)	0 (.%)	3 (50.00%)	14 (48.28%)	7 (43.75%)	5 (35.71%)	15 (57.69%)	10 (41.67%)
Not known/Not recorded	2 (3.08%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (6.67%)	0 (.%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.14%)	1 (3.85%)	1 (4.17%)

Of the patients who had a negative MRD at last cycle of InO, 68.0% had complete remission as the best response to CAR-T treatment after 1 month (please see **Table 64** below). Of the patients who received InO post-apheresis, 73.5% had complete remission as the best response to CAR-T treatment after 1 month (please see **Table 64** below).

Table 64: Patient's Best Response to CAR-T (after 1 Month)

	Overall	MRD status (1st cycle of InO)		MRD status (last cycle of InO)		MRD status (CAR-T infusion)		MRD status (prior to HPST)		BMI at index (initiation of InO)			InO received:	
	Total	Positive	Negative	Positive	Negative	Positive	Negative	Positive	Negative	(18.5, 25)	(25, 30)	30+	Pre-apheresis	Post-apheresis
Best Response to CAR-T treatment, n (%)														
n	64.00	27.00	24.00	24.00	25.00	26.00	35.00	3.00	6.00	27.00	20.00	12.00	29.00	34.00
Complete remission (CR)	44.00 (68.75%)	20.00 (74.07%)	15.00 (62.50%)	17.00 (70.83%)	17.00 (68.00%)	22.00 (84.62%)	21.00 (60.00%)	3.00 (100.00%)	5.00 (83.33%)	16.00 (59.26%)	14.00 (70.00%)	9.00 (75.00%)	18.00 (62.07%)	25.00 (73.53%)
CR with partial hematologic recovery (CRh)	3.00 (4.69%)	2.00 (7.41%)	1.00 (4.17%)	2.00 (8.33%)	1.00 (4.00%)	1.00 (3.85%)	2.00 (5.71%)	0.00 (0.00%)	0.00 (0.00%)	2.00 (7.41%)	0.00 (0.00%)	1.00 (8.33%)	3.00 (10.34%)	0.00 (0.00%)
CR with incomplete haematologic recovery (CRI)	6.00 (9.38%)	2.00 (7.41%)	4.00 (16.67%)	2.00 (8.33%)	3.00 (12.00%)	0.00 (0.00%)	6.00 (17.14%)	0.00 (0.00%)	0.00 (0.00%)	4.00 (14.81%)	2.00 (10.00%)	0.00 (0.00%)	4.00 (13.79%)	2.00 (5.88%)
Morphologic leukaemia-	3.00 (4.69%)	1.00 (3.70%)	0.00 (0.00%)	1.00 (4.17%)	0.00 (0.00%)	1.00 (3.85%)	1.00 (2.86%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (3.70%)	2.00 (10.00%)	0.00 (0.00%)	0.00 (0.00%)	3.00 (8.82%)



free state (MLFS)														
Aplastic marrow	2.00 (3.12%)	0.00 (0.00%)	2.00 (8.33%)	0.00 (0.00%)	2.00 (8.00%)	0.00 (0.00%)	2.00 (5.71%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (3.70%)	0.00 (0.00%)	1.00 (8.33%)	0.00 (0.00%)	2.00 (5.88%)
Refractory disease	1.00 (1.56%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (2.86%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (5.00%)	0.00 (0.00%)	1.00 (3.45%)	0.00 (0.00%)
Progressive disease (PD)	1.00 (1.56%)	1.00 (3.70%)	0.00 (0.00%)	1.00 (4.17%)	0.00 (0.00%)	1.00 (3.85%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (8.33%)	1.00 (3.45%)	0.00 (0.00%)
Uncertain response	1.00 (1.56%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (3.70%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (2.94%)
Not applicable	2.00 (3.12%)	1.00 (3.70%)	1.00 (4.17%)	1.00 (4.17%)	1.00 (4.00%)	1.00 (3.85%)	1.00 (2.86%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (3.70%)	1.00 (5.00%)	0.00 (0.00%)	1.00 (3.45%)	1.00 (2.94%)
Not known	1.00 (1.56%)	0.00 (0.00%)	1.00 (4.17%)	0.00 (0.00%)	1.00 (4.00%)	0.00 (0.00%)	1.00 (2.86%)	0.00 (0.00%)	1.00 (16.67%)	1.00 (3.70%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (3.45%)	0.00 (0.00%)

Of the patients who had a positive MRD at CAR-T infusion, 76.9% had complete remission as the best response to CAR-T treatment after 3 months (please see **Table 65** below). Of the patients who received InO post-apheresis, 76.5% had complete remission as the best response to CAR-T treatment after 3 months (please see **Table 65** below).

