NON-INTERVENTIONAL STUDY REPORT ABSTRACT

Title: A Non-Interventional Post-Authorization Safety Study (PASS) of Inotuzumab Ozogamicin to Characterize Complications Post-Hematopoietic Stem Cell Transplantation (HSCT) Following Inotuzumab Ozogamicin Treatment in Adult and Pediatric Patients with B-Cell Precursor Acute Lymphoblastic Leukemia (ALL).

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Keywords: Inotuzumab ozogamicin; post-HSCT toxicities; veno-occlusive disease/sinusoidal obstruction syndrome (VOD/SOS); transplant-related mortality (TRM) or non-relapse mortality; non-transplant-related mortality (NTRM).

Rationale and background: Inotuzumab ozogamicin is an antibody-drug conjugate (ADC) composed of a cluster of differentiation 22 (CD22)-directed monoclonal antibody that is covalently linked to N-acetyl-gamma-calicheamicin dimethylhydrazide. In the United States (US), inotuzumab ozogamicin was approved by the Food and Drug Administration (FDA) on 17 August 2017 for the treatment of adults with relapsed or refractory B-cell precursor ALL. In clinical trials, inotuzumab ozogamicin has been associated with severe, life-threatening, and potentially fatal adverse events, including hepatotoxicity and hepatic veno-occlusive disease/sinusoidal obstruction syndrome (VOD/SOS). In pivotal study B1931022, inotuzumab ozogamicin was associated with the occurrence of VOD/SOS, particularly following HSCT. Among the 79 patients in the study treated with inotuzumab ozogamicin who proceeded to a subsequent HSCT, 18/79 patients (23%) developed VOD/SOS post-HSCT, compared to 3/34 patients (9%) in the treating physicians' choice of chemotherapy arm.

The following post-marketing requirement (PMR 3259-1) was agreed with the US FDA:

> *"Characterize toxicity after HSCT in adult and pediatric patients who receive inotuzumab ozogamicin. Include hepatic VOD, TRM (non-relapse mortality), and NTRM. Conduct an analysis of registry data (for example the CIBMTR registry) to evaluate safety at least through day 180 after transplantation. The number of available patients in the database will determine the sample size. Include details of all prior therapies. The minimum duration of the study is to be no less than five years."*

This non-interventional study was conducted to fulfill this PMR and is designated as a PASS.

Research question and objectives: Objectives: Based on collected data obtained from the Center for International Blood and Marrow Transplant Research® (CIBMTR®) Research Database, the following were evaluated in adult and pediatric patients with B-cell ALL who received inotuzumab ozogamicin and proceeded to HSCT:

- Patient-, disease- and HSCT-related characteristics, including details of all prior anti-cancer therapies;
- Timing of inotuzumab ozogamicin treatment prior to HSCT;
- TRM or non-relapse mortality; NTRM; relapse; and overall survival (OS);
- Post-HSCT adverse events of interest, including hepatic VOD/SOS;
- Cause of death.

Study design: This secondary data collection non-interventional PASS uses de-identified healthcare data from the CIBMTR database. This retrospective study evaluated safety outcomes post-HSCT in patients with B-cell precursor ALL who have been treated with inotuzumab ozogamicin prior to HSCT. The study utilized all relevant data available in the CIBMTR database from US transplant centers for a 5-year period following the approval of inotuzumab ozogamicin in the US (i.e., 18 August 2017 – 17 August 2022).

Setting: The data source is the CIBMTR Research Database. CIBMTR is a collaboration between the National Marrow Donor Program (NMDP)/Be The Match and the Medical College of Wisconsin (MCW). CIBMTR facilitates critical observational and interventional research through scientific and statistical expertise, a large network of transplant centers, and a unique and extensive clinical outcomes database. CIBMTR is also mandated by the US Health Resources and Services Administration (HRSA) to collect data from all patients who underwent allogeneic HSCT in the US.

The CIBMTR receives data for approximately 26,000 new HSCT recipients annually, as well as follow-up data on previously reported patients. In 2014-2016, a total of 2,506 US patients with B-cell ALL (1,984 adults [age ≥ 18 years] and 522 pediatric patients [age < 18 at the time of HSCT]), underwent their first allogeneic HSCT and provided consent to CIBMTR for research.

