INOtuzumab Treatment Retrospective Analysis for Navigating tranSITion 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) (INO-TRANSIT)

First published: 24/05/2024

Last updated: 24/10/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000118

Study ID

1000000118

DARWIN EU® study

No

Study countries

- ☐ Spain
- ☐ United Kingdom
- ☐ United States

Study description

The study will be an international site-led (approximately 13 sites) retrospective observational chart review, assessing the characteristics and clinical outcomes of R/R ALL patients who received InO as a bridging therapy to CAR-T. Sites will be based in the US, UK, and Spain. This non-interventional study is designated as a Post-Authorization Safety Study (PASS) and is conducted voluntarily by Pfizer.

Study status

Ongoing

Research institutions and networks

Institutions

Adelphi Real World

☐ United Kingdom

First published: 22/07/2016

Last updated: 06/03/2024

Institution | Non-Pharmaceutical company | ENCePP partner

Pfizer

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

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Study contact

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Primary lead investigator

Alexander Russell-Smith

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 22/08/2023

Actual: 22/08/2023

Study start date

Planned: 01/07/2024

Actual: 16/12/2024

Date of final study report
Planned: 14/11/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer Inc

Study protocol

B1931044 Non Interventional Study Protocol v1.0_11Apr24_Redacted.pdf (16.09 MB)

B1931044_NON-INTERVENTONAL STUDY PROTOCOL _V2_09May2025_Redacted.pdf (3.32 MB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Other study registration identification numbers and links

Pfizer study number B1931044

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Other

If ‘other’, further details on the scope of the study

Describe the demographics and clinical characteristics of R/R ALL patients treated with InO as a bridging therapy for CAR-T

Data collection methods:

Secondary use of data

Study design:

The study will be an international site-led (approximately 13 sites) retrospective observational chart review, assessing the characteristics and clinical outcomes of R/R ALL patients who received InO as a bridging therapy to CAR-T. Sites will be based in the US, UK, and Spain.

Main study objective:

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

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

BESPONSA

Study drug International non-proprietary name (INN) or common name

INOTUZUMAB OZOGAMICIN

Anatomical Therapeutic Chemical (ATC) code

(L01FX06) dinutuximab beta

dinutuximab beta

Medical condition to be studied

Acute lymphocytic leukaemia

Population studied

Short description of the study population

1. Patient has a clinical diagnosis of R/R (precursor B-cell) ALL

2. Patient is 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 (is 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 are 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 are eligible for inclusion within the study. Permitted exceptions to the minimum 3-month follow-up requirement include:

a. Patients who die within the 3 months

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

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Age groups

- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
  - Elderly (≥ 65 years)
    - Adults (65 to < 75 years)
    - Adults (75 to < 85 years)
    - Adults (85 years and over)

Estimated number of subjects

66

Study design details

Setting

R/R 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) will be identified within the sites based in UK, US and Spain, using the inclusion and exclusion criteria.

The indexing period should allow for a large proportion of patients treated with InO prior to CAR-T at these sites to be gathered, following US Food and Drug Administration (FDA) and European Medicines Agency (EMA) approval of InO in 2017, and CAR-T approval from 2017. No formal sampling will be conducted in any country. Sites selected for chart review methodology will complete data collection for all eligible patients.

Potential sites participating in the retrospective chart review will be invited to complete a short feasibility questionnaire prior to site selection. The feasibility questionnaire will be 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 will also be assessed. A number of sites across the three countries have already been assessed to provisionally confirm feasibility.

Following completion of the feasibility phase of the study and the subsequent set-up activities for selected sites, eCRFs will be completed by clinicians and site staff at the sites for patients meeting the inclusion/exclusion criteria.

Outcomes

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 objectives

• To describe relevant treatment effectiveness outcomes for the study

population, including response to treatment, time-to-next salvage treatment and survival.
• To describe InO treatment patterns in the study population, including the use of InO in combination or monotherapy, timing of treatment and dosage information.

Data analysis plan

The study is not intended to test hypotheses and is primarily descriptive in nature, therefore descriptive analysis will be conducted to meet the majority of the pre-specified objectives.
Frequencies and percentages will be 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 will be reported for continuous numeric variables. Where applicable, all estimates will be described with accompanying 95% confidence intervals (CI). Outcomes such as OS will be assessed via time to event analyses, with Kaplan-Meier (KM) curves and 95% CI estimated for KM curves outputted. This will be calculated using variables in the CRF. For example, OS will be calculated from the first dose of InO to point of death. Censoring will be applied if the patient is alive at the point of data capture.
Data analysis will be aligned with data extracted/collected from all data sets. Where specific variables or outcomes cannot be assessed/described subgroup analyses could be conducted for a subset of patients from certain data sources. All analyses will be conducted using Stata 17 software, version 17 or the latest available version (StataCorp, College Station, Texas).
Detailed methodology for summary and statistical analyses of data collected in this study will be documented in a statistical analysis plan (SAP), which will be dated, filed, and maintained by the sponsor. The SAP may modify the plans outlined in the protocol; any major modifications of primary endpoint definitions

or their analyses would be reflected in a protocol amendment.

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data source(s)

Other data source

Data source(s), other

Data will be collected/extracted from sites based in the UK, US and Spain.
The study will involve the abstraction of data from patients' medical charts by healthcare professionals involved in the care of the participants into a secure eCRF.
Sites will be asked to provide eCRFs for all patients which they have access to who meet the inclusion criteria. Sites will be instructed to refer to the patients' complete medical record whilst completing the eCRF and not to answer any question from memory or that is not listed within the patients' medical records.

Data sources (types)

Other

Data sources (types), other

Data will be collected/extracted from sites based in the UK, US and Spain. The study will involve the abstraction of data from patients' medical charts by healthcare professionals involved in the care of the patients into a secure eCRF. Sites will be asked to provide eCRFs for all patients which they have access to who meet the inclusion criteria. Sites will be instructed to refer to the patients' complete medical record whilst completing the eCRF and not to answer any question from memory or that is not listed within the patients' medical records.

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No