Table 65: Patient's Best Response to CAR-T (after 3 Months)

	Overall	MRD status (1st cycle of InO)		MRD status (last cycle of InO)		MRD status (CAR-T infusion)		MRD status (prior to HPSCt)		BMI at index (initiation of InO)			InO received:	
	Total	Positive	Negative	Positive	Negative	Positive	Negative	Positive	Negative	(18.5, 25)	(25, 30)	30+	Pre-apheresis	Post-apheresis
Best Response to CAR-T treatment, n (%)														
n	64.00	27.00	24.00	24.00	25.00	26.00	35.00	3.00	6.00	27.00	20.00	12.00	29.00	34.00
Complete remission (CR)	44.00 (68.75%)	20.00 (74.07%)	15.00 (62.50%)	17.00 (70.83%)	17.00 (68.00%)	20.00 (76.92%)	22.00 (62.86%)	2.00 (66.67%)	5.00 (83.33%)	17.00 (62.96%)	14.00 (70.00%)	8.00 (66.67%)	17.00 (58.62%)	26.00 (76.47%)
CR with partial hematologic	2.00 (3.12%)	1.00 (3.70%)	1.00 (4.17%)	1.00 (4.17%)	1.00 (4.00%)	1.00 (3.85%)	1.00 (2.86%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (3.70%)	0.00 (0.00%)	1.00 (8.33%)	2.00 (6.90%)	0.00 (0.00%)



recovery (CRh)														
CR with incomplete haematologic recovery (CRi)	4.00 (6.25%)	1.00 (3.70%)	3.00 (12.50%)	1.00 (4.17%)	2.00 (8.00%)	0.00 (0.00%)	4.00 (11.43%)	0.00 (0.00%)	0.00 (0.00%)	3.00 (11.11%)	1.00 (5.00%)	0.00 (0.00%)	2.00 (6.90%)	2.00 (5.88%)
Morphologic leukaemia-free state (MLFS)	1.00 (1.56%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (2.86%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (5.00%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (2.94%)
Aplastic marrow	1.00 (1.56%)	0.00 (0.00%)	1.00 (4.17%)	0.00 (0.00%)	1.00 (4.00%)	0.00 (0.00%)	1.00 (2.86%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (3.70%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (2.94%)
Refractory disease	2.00 (3.12%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (2.86%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (3.70%)	1.00 (5.00%)	0.00 (0.00%)	1.00 (3.45%)	1.00 (2.94%)
Progressive disease (PD)	3.00 (4.69%)	1.00 (3.70%)	1.00 (4.17%)	1.00 (4.17%)	1.00 (4.00%)	1.00 (3.85%)	2.00 (5.71%)	1.00 (33.33%)	0.00 (0.00%)	1.00 (3.70%)	2.00 (10.00%)	0.00 (0.00%)	2.00 (6.90%)	1.00 (2.94%)
Relapsed disease	3.00 (4.69%)	1.00 (3.70%)	2.00 (8.33%)	1.00 (4.17%)	2.00 (8.00%)	1.00 (3.85%)	2.00 (5.71%)	0.00 (0.00%)	1.00 (16.67%)	2.00 (7.41%)	0.00 (0.00%)	1.00 (8.33%)	2.00 (6.90%)	1.00 (2.94%)
Not applicable	4.00 (6.25%)	3.00 (11.11%)	1.00 (4.17%)	3.00 (12.50%)	1.00 (4.00%)	3.00 (11.54%)	1.00 (2.86%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (3.70%)	1.00 (5.00%)	2.00 (16.67%)	3.00 (10.34%)	1.00 (2.94%)

Of the patients who had a BMI in the range 18.5-25 at index, 59.3% had complete remission as the best response to CAR-T treatment after 6 months (please see **Table 66** below). Of the patients who received InO pre-apheresis, 55.2% had complete remission as the best response to CAR-T treatment after 6 months (please see **Table 66** below).

Table 66: Patient's best response to CAR-T (after 6 months)

	Overall	MRD status (1st cycle of InO)		MRD status (last cycle of InO)		MRD status (CAR-T infusion)		MRD status (prior to HPSCt)		BMI at index (initiation of InO)			InO received:	
	Total	Positive	Negative	Positive	Negative	Positive	Negative	Positive	Negative	(18.5, 25)	(25, 30)	30+	Pre-apheresis	Post-apheresis
Best Response to CAR-T treatment, n (%)														
n	64.00	27.00	24.00	24.00	25.00	26.00	35.00	3.00	6.00	27.00	20.00	12.00	29.00	34.00

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Complete remission (CR)	29.00 (45.31%)	12.00 (44.44%)	11.00 (45.83%)	11.00 (45.83%)	12.00 (48.00%)	12.00 (46.15%)	15.00 (42.86%)	1.00 (33.33%)	3.00 (50.00%)	16.00 (59.26%)	7.00 (35.00%)	4.00 (33.33%)	16.00 (55.17%)	13.00 (38.24%)
CR with incomplete haematologic recovery (CRi)	1.00 (1.56%)	0.00 (0.00%)	1.00 (4.17%)	0.00 (0.00%)	1.00 (4.00%)	0.00 (0.00%)	1.00 (2.86%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (3.70%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (2.94%)
Aplastic marrow	1.00 (1.56%)	0.00 (0.00%)	1.00 (4.17%)	0.00 (0.00%)	1.00 (4.00%)	0.00 (0.00%)	1.00 (2.86%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (3.70%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (2.94%)
Refractory disease	1.00 (1.56%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (3.70%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (2.94%)
Progressive disease (PD)	2.00 (3.12%)	2.00 (7.41%)	0.00 (0.00%)	1.00 (4.17%)	0.00 (0.00%)	0.00 (0.00%)	2.00 (5.71%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (3.70%)	0.00 (0.00%)	0.00 (0.00%)	2.00 (6.90%)	0.00 (0.00%)
Relapsed disease	6.00 (9.38%)	2.00 (7.41%)	3.00 (12.50%)	2.00 (8.33%)	3.00 (12.00%)	2.00 (7.69%)	4.00 (11.43%)	0.00 (0.00%)	1.00 (16.67%)	1.00 (3.70%)	3.00 (15.00%)	2.00 (16.67%)	3.00 (10.34%)	3.00 (8.82%)
Uncertain response	2.00 (3.12%)	1.00 (3.70%)	0.00 (0.00%)	1.00 (4.17%)	0.00 (0.00%)	0.00 (0.00%)	2.00 (5.71%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (5.00%)	1.00 (8.33%)	0.00 (0.00%)	2.00 (5.88%)
Not applicable	21.00 (32.81%)	10.00 (37.04%)	8.00 (33.33%)	9.00 (37.50%)	8.00 (32.00%)	11.00 (42.31%)	10.00 (28.57%)	1.00 (33.33%)	2.00 (33.33%)	6.00 (22.22%)	8.00 (40.00%)	5.00 (41.67%)	8.00 (27.59%)	12.00 (35.29%)
Not known	1.00 (1.56%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (3.85%)	0.00 (0.00%)	1.00 (33.33%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (5.00%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (2.94%)