The CIBMTR collects data on two levels, using a Transplant Essential Data (TED) form and a Comprehensive Report Form (CRF). The TED data set is an internationally accepted standard data set that contains a limited number of key variables for all consecutive HSCT recipients. The CRF captures additional patient-, disease-, and treatment-related data in a subset of patients. (i.e., the CRF does not include data from all patients in the registry).

Subjects and study size, including dropouts: The study population included all adult and pediatric US patients with B-cell ALL treated with inotuzumab ozogamicin who proceeded to HSCT and whose data were available in the CIBMTR database. Data from pediatric

patients was included in accordance with the agreement reached during negotiation of the PMR with the FDA.

Data from all available adult (age ≥ 18) and pediatric (age < 18 years at the time of HSCT) US patients with B-cell ALL in the CIBMTR database who were treated with inotuzumab ozogamicin and who underwent allogeneic HSCT during the accrual period were included in the present analysis.

Variables and data sources: There was no hypothesis testing in this study. All statistical analyses were descriptive. Data from all patients who proceeded to HSCT were obtained using routine CIBMTR data collection forms, as well as an additional form to specifically collect inotuzumab ozogamicin exposure data.

Data are presented for adult and pediatric patients, separately and combined.

Patients who received a prior allogeneic HSCT for B-cell ALL are presented separately from those patients who underwent their first allogeneic HSCT for B-cell ALL, because the underlying disease, risk for relapse and post-HSCT complications are different for patients with a prior allogeneic HSCT for B-cell ALL than for patients who underwent their first allogeneic HSCT for B-cell ALL.

Results: This is the final study report containing cumulative data from 18 August 2017 – 17 August 2022 (5 years), as requested by the FDA.

Overall patients included in analyses
A total of 5,891 B-cell ALL patients underwent an allogeneic HSCT transplant in the US between 18 August 2017 and 17 August 2022. Out of those 5,891 patients, 577 patients were excluded from this study as they had not consented to research, 131 patients were excluded from embargoed centers, and 2,669 patients were excluded as they belonged to centers not participating in the study. Of the remaining 2,514 patients, 371 received at least one dose of inotuzumab ozogamicin.

Between 18 August 2017 and 17 August 2022, 371 patients (304 adult and 67 pediatric) were accrued and included in the study. The data lock date for this final report, when data collection forms were last evaluated, was 17 August 2022.

Of the 371 patients included in the study, 319 patients (261 adult and 58 pediatric) underwent their first allogeneic HSCT for B-cell ALL; and 52 patients (43 adult and 9 pediatric) had received a prior allogeneic HSCT for B-cell ALL before receiving inotuzumab ozogamicin.

Most patients whose B-cell ALL relapses post first allogeneic HSCT do not proceed to a second. Patients who proceed for a 2nd allogeneic HSCT are extremely carefully selected.

The 52 patients who had a prior allogeneic HSCT for B-cell ALL before receiving inotuzumab ozogamicin are described separately since the underlying disease, patient-related factors, risk of relapse, and post-HSCT complications are different for patients with a prior HSCT than for patients who underwent their first allogeneic HSCT for B-cell ALL.

Patients who underwent their first allogeneic HSCT for B-cell ALL
In total, 319 patients (261 adults and 58 pediatric patients, with a median age of 32 years) underwent their first allogeneic HSCT for B-cell ALL after treatment with inotuzumab ozogamicin. Among the 319 patients (261 adults and 58 pediatric patients) who underwent first allogeneic HSCT for B-cell ALL, 137 patients (43%) had Sorror HCT-CI score ≥ 3 prior to HSCT.

Lines of therapy prior to transplant were:

- 9 (3%) patients had 1 line of therapy: 8 (3%) adult, 1 (2%) pediatric;
- 66 (21%) patients had 2 lines of therapy: 57 (22%) adult, 9 (16%) pediatric;
- 63 (20%) patients had 3 lines of therapy: 59 (23%) adult, 4 (7%) pediatric; and
- 144 (45%) patients had 4 or more lines of therapy: 114 (44%) adult, 30 (52%) pediatric.
- Data were not available for 37 patients.

