Efficacy and safety of currently approved and lower starting doses of inotuzumab ozogamicin in adult patients with relapsed or refractory acute lymphoblastic leukemia: a phase IV study

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SUPPLEMENTARY MATERIALS

Additional methods

Safety endpoints were assessed during treatment and post HSCT and included adverse events (AEs; graded according to the National Cancer Institute Common Terminology Criteria for Adverse Events [NCI CTCAE] version 3.0) and laboratory abnormalities.

Bone marrow aspirates and disease assessments were performed at screening, once at Days 16-28 of cycles 1 and 2, or until CR/CRi and MRD negativity were achieved, then after every 1-2 cycles as clinically indicated, and at the end of treatment. Bone marrow aspirates were analyzed at the study site. Disease assessments were determined using information from bone marrow evaluations, laboratory assessments (e.g., hematology), and clinical and radiological information (e.g., extramedullary disease).

CR was defined as <5% blasts in bone marrow and absence of peripheral blood leukemic blasts, full recovery of peripheral blood counts (platelets ≥100 x 10^9/L and absolute neutrophil counts [ANC] ≥1 x 10^9/L), and resolution of any extramedullary disease. CRi was defined as <5% blasts in the bone marrow and absence of peripheral blood leukemic blasts, incomplete recovery of peripheral blood counts (platelets <100 x 10^9/L and/or ANC <1 x 10^9/L), and resolution of any extramedullary disease. For determination of MRD, bone marrow aspirates were analyzed at a central laboratory (Navigate, Carlsbad, CA, USA) by flow cytometry for cell surface markers associated with B-cell ALL. MRD negativity (in patients who achieved CR/CRi) was defined as minimum MRD percentage <0.01% between the date of CR/CRi and end of treatment test.[6, 8]

Blood samples were collected for pharmacokinetics of InO and unconjugated calicheamicin at protocol-specified time points and analyzed by a specific and sensitive LC-MS/MS method. Blood samples for the anti-drug antibody (ADA) assessment were collected at protocol-specified time points and analyzed using a validated, electro-chemiluminescent bridging assay. ADA-positive samples were evaluated for neutralizing antibody (NAb) using a cell-based assay.

Statistical analysis

Twenty-two patients were enrolled in the run-in phase. In order to minimize the expected number of patients enrolled in the event that the lower dose level (1.2 mg/m^2/cycle of InO, dose level 2) proves to be of minimal efficacy benefit, a Simon Two-Stage optimal design was used for the run-in phase. The run-in phase tested the null hypothesis (H0) that the CR/CRi rate is ≤31.2% versus the alternative hypothesis (Ha) that the CR/CRi rate is ≥57% (ie, predicted based on the exposure response model) with a significance level of 0.10 and 80% power.

Seven patients were enrolled in Stage 1. If ≤2 CR/CRi responders were observed in Stage 1, accrual was stopped for further evaluation. Once at least 3 (ie, 42.9%) CR/CRi responders were documented, an additional 15 enrolled patients were evaluated in Stage 2. If ≥10 CR/CRi responders were observed in the total of 22 patients from both stages, it was concluded that the true CR/CRi rate for the lower dose is higher than the historical control (31.2% for Study

B1931022 control arm subgroup of patients with risk factors for VOD post-HSCT).

The expected MRD negativity rate among the patients who achieved CR/CRi was ≥70%. With ≥10 CR/CRi responders expected at the end of Stage 2, the expected number of patients with MRD negativity among the 22 patients in the run-in phase was ≥7. Given a CR/CRi rate of 57%, predicted by the exposure response model, and ≥70% expected MRD negativity rate among CR/CRi responders, 40% was the expected MRD negativity rate among all patients enrolled in the run-in phase. Twenty-two (22) patients also provided 80% power to reject the null hypothesis of the MRD negativity rate ≤20% when the alternative hypothesis of the true MRD negativity rate was ≥40% with significance level of 0.10. There was an 84% probability to observe a minimum of 7 patients who achieved MRD negativity if the true MRD negativity rate was at least 40%.