Of the patients who had a BMI at index of (18.5,25), 25.9% had complete remission as the best response to CAR-T treatment after 12 months (please see **Table 67** below). Of the patients who had a negative MRD at last cycle of InO, 20.0% had complete remission as the best response to CAR-T treatment after 12 months (please see **Table 67** below).

Table 67: Patient's Best response to CAR-T (after 12 Months)

	Overall	MRD status (1st cycle of InO)		MRD status (last cycle of InO)		MRD status (CAR-T infusion)		MRD status (prior to HPSCt)		BMI at index (initiation of InO)			InO received:	
	Total	Positive	Negative	Positive	Negative	Positive	Negative	Positive	Negative	(18.5, 25)	(25, 30)	30+	Pre-apheresis	Post-apheresis
Best Response to CAR-T treatment, n (%)														



n	64.00	27.00	24.00	24.00	25.00	26.00	35.00	3.00	6.00	27.00	20.00	12.00	29.00	34.00
Complete remission (CR)	14.00 (21.88%)	5.00 (18.52%)	4.00 (16.67%)	5.00 (20.83%)	5.00 (20.00%)	5.00 (19.23%)	7.00 (20.00%)	0.00 (0.00%)	1.00 (16.67%)	7.00 (25.93%)	4.00 (20.00%)	2.00 (16.67%)	6.00 (20.69%)	8.00 (23.53%)
Aplastic marrow	1.00 (1.56%)	0.00 (0.00%)	1.00 (4.17%)	0.00 (0.00%)	1.00 (4.00%)	0.00 (0.00%)	1.00 (2.86%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (3.70%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (2.94%)
Refractory disease	1.00 (1.56%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (3.70%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (2.94%)
Progressive disease (PD)	4.00 (6.25%)	1.00 (3.70%)	3.00 (12.50%)	1.00 (4.17%)	3.00 (12.00%)	0.00 (0.00%)	4.00 (11.43%)	0.00 (0.00%)	0.00 (0.00%)	3.00 (11.11%)	0.00 (0.00%)	1.00 (8.33%)	3.00 (10.34%)	1.00 (2.94%)
Relapsed disease	3.00 (4.69%)	2.00 (7.41%)	1.00 (4.17%)	2.00 (8.33%)	1.00 (4.00%)	1.00 (3.85%)	2.00 (5.71%)	0.00 (0.00%)	0.00 (0.00%)	2.00 (7.41%)	1.00 (5.00%)	0.00 (0.00%)	2.00 (6.90%)	1.00 (2.94%)
Uncertain response	1.00 (1.56%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (2.86%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (8.33%)	0.00 (0.00%)	1.00 (2.94%)
Not applicable	38.00 (59.38%)	18.00 (66.67%)	15.00 (62.50%)	16.00 (66.67%)	15.00 (60.00%)	19.00 (73.08%)	19.00 (54.29%)	2.00 (66.67%)	5.00 (83.33%)	13.00 (48.15%)	14.00 (70.00%)	8.00 (66.67%)	17.00 (58.62%)	20.00 (58.82%)
Not known	2.00 (3.12%)	1.00 (3.70%)	0.00 (0.00%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (3.85%)	1.00 (2.86%)	1.00 (33.33%)	0.00 (0.00%)	0.00 (0.00%)	1.00 (5.00%)	0.00 (0.00%)	1.00 (3.45%)	1.00 (2.94%)

Of the patients who had a negative MRD status prior to HPSCT, 83.3% had 1 salvage treatment line at index (please see **Table 68** below). Of the patients who received InO post-apheresis, 32.3% had 2 salvage treatment lines at index (please see **Table 68** below).