As of the data lock date, post-HSCT follow-up information was available for 296 / 319 (93%) patients: 244 (93%) adult, 52 (90%) pediatric:

- 182 / 296 (61%) patients did not experience post-HSCT relapse: 151 (62%) adult, 31 (60%) pediatric; of these:
    - 56 / 182 (31%) patients (50 [33%] adult and 6 [19%] pediatric) died in remission within 18 months, with a median time from transplant to TRM of 2.23 months; primary causes of death were:
        - VOD/SOS – 15 (27%) patients: 13 (26%) adult, 2 (33%) pediatric
        - Graft-versus-host disease (GVHD) – 12 (21%) patients: 11 (22%) adult, 1 (17%) pediatric
        - Organ failure – 11 (20%) patients: 10 (20%) adult, 1 (17%) pediatric
        - Hemorrhage – 3 (5%) patients: 3 (6%) adult, 0 pediatric
        - Interstitial pneumonitis – 4 (7%) patients: 4 (8%) adult, 0 pediatric
        - Infection – 6 (11%) patients: 5 (10%) adult, 1 (17%) pediatric
        - Septic shock – 2 (4%) patients: 2 (4%) adult, 0 pediatric
        - Thrombotic microangiopathy – 1 (2%) patient: 0 adult, 1 (17%) pediatric

- Graft failure – 1 (2%) patient: 1 (2%) adult, 0 pediatric
- Other – 1 (2%) patient: 1 (2%) adult, 0 pediatric

- 114 / 296 (39%) patients experienced post-HSCT relapse: 93 (38%) adult, 21 (40%) pediatric; of these:
  - 56 / 114 (49%) patients died after post-HSCT relapse of B-cell ALL within 18 months, with a median time from transplant to NTRM of 6.92 months: 49 (53%) adult, 7 (33%) pediatric.

- 51 / 296 (17%) patients (35 (14%) adult, 16 (31%) pediatric) experienced post-transplant VOD/SOS; of these:
  - 23 (45%) cases were mild: 15 (43%) adult, 8 (50%) pediatric
  - 28 (55%) cases were severe: 20 (57%) adult, 8 (50%) pediatric
  - 3 (6%) patients did not receive liver toxicity prophylaxis: 2 (6%) adult, 1 (6%) pediatric
  - 29 (57%) patients died after reporting VOD with a median follow-up of 1.34 months after VOD: 22 (63%) adult, 7 (44%) pediatric.
    - 16 out of the 29 (55%) patients had VOD as cause of death and had a median follow-up of 1.36 months after VOD: 14 (64%) adult, 2 (29%) pediatric.
      - 1 out of the 16 (6%) patients with reported VOD as cause of death had not received liver toxicity prophylaxis: 1 (7%) adult.
  - Other causes of death were:
    - Recurrence of B-cell ALL – 5 (17%) patients: 3 (14%) adult patients died 0.3, 2.9, and 7.2 months after VOD, 2 (29%) pediatric patients died 0.3 and 1.5 months after VOD,
    - GVHD – 3 (10%) patients: 2 (9%) adult patients died after 0.3 and 1.8 months after VOD, 1 pediatric (14%) died after 29.9 months,
    - Organ failure – 3 (10%) patients: 2 (9%) adult patients died after 1.1 and 1.3 months after VOD; 1 (14%) pediatric patient died 0.1 months after VOD,
    - Septic shock– 1 (3%) patient: 1 (5%) adult patient died 0.5 months after VOD,

- Infection – 1 (3%) patient: 1 (14%) pediatric patient died 2.0 months after VOD.

Liver toxicity prophylaxis:

- 20 / 296 (7%) patients did not receive liver toxicity prophylaxis: 14 (6%) adult and 6 (12%) pediatric
- 217 / 296 (73%) patients received liver toxicity prophylaxis with ursodiol alone: 198 (81%) adult and 19 (37%) pediatric
- 42 / 296 (14%) patients received liver toxicity prophylaxis with ursodiol and defibrotide: 20 (8%) adult and 22 (42%) pediatric
- 9 / 296 (3%) patients received liver toxicity prophylaxis with ursodiol and other drugs (not specified): 6 (2%) adult and 3 (6%) pediatric
- 3 / 296 (1%) patients received liver toxicity prophylaxis with defibrotide alone: 2 (1%) adult and 1 (2%) pediatric
- 5 / 296 (2%) patients did not have data reported for liver toxicity prophylaxis: 4 (2%) adult and 1 (2%) pediatric

The summary table below shows the incidence of VOD/SOS, post-transplant VOD/SOS mortality, transplant-related mortality (TRM), and relapse in adult patients without a prior HSCT in this non-interventional study.