Table 68: Salvage Treatment Line at Index

	Overall	Total	MRD status (1st cycle of InO)		MRD status (last cycle of InO)		MRD status (CAR-T infusion)		MRD status (prior to HPSCT)		BMI at index (initiation of InO)			InO received:	
	Total	Total	Positive	Negative	Positive	Negative	Positive	Negative	Positive	Negative	(18.5, 25)	(25, 30)	30+	Pre-apheresis	Post-apheresis
Salvage treatment line at index, n (%)															
n	84	84	37	27	35	28	26	35	3	6	34	22	15	29	34
1	51 (60.71%)	51 (60.71%)	18 (48.65%)	19 (70.37%)	20 (57.14%)	18 (64.29%)	16 (61.54%)	18 (51.43%)	2 (66.67%)	5 (83.33%)	17 (50.00%)	15 (68.18%)	10 (66.67%)	16 (55.17%)	19 (55.88%)



2	21 (25.00 %)	21 (25.00 %)	12 (32.43 %)	5 (18.52 %)	10 (28.57 %)	6 (21.43 %)	7 (26.92 %)	10 (28.57 %)	0 (0.00%)	1 (16.67 %)	12 (35.29 %)	4 (18.18 %)	3 (20.00 %)	7 (24.14%)	11 (32.35%)
3	10 (11.90 %)	10 (11.90 %)	6 (16.22 %)	2 (7.41%)	4 (11.43 %)	3 (10.71 %)	2 (7.69%)	6 (17.14 %)	1 (33.33 %)	0 (0.00%)	3 (8.82%)	3 (13.64 %)	2 (13.33 %)	5 (17.24%)	3 (8.82%)
4+	2 (2.38%)	2 (2.38%)	1 (2.70%)	1 (3.70%)	1 (2.86%)	1 (3.57%)	1 (3.85%)	1 (2.86%)	0 (0.00%)	0 (0.00%)	2 (5.88%)	0 (0.00%)	0 (0.00%)	1 (3.45%)	1 (2.94%)
Cumulative dose of InO over all cycles															
n	74	74	32	24	31	25	23	30	2	6	30	20	12	25	30
Mean	2.13	2.13	2.13	2.18	2.07	2.24	1.72	2.26	1.15	1.88	1.95	1.74	2.06	2.30	1.68
Standard deviation	1.37	1.37	1.44	1.12	1.37	1.01	0.91	1.30	0.21	0.74	1.15	0.80	1.08	1.02	1.24
Standard error of the mean	0.16	0.16	0.25	0.23	0.25	0.20	0.19	0.24	0.15	0.30	0.21	0.18	0.31	0.20	0.23
Median	1.80	1.80	1.80	1.80	1.80	1.80	1.30	1.80	1.15	1.80	1.80	1.80	1.80	1.80	1.30
Interquartile Range (IQR)	1.30 - 2.50	1.30 - 2.50	1.30 - 2.80	1.80 - 1.80	1.30 - 2.80	1.80 - 2.50	1.30 - 1.80	1.80 - 2.50	1.00 - 1.30	1.30 - 1.80	1.30 - 2.10	1.30 - 1.80	1.15 - 3.05	1.80 - 2.80	1.00 - 1.80
Range	0.50 - 7.20	0.50 - 7.20	0.50 - 6.30	0.50 - 6.00	0.50 - 6.30	0.50 - 5.10	0.50 - 4.00	0.50 - 6.30	1.00 - 1.30	1.30 - 3.30	0.50 - 6.30	0.50 - 3.70	0.80 - 4.00	0.50 - 5.60	0.50 - 6.30
95% CI	1.81 - 2.44	1.81 - 2.44	1.61 - 2.65	1.71 - 2.65	1.57 - 2.58	1.82 - 2.66	1.33 - 2.12	1.77 - 2.74	-0.76 - 3.06	1.11 - 2.66	1.52 - 2.38	1.37 - 2.11	1.37 - 2.75	1.88 - 2.72	1.22 - 2.14
Cumulative dose of InO over cycle 1															
n	74	74	32	24	31	25	23	30	2	6	30	20	12	25	30
Mean	1.68	1.68	1.64	1.90	1.64	1.91	1.48	1.80	0.90	1.63	1.59	1.58	1.62	1.66	1.57
Standard deviation	0.78	0.78	0.74	0.77	0.75	0.66	0.69	0.81	0.14	0.26	0.71	0.68	0.84	0.47	0.97
Standard error of the mean	0.09	0.09	0.13	0.16	0.13	0.13	0.14	0.15	0.10	0.11	0.13	0.15	0.24	0.09	0.18
Median	1.80	1.80	1.80	1.80	1.80	1.80	1.30	1.80	0.90	1.80	1.80	1.80	1.55	1.80	1.30
Interquartile Range (IQR)	1.30 - 1.80	1.30 - 1.80	1.30 - 1.80	1.80 - 1.80	1.30 - 1.80	1.80 - 1.80	1.00 - 1.80	1.80 - 1.80	0.80 - 1.00	1.30 - 1.80	1.30 - 1.80	1.15 - 1.80	1.10 - 1.80	1.80 - 1.80	0.90 - 1.80
Range	0.50 - 4.00	0.50 - 4.00	0.50 - 3.70	0.50 - 4.00	0.50 - 3.70	0.50 - 4.00	0.50 - 4.00	0.50 - 3.70	0.80 - 1.00	1.30 - 1.80	0.50 - 3.60	0.50 - 3.70	0.80 - 4.00	0.50 - 2.80	0.50 - 4.00
95% CI	1.50 - 1.86	1.50 - 1.86	1.37 - 1.90	1.57 - 2.23	1.36 - 1.91	1.64 - 2.18	1.19 - 1.78	1.50 - 2.10	-0.37 - 2.17	1.36 - 1.90	1.33 - 1.85	1.27 - 1.90	1.09 - 2.16	1.47 - 1.86	1.21 - 1.94