Patients without a prior HSCT: Summary of VOD/SOS incidence, post-transplant VOD/SOS mortality, overall survival, transplant-related mortality and relapse, up to 18 months

	Day 100 incidence VOD/SOS[a]	Post-HSCT VOD/SOS mortality[b]	6-mo OS[c]	12-mo OS[c]	18-mo OS	6-mo TRM[d]	12-mo TRM[d]	18-mo TRM	6-mo relapse[e]	12-mo relapse[e]	18-mo relapse[e]
All adult patients n=261[f]	14%	36%	75%	61%	54%	17%	20%	22%	23%	33%	40%
Adult R/R n= 166[g]	18%	40%	70%	56%	50%	20%	23%	25%	23%	34%	40%
All pediatric patients n = 52 [h]	31%	63%	85%	71%	NE	8%	NE	NE	24%	NE	NE
Pediatric R/R n = 43 [i]	30%	54%	81%	68%	NE	9%	NE	NE	21%	NE	NE

Abbreviations: ALL, acute lymphoblastic leukemia; HSCT, hematopoietic stem cell transplantation; OS, overall survival; R/R, relapsed or refractory; TRM, transplant-related mortality; VOD/SOS, veno-occlusive disease / sinusoidal obstruction syndrome.

Patients without a prior HSCT: Summary of VOD/SOS incidence, post-transplant VOD/SOS mortality, overall survival, transplant-related mortality and relapse, up to 18 months

	Day 100 incidence VOD/SOS[a]	Post-HSCT VOD/SOS mortality[b]	6-mo OS[c]	12-mo OS[c]	18-mo OS	6-mo TRM[d]	12-mo TRM[d]	18-mo TRM	6-mo relapse[e]	12-mo relapse[e]	18-mo relapse[e]

[a] VOD/SOS cumulative incidence estimate at 100 days following HSCT. Death without VOD/SOS was treated as a competing risk. Surviving patients without VOD/SOS were censored on the date of last follow-up, if applicable.
[b] Mortality cumulative incidence estimate at 18 months following post-transplant VOD/SOS. Caution must be exercised in assessing unadjusted mortality rates. There were n=35 adults who experienced post-transplant VOD/SOS and n=27 adults with R/R B-cell ALL who experienced post-transplant VOD/SOS.
[c] OS Kaplan-Meier estimate at 6 months, 12 months, and 18 months following HSCT. Surviving patients were censored on the date of last follow-up.
[d] TRM cumulative incidence estimate at 6 months, 12 months, and 18 months following HSCT. Post-HSCT relapse was treated as a competing risk. Surviving patients without post-HSCT relapse were censored on the date of last follow-up, if applicable.
[e] Relapse cumulative incidence estimate at 6 months, 12 months, and 18 months following HSCT. TRM was treated as a competing risk. Surviving patients without post-HSCT relapse were censored on the date of last follow-up, if applicable.
[f] Follow-up information available for 244 / 261 adult patients.
[g] Follow-up information available for 156 / 166 adult R/R patients.
[h] Follow-up information available for 52 / 58 pediatric patients.
[i] Follow-up information available for 43 / 48 pediatric R/R patients.

Post-transplant follow-up information was available for 296/319 (93%) patients who underwent their first allogeneic HSCT for B-cell ALL. Of these 296 patients, post-transplant VOD/SOS occurred in 51 patients (17%; 35 adult, 16 pediatric). Twenty-nine (57%; 22 adult, 7 pediatric) of the 51 patients (35 adult, 16 pediatric) who developed post-transplant VOD/SOS died within 18 months post-transplant; 13 patients (49%) had a primary cause of death that was not VOD/SOS (n=5 recurrence of B-cell ALL, n=3 acute GVHD, n=3 organ failure, n=1 septic shock, n=1 infection).

Of the 296 patients with post-transplant follow-up information available, 112 patient deaths occurred within the first 18 months post-transplant, with TRM occurring in 56 patients.

In an adjusted analysis of 18-month outcomes of 204 adult patients with at least 12 months of follow-up, disease status, namely advanced disease stage, age and donor type were negative prognostic factors for 18 months overall survival. Karnofsky performance score and conditioning regimen intensity (dual alkylators) were negative prognostic factors for 18 months TRM. Only choice of conditioning regimen (dual alkylators), and not cumulative inotuzumab exposure, was a negative prognostic factor of day-100 VOD incidence.