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Cumulative dose of InO over cycle 2															
n	19	19	9	5	8	6	5	7	1	1	7	3	4	11	1
Mean	1.47	1.47	1.46	1.60	1.36	1.63	1.10	1.53	0.50	1.50	1.11	1.53	1.30	1.43	0.50
Standard deviation	0.65	0.65	0.81	0.69	0.64	0.50	0.42	0.65	.	.	0.40	0.25	0.24	0.55	.
Standard error of the mean	0.15	0.15	0.27	0.31	0.23	0.20	0.19	0.25	.	.	0.15	0.15	0.12	0.17	.
Median	1.50	1.50	1.50	1.50	1.35	1.50	1.00	1.50	0.50	1.50	1.00	1.50	1.35	1.50	0.50
Interquartile Range (IQR)	1.00 - 1.80	1.00 - 1.80	1.00 - 1.80	1.50 - 1.50	1.00 - 1.50	1.50 - 1.80	1.00 - 1.50	1.00 - 1.80	0.50 - 0.50	1.50 - 1.50	0.80 - 1.50	1.30 - 1.80	1.10 - 1.50	1.00 - 1.50	0.50 - 0.50
Range	0.50 - 2.80	0.50 - 2.80	0.50 - 2.80	0.80 - 2.70	0.50 - 2.70	1.00 - 2.50	0.50 - 1.50	0.80 - 2.80	0.50 - 0.50	1.50 - 1.50	0.50 - 1.50	1.30 - 1.80	1.00 - 1.50	0.80 - 2.80	0.50 - 0.50
95% CI	1.15 - 1.78	1.15 - 1.78	0.83 - 2.08	0.75 - 2.45	0.83 - 1.90	1.11 - 2.15	0.58 - 1.62	0.93 - 2.13	..	..	0.75 - 1.48	0.91 - 2.16	0.91 - 1.69	1.06 - 1.80	..
Cumulative dose of InO over cycle 3															
n	2	2	0	1	0	0	0	1	0	0	1	0	0	1	0
Mean	1.05	1.05		0.30				0.30			0.30			0.30	
Standard deviation	1.06	1.06		.				.			.			.	
Standard error of the mean	0.75	0.75	.	.	.	.	.	.	.	.	.	.	.	.	.
Median	1.05	1.05	.	0.30	.	.	.	0.30	.	.	0.30	.	.	0.30	.
Interquartile Range (IQR)	0.30 - 1.80	0.30 - 1.80	..	0.30 - 0.30	..	..	..	0.30 - 0.30	..	..	0.30 - 0.30	..	..	0.30 - 0.30	..
Range	0.30 - 1.80	0.30 - 1.80		0.30 - 0.30				0.30 - 0.30			0.30 - 0.30			0.30 - 0.30	
95% CI	-8.48 - 10.58	-8.48 - 10.58	..	..	..	..	..	..	..	..	..	..	..	..	..
Cumulative dose of InO over cycle 4															
n	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0
Mean	1.80	1.80													
Standard deviation	.	.													



Standard error of the mean	.	.	.	.	.	.	.	.	.	.	.	.	.	.	.
Median	1.80	1.80	.	.	.	.	.	.	.	.	.	.	.	.	.
Interquartile Range (IQR)	1.80 - 1.80	1.80 - 1.80	..	..	..	..	..	..	..	..	..	..	..	..	..
Range	1.80 - 1.80	1.80 - 1.80													
95% CI	..	..	..	..	..	..	..	..	..	..	..	..	..	..	..
Days between last dose of InO and leukapheresis															
n	62	62	25	24	23	25	25	34	2	6	26	20	12	28	33
Mean	-11.13	-11.13	-4.48	-5.04	-9.00	-1.96	-18.64	5.50	-16.00	14.17	4.85	-3.10	-60.67	17.43	-35.45
Standard deviation	61.85	61.85	39.39	47.79	36.81	49.23	33.63	41.54	8.49	33.10	33.77	37.29	112.50	40.61	67.64
Standard error of the mean	7.85	7.85	7.88	9.76	7.67	9.85	6.73	7.12	6.00	13.51	6.62	8.34	32.48	7.68	11.77
Median	-10.50	-10.50	-11.00	-7.50	-11.00	-7.00	-12.00	2.50	-16.00	3.00	-7.00	-9.00	-17.50	19.00	-19.00
Interquartile Range (IQR)	-20.00 - 14.00	-20.00 - 14.00	-22.00 - 14.00	-20.50 - 23.00	-22.00 - -1.00	-20.00 - 24.00	-20.00 - -8.00	-19.00 - 29.00	-22.00 - -10.00	-12.00 - 52.00	-14.00 - 22.00	-22.00 - 17.50	-70.50 - -11.50	-7.50 - 38.00	-26.00 - -11.00
Range	-383.00 - 113.00	-383.00 - 113.00	-82.00 - 113.00	-139.00 - 60.00	-82.00 - 113.00	-139.00 - 71.00	-139.00 - 33.00	-121.00 - 113.00	-22.00 - -10.00	-17.00 - 56.00	-50.00 - 113.00	-82.00 - 71.00	-383.00 - 29.00	-121.00 - 113.00	-383.00 - -1.00
95% CI	-26.83 - 4.58	-26.83 - 4.58	-20.74 - 11.78	-25.22 - 15.14	-24.92 - 6.92	-22.28 - 18.36	-32.52 - -4.76	-8.99 - 19.99	-92.24 - 60.24	-20.57 - 48.91	-8.80 - 18.49	-20.55 - 14.35	-132.15 - 10.81	1.68 - 33.18	-59.44 - -11.47

10.6. Adverse Events/Adverse Reactions

As this study design was a non-interventional, retrospective chart review study (without any comparator group), involving human review of patient-level unstructured data; unstructured data refers to verbatim medical data, including text-based descriptions and visual depictions of medical information, such as medical records, images of physician notes, neurological scans, x-rays, or narrative fields in electronic health care records, it is not feasible to make a causality assessment at the individual case level. Please see the protocol Section 11 'Management and Reporting of Adverse Events/Adverse Reactions' for further information regarding Adverse events/adverse reactions.

The prespecified AE of interest in this study was VOD and data was collected in the EDC. VOD was reported in n=10/84 (i.e. 11.9%) of the overall study sample. VOD was diagnosed in 7.1% of patients at any point during their ALL treatment; a further 4.8% had suspected VOD. As per the CT-24 document we have included those where either "VOD confirmed" or "VOD suspected". In addition, Pfizer confirmed that five AE reports were sent to Pfizer pharmacovigilance, of which two were serious AEs.

11. DISCUSSION

11.1. Key Results

Due to the current paucity and lack of conclusive data demonstrating the use and outcomes of anti-CD22 antibody therapy i.e. InO prior to or as a bridging therapy to CAR-T in ALL adult patients, particularly in the real-world setting, Pfizer conducted a non-interventional, retrospective chart review study (without any comparator group) to understand and describe the patient demographics, treatment patterns and clinical outcomes associated with InO when used as a bridging therapy prior to CD19 directed CAR-T cell treatment.

Overall, of the 84 patients analyzed the median (IQR) age was 40.0 (24.0, 59.0) years, 78.6% were White and 57.1% were male (see Table 9). These proportions align with reported B-ALL incidence profiles from registries (Centre for International Blood and Marrow Transplant Research (CIBMTR) median age 43 years, 50% white and 52% male) (15) and real-world studies (Aristides *et al.*, 55.2% age group 30-59 years, 87.8% white and 50.4% male (16) ; Wudhikarn *et al.*, median age 45.3 and male 58.6%). (17) This alignment demonstrates the relevance and generalizability of the study sample to the broader European and US population of R/R B-ALL.

At index, 14.3% of patients were Ph positive, 44.0% were Ph negative, 6.0% were Ph-like and 25.0% of patients had other cytogenetic abnormalities (see Table 11). These findings are in line with those reported by recent real-world InO studies in Spain (28.8% Ph positive) and Italy (21.9% Ph positive) (18, 19). In this study, most patients (73.2%) had relapsed disease and 25.5% were refractory. Interestingly, the Spanish InO study reported better OS for patients with relapsed B-ALL versus refractory disease (10.4 vs. 2.5 months, respectively) (18). Median (IQR) BMB count at index was 62.5% (n=48) (18.0%, 89.5%) (see Table 12). Median (IQR) BMB count after last dose of InO was 2.0% (n=47) (0.0%, 41.0%), and 66.0% (n=47) patients had a BMB <5% (see Table 13). Lower BMB count has been associated with better outcomes e.g. higher CR rates and longer remission durations, better long-term survival and less toxicity, as reported by the INO-VATE trial (20) and CAR-T real-world data CIBMTR (21) and ZUMA-3(22).

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All patients received at least 1 cycle of InO prior to CAR-T, 21.4% received 2 cycles and 3.6% received ≥ 3 cycles. Other European and US real-world InO studies have reported the majority of R/R B-ALL patients as receiving 1 to 2 cycles (19, 23, 24). This study reported that InO dosing was in line with the recommended InO dosage schedule (25). At index, 38.1% of patients were in salvage treatment line 1, 36.9% were in salvage treatment line 2 and 19.0% were in salvage treatment line 3. In the INO-VATE trial, 73% of patients had a CR/CRi rate with the standard treatment arm after cycle 1 for R/R B-ALL whilst the response rate for InO was significantly higher at 80.7%. The CR/CRi rate for the InO arm was higher at 80.7% compared to the standard of care (29.4%) after cycle 1 (20).

VOD is a major adverse event associated with InO therapy. In this study, the incidence of VOD at any point during ALL treatment was comparable to that reported in the INOVATE trial; 7.1% versus 11%, respectively (3). In addition, in this study, the most severe grade of VOD was grade 1 (mild). Further studies systematically evaluating InO safety are warranted to better define the balance between efficacy and toxicity in patients with R/R B-ALL. In this study, upon InO completion more than a third of patients (40.5%) achieved CR/CRi after the last cycle of bridging InO which was lower compared to the INO-VATE trial (3). However, other real-world InO studies reported lower rates such as 61% (12), 73.9% (19) and 77% (27).