Patients who underwent second, or greater HSCT for B-cell ALL

As of the data lock date, post-HSCT follow-up information was available for all patients (43 adult, 9 pediatric). The table below includes adult patients only, as sample size for pediatric population is too small for evaluation.

Adults with a prior HSCT: Summary of VOD/SOS incidence, post-transplant VOD/SOS mortality, overall survival, non-relapse mortality and relapse, up to 18 months

	Day 100 incidence VOD/SOS[a]	Post-HSCT VOD/SOS mortality[b]	6-mo OS[c]	12-mo OS[c]	18-mo OS	6-mo TRM[d]	12-mo TRM[d]	18-mo TRM	6-mo relapse[e]	12-mo relapse[e]	18-mo relapse[e]
All adult patients n=43	21%	75%	73%	NE	NE	20%	27%	NE	5%	8%	NE
Adult R/R n= 41	22%	75%	74%	NE	NE	21%	28%	NE	3%	3%	NE

Abbreviations: ALL, acute lymphoblastic leukemia; HSCT, hematopoietic stem cell transplantation; OS, overall survival; R/R, relapsed or refractory; TRM, transplant-related mortality; VOD/SOS, veno-occlusive disease / sinusoidal obstruction syndrome.

[a] VOD/SOS cumulative incidence estimate at 100 days following HSCT. Death without VOD/SOS was treated as a competing risk. Surviving patients without VOD/SOS were censored on the date of last follow-up, if applicable.

[b] Mortality cumulative incidence estimate at 18 months following post-transplant VOD/SOS. Caution must be exercised in assessing unadjusted mortality rates. There were n=35 adults who experienced post-transplant VOD/SOS and n=27 adults with R/R B-cell ALL who experienced post-transplant VOD/SOS.

[c] OS Kaplan-Meier estimate at 6 months, 12 months, and 18 months following HSCT. Surviving patients were censored on the date of last follow-up.

[d] TRM cumulative incidence estimate at 6 months, 12 months, and 18 months following HSCT. Post-HSCT relapse was treated as a competing risk. Surviving patients without post-HSCT relapse were censored on the date of last follow-up, if applicable.

[e] Relapse cumulative incidence estimate at 6 months, 12 months, and 18 months following HSCT. TRM was treated as a competing risk. Surviving patients without post-HSCT relapse were censored on the date of last follow-up, if applicable.

Among the 52 patients (43 adult, 9 pediatric) who had a prior allogeneic HSCT for B-cell ALL before receiving inotuzumab ozogamicin, 27 patients (52%) had Sorror HCT-CI scores ≥ 3 prior to HSCT, and 16 patients (31%) had mild hepatic disease prior to HSCT. Fifty (50) patients (96%) underwent HSCT for relapsed or refractory disease and for another 2 patients (4%), disease status prior to transplant was not reported. Out of 52 patients, 9 patients (18%) had a history of proven invasive fungal infection.

Nine (9) of the 52 patients who had a prior allogeneic HSCT before receiving inotuzumab ozogamicin (17%) had received a bone marrow product, 7 patients (13%) received a cord blood product, and the remaining 36 patients (69%) received peripheral blood stem cells. Thirty-four (34) patients (65%) received their product from an unrelated donor, 4 patients (8%) had an HLA-identical sibling donor, and the remaining 14 patients (27%) had another related donor (though not a human leukocyte antigen [HLA]-identical sibling). The median time from B-cell ALL diagnosis to transplant was 39 months, and the median time from B-cell ALL diagnosis to first dose of inotuzumab ozogamicin was 33 months.

Twelve (12) of the 52 patients for whom post-HSCT follow-up information was available with prior allogeneic HSCT (23%) experienced VOD/SOS after the second allogeneic HSCT. Seven (7) patients (58%) experienced severe VOD/SOS and 5 patients (42%) experienced mild VOD/SOS. Of the patients who had VOD/SOS, 7 (58%) patients (3 adult, 4 pediatric) died after reporting VOD/SOS at 0.1 months, 0.5 months, 0.5 months, 1.1 months, 2.8 months, 22.5 months, and 43.1 months after VOD.