MRD negativity is associated with better outcomes e.g. improved survival and increased likelihood of remaining relapse-free (28). In the INO-VATE trial, amongst responders the MRD negativity rate was 78.4% for the InO recipients vs 28.1% in the standard chemotherapy arm (26), this is greater than what is reported in this study, where of those assessed (n=65), 41.5% tested negative for MRD after their first and 43.1% after their last cycle of InO. In the INO-VATE study, the between-group difference was significant for all tested baseline characteristics such as disease burden, degree of CD22 expression on peripheral blasts (above or below 90%), and cytogenetics with the exception of having translocation of 4;11 (26). These improvements were present whether InO was given as a first or second salvage therapy (26) and highlight the efficacy of InO compared to the standard treatment. The German GMALL-Initial1 study investigated InO as a combination therapy for newly diagnosed older adults, where (n=31/42) 74% of patients tested negative for MRD after the 2nd and 3rd induction cycles respectively which was nearly two times greater compared to in this study (29). Similarly, in the DeAngelo *et al.*, study MRD was negative for a high proportion of patients with CR/CRi (n=41/49, 84%). The MRD negativity from this study was more in-line with real-world studies, such as the INO-CD22 study which reported MRD negativity for 57.8% of InO patients (19) and the Macroni *et al.*, study, where MRD negativity was seen in (n=7/20), 35% of patients (30).

In this study, 46.4% of patients were diagnosed with neutropenic sepsis at any time, which was much higher compared to the INO-VATE trial where only 1.8% of patients treated with InO experienced neutropenic sepsis (3). However, this study was not specific to InO treatment as it was at any point during ALL treatment. Importantly, a real-world study treating PH-ALL patients, found that 60.0% of patients experienced at least one infectious episode (31), which was higher than that reported in this current study.

Leukapheresis was performed successfully on all patients (n=84) in this study. This suggested that significant T-cell depletion or dysfunction did not occur after InO before CAR-T and leukapheresis after InO treatment was feasible. Despite the high initial response rate, the majority of adult patients with B-ALL progress after CD19 CAR-T therapy. B-ALL

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progression after CD19 CAR-T therapy carries poor prognosis and remains an unmet clinical need (34).. In this study, the majority of patients received CAR-T (84.5%), with the remainder receiving another therapy or going into palliative care. Overall, 76.7% (n=56/73) of patients achieved CR/CRh/CRi after CAR-T or another therapy, which was greater than the 46.5% upon InO completion. A further 6.8% had refractory disease, which had reduced from 26.2% at InO completion, which suggests that InO may be used effectively prior to CAR-T. CAR-T treatment details were available for 64 patients. CR was maintained for 68.8% of patients until six months after CAR-T which was greater than the ZUMA-3 trial (CR 56%) and similar to other trials and real-world reports of 70-80% CR/Cri post CAR-T treatment (15, 35). In addition, this study administering InO as a bridge to CAR-T showed comparable CR to a study reporting CR as 58.3% after blina and/or InO administered following post-CAR T failure. B-cell recovery is associated with increased risk of ALL relapse after CAR-T (36). In this study, after CAR-T infusion, 35.9% of patients had B-cell recovery, suggesting that CAR-T was maintained for the majority of patients. At 12 months after CAR-T infusion, an estimated 72.5% patients survived and 62.4% had not initiated another salvage therapy. Median OS was not reached. The OS in this study was greater than some other real-world studies reporting 35% and 68% OS after CAR-T for relapsed B-ALL (11, 37).

Overall, despite larger comparative studies being required to determine optimal strategies before CAR-T, this study adds to the scientific literature surrounding InO and CAR-T. .

11.2. Limitations

- As subgroup numbers were low, comparisons were not viable and so were not included in this report. However, as this was purely a descriptive study with no statistical comparisons, the assessment of treatment patterns and effectiveness outcomes were not affected by small sample sizes.
- As there is limited InO prior to CAR-T use, data was collected from centres with indication where it was used as such, but it was not checked with every centre in each country therefore the sample is reflective only of the centres from which data was collected.
- InO treatment regimens and dosing schedules may have differed by country, adding to the complexity of the assessment of effectiveness outcomes. Subgroup analyses could be conducted for subsets of patients receiving the same or similar treatment regimens and/or dosage schedules.
- The short follow-up period, which made the sample viable, adversely affected the likelihood that OS median point would be reached, as was observed.
- For the chart review, selection bias may have arisen. Site participation was influenced by willingness to take part, and may have been based on workload, levels of consulting patients during the data collection period, or familiarity with the research nature of the study. Efforts were made to seek waivers for informed consent to prevent the requirement for consent from being a biasing factor, eg, patients who were particularly severe may have been unwilling/unable to consent which may have biased the living sample of patients towards those with a more

positive prognosis. These efforts were successful and waivers of consent were secured in all countries.

- This retrospective chart review did not include source data verification, which may introduce the potential for inaccuracies or incomplete data. Missing data from the eCRF was a potential limitation that was considered in this study. Some variables included in the eCRF were not present within a patient's medical record and so could not have been extracted into the eCRF. To mitigate this limitation, the standardised eCRF underwent a thorough review process prior to implementation which helped ensure that the content was appropriate for the listed research objectives and could reasonably be expected to be captured within patients' medical notes. Furthermore, the eCRF was designed in such a way that incomplete variables were flagged and eCRFs were not able to be locked until all variables had been completed. Despite these mitigations, it was expected that there would be an embargo on data from CAR-T infusion onwards for a proportion of patients (up to approximately 50%) in Spain due to an ongoing clinical trial, which prevented data on CAR-T treatment patterns or post-CAR-T outcomes from being assessed. Nonetheless, given the paucity of data for patients receiving InO as bridging therapy to CAR-T, these patients were included given this limitation did not impact on the primary objective of the study.

11.3. Interpretation

Generally, the introduction of InO into treatment regimens for R/R B-ALL has shown favourable outcomes compared to standard of care chemotherapy. Clinical trials have shown improved remission rates and OS when using InO as a therapy to transition/bridge to SCT. The results of this real-world study adds to the scientific literature surrounding InO and CAR-T. Leukapheresis after InO treatment was feasible, with meaningful 12-month post-CAR-T OS, and the incidence of VOD at any time was low. The treatment outcomes and low AE occurrence highlight the importance of InO use in this setting.

11.4. Generalizability

The population presented within the report included patients that had a clinical diagnosis of R/R B-ALL, aged ≥ 18 years at index and received InO to facilitate CD19-directed CAR-T (even if CAR-T was not administered) (see section 9.3 Subjects for the inclusion / exclusion criteria). The inclusion / exclusion criteria reflect the current marketing authorization for InO. Therefore, the population included in this study is likely to reflect most patients for whom InO would be prescribed. Furthermore, as there is limited InO prior to CAR-T use, data was collected from centres with indication where it was used as such, but it was not checked with every centre in each country therefore the sample is reflective only of the centres from which data was collected. As the patient data originated from multiple countries, sites and settings and sample sizes varied between those, the generalizability of the results to individual country markets is lacking and cross-country comparisons cannot be made.

12. OTHER INFORMATION

Not Applicable.



13. CONCLUSIONS

Most patients who received InO prior to CAR-T successfully received treatment, achieving CR after CAR-T. Leukapheresis after InO treatment was feasible, with meaningful 12-month post-CAR-T OS, and the incidence of VOD at any time was low. While larger, comparative studies are required to determine optimal strategies before CAR-T, this study suggests that InO may be used effectively prior to CAR-T.

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15. LIST OF SOURCE TABLES AND FIGURES

Not Applicable

Appendix 1. SIGNATURES

Appendix 2. PROTOCOL

Please refer to the separate final protocol document titled 'B1931044_NON-INTERVENTIONAL STUDY PROTOCOL _V2_09May2025'.

Appendix 3. INVESTIGATORS AND CORRESPONDING INDEPENDENT ETHICS COMMITTEES (IECs) OR INSTITUTIONAL REVIEW BOARDS (IRBs)

Appendix 3.1 List of Investigators by Country

Lead Investigator(s) from Sites

Name, degree(s)	Title	Affiliation
Dr Núria Martínez Cibrián, MD Dr Valentín Ortiz. MD	Principal Investigator	Hospital Clinic de Barcelona
Dr Mi Kwon, MD	Principal Investigator	Hospital Gregorio Marañón
Dr Pere Barba Suñol, MD	Principal Investigator	Hospital Vall d'Hebron
Dr Cristina Blázquez Goñi, MD	Principal Investigator	Hospital Virgen del Rocío
Dr Mónica Cabrero Calvo, MD	Principal Investigator	Hospita de Salamanca
Dr Lindsay George, MD	Principal Investigator	Birmingham
Dr Anna Castleton, MD	Principal Investigator	Manchester (The Christie)
Dr Emma Nicholson, MD	Principal Investigator	The Royal Marsden
Dr Deborah Richardson, MD	Principal Investigator	Southampton
Dr Marc Schwartz, MD	Principal Investigator	Colorado
Dr Ryan Cassaday, MD	Principal Investigator	Seattle
Dr Guru Murthy, MD	Principal Investigator	Wisconsin

Appendix 3.2 List of Independent Ethics Committee (IEC) or Institutional Review Board (IRB) and Corresponding Protocol Approval Dates

IEC	PI	Date of Approval
Health Research Authority/Research Ethics Committee	Dr Anna Castleton, MD	10 th September 2024
Comité Ético de Investigación con medicamentos del Hospital Clínic de Barcelona	Núria Martínez Cibrián, MD	30 th September 2024
Colorado Multiple Institutional Review Board	Dr Marc Schwartz, MD	21 st January 2025
WCG IRB	Dr Ryan Cassaday, MD	6 th February 2025
Medical College of Wisconsin IRB	Dr Guru Murthy, MD	13 th November 2024

Appendix 4. STATISTICAL ANALYSIS PLAN

Please refer to the separate final SAP document titled 'SAP_B1931044_v2.0_28Oct25'.

Appendix 5. SAMPLE CASE REPORT FORM (CRF)

Please refer to the separate final CRF document titled 'PI9724 eCRF v7.0 Clean Final 14Jun24'.

Appendix 6. SAMPLE STANDARD SUBJECT INFORMATION SHEET AND INFORMED CONSENT DOCUMENT (ICD)

Not applicable.

Appendix 7. LIST OF SUBJECT DATA LISTINGS

Not applicable.

Appendix 8. ADDITIONAL DOCUMENTS

Not applicable.

Document Approval Record

Document Name:

B1931044_PI9724 INO-TRANSIT Non-interventional Study Report_v1.
0_23Apr26

Document Title:

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0_23Apr26

Signed By:

Date(GMT)

Signing Capacity

Redacted

29-May-2026 16:45:15

Manager Approval

Redacted

05-Jun-2026 12:53:32

EUQPPV Approval