Causes of death for the 7 patients included:

- 3 due to primary disease: 1 (33%) adult and 2 (50%) pediatric
- 4 due to VOD/SOS: 2 (67%) adult and 2 (50%) pediatric

Four (4) of the 9 pediatric patients (44%) experienced VOD/SOS after the second allogeneic HSCT. Three of the 4 patients (75%) experienced severe VOD/SOS and 1 patient (25%) experienced mild VOD/SOS. Four (4) pediatric patients (44%) died after reporting VOD/SOS at 0.1 months, 0.5 months, 1.1 months, and 22.5 months after VOD.

Eight (8) of the 43 adult patients (19%) experienced VOD/SOS after the second allogeneic HSCT. Four patients (50%) had mild VOD/SOS grade and 4 patients (50%) experienced severe VOD/SOS. Three (3) adult patients (37%) died after reporting VOD/SOS at 0.5 months, 2.8 months, and 43.1 months.

For the 52 patients, relapse status was:

- 7/52 (13%) patients experienced post-HSCT relapse: 4 (9 %) adult, 3 (33%) pediatric
- 43/52 (83%) patients did not experience post-HSCT relapse: 38 adult (88%), 5 pediatric (56%), of these:
    - 13/43 (30%) patients died in remission within 18 months: 11 (29 %) adult and 2 (40 %) pediatric
- 2/52 (4%) patients had relapse status not reported: 1 (2 %) adult, 1 (11 %) pediatric

Discussion: Overall, data collected between August 2017 and August 2022 in the CIBMTR Research Database appear to be consistent with the results observed in completed Phase 3 Study B1931022.

In Phase 3 Study B1931022, the safety and efficacy of inotuzumab ozogamicin was examined in adult patients with relapsed or refractory B-cell ALL who received either 1 or 2 lines of therapy prior to inotuzumab ozogamicin. In this study, the VOD incidence was 18% among adult patients who underwent a first HSCT for relapsed or refractory B-cell ALL. Based on data collected between August 2017 and August 2022 in the CIBMTR Research Database, the VOD incidence rate was 18% (95% CI, 12-24) in adult patients with relapsed or refractory B-cell ALL who received a median of 4 lines of therapy prior to HSCT.

Although there are only data from n=52 pediatric patients who underwent a first transplant collected between August 2017 and August 2022 in the CIBMTR Research Database with post-HSCT follow-up information available, the incidence of 100-day VOD post-HSCT appears to be higher than in adult patients at 30% (95% CI, 17-45).

Among patients who underwent first alloHSCT for B-cell ALL and have follow-up (n=296), 17% had VOD/SOS (69% adults and 31% pediatrics). VOD incidence of relapsed/refractory adult patients at 100 days is 18%. For patients who underwent second, or greater HSCT for B-cell ALL (n = 52), 23% developed VOD/SOS (66% adults and 33% pediatrics). Incidence of VOD for relapsed/refractory adult patients after their second or greater HSCT is 22%.

Among patients who underwent first alloHSCT for B-cell ALL and developed VOD (51 patients), median follow-up was 2.92 months (adult, 6.57 months, pediatric, 1.83 months) after VOD with survival of 13 adults and 9 pediatrics out of total 35 adults and 16 pediatrics.

Among patients who underwent second, or greater HSCT for B-cell ALL and developed VOD (12 patients), median follow-up was 4.07 months (adult,13.60 months, pediatric, 0.85 months) after VOD. All 4 pediatric patients and 3 out of 8 adult patients died.

In adult patients (n=244), the 18-month OS was 54% (95% CI, 47-61) and 18-month TRM was 22% (95% CI, 17-27.)

Given the relatively small number of pediatric patients accrued for this final report, these time-to-event endpoints were not calculated.

A comprehensive analysis of the association between patient baseline characteristics, pre-HSCT exposure to inotuzumab ozogamicin, patient characteristics at the time of HSCT and the occurrence of post-transplant VOD/SOS will require a larger sample size.

In conclusion, data collected between August 2017 and August 2022 in the CIBMTR Research Database suggest that the safety data obtained from the use of inotuzumab ozogamicin in the real-world post-transplant setting appear to be consistent with the data observed in Phase 3 Study B1931022. Among pre-HSCT inotuzumab recipients, in an analysis of a subset of patients, the cumulative exposure did not increase the day 100 VOD risk.

Marketing Authorization Holder(s): Pfizer Limited

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