Once at least 10 CR/CRi responders and at least 7 patients achieving MRD negativity were documented among the 22 patients in the run-in phase, patients enrolled in the randomized phase were then evaluated, with approximately 80 patients randomized (1:1) to the approved dose level of 1.8 mg/m^2/cycle (dose level 1, Arm 1) or the lower dose level of 1.2 mg/m^2/cycle (dose level 2, Arm 2). A sample size of 40 patients per arm provided the estimated VOD rate in each dose level with a maximum standard error of 0.08.

All efficacy and safety endpoints were analyzed descriptively (i.e., the number and percent of patients achieving the endpoint and 2-sided 95% confidence interval [CI]) using SAS version 9.4 (Cary, NC) without formal hypothesis testing across dose levels. Efficacy data were analyzed in the full analysis population, which included all patients enrolled and randomly assigned into the study. Safety data were analyzed in the safety population, which included all enrolled patients who received at least 1 dose of InO, with treatment assignment designated according to actual treatment received. Safety data post HSCT were evaluated in the HSCT safety population, which included all enrolled patients who receive at least 1 dose of InO, with treatment assignment designated according to actual treatment received, and who had undergone HSCT after InO treatment.

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Supplementary Tables and Figures

Supplementary Table S1. Inclusion and exclusion criteria

Inclusion criteria

Participants must meet all of the following inclusion criteria to be eligible for enrollment into the study:

1. Relapsed or refractory precursor CD22-positive B-cell ALL with M2 or M3 marrow (≥5% blasts) and who are eligible for HSCT.
2. Have 1 or more of the following risk factors for developing SOS:
    a. Due to receive Salvage 2 or greater;
    b. Prior HSCT;
    c. Age ≥55 years;
    d. Ongoing or prior hepatic disease which may include a prior history of hepatitis or drug-induced liver injury, as well as hepatic steatosis, nonalcoholic steatohepatitis, baseline elevations of bilirubin >ULN and ≤1.5 x ULN.
3. Ph+ ALL patients must have failed treatment with at least 1 second- or third-generation tyrosine kinase inhibitor and standard multi-agent induction chemotherapy.
4. Patients in Salvage 1 with late relapse should be deemed poor candidates for reinduction with initial therapy.
5. Patients with lymphoblastic lymphoma and bone marrow involvement ≥5% lymphoblasts by morphologic assessment.
6. Age 18 years to 75 years.
7. ECOG performance status 0-2.
8. Adequate liver function, including total serum bilirubin ≤1.5 x ULN unless the patient has documented Gilbert syndrome, and AST and ALT ≤2.5 x
9. Serum creatinine ≤1.5 x ULN or any serum creatinine level associated with a measured or calculated creatinine clearance of ≥40 mL/min.
10. Male and female patients of childbearing potential and at risk for pregnancy must agree to use a highly effective method of contraception throughout the study and for a minimum of 8 months (females) and 5 months (males) after the last dose of assigned treatment. A patient is of childbearing potential if, in the opinion of the Investigator, he/she is biologically capable of having children and is sexually active. Female subjects of nonchildbearing potential must meet at least 1 of the following criteria:
    a. Achieved postmenopausal status, defined as follows: cessation of regular menses for at least 12 consecutive months with no alternative pathological or physiological cause; and have a serum FSH level confirming the postmenopausal state;
    b. Have undergone a documented hysterectomy and/or bilateral oophorectomy;
    c. Have medically confirmed ovarian failure.

All other female subjects (including female subjects with tubal ligations) are considered to be of childbearing potential.

11. Evidence of a personally signed and dated informed consent document indicating that the subject has been informed of all pertinent aspects of the study; patients with mental capacity which requires the presence of a legally authorized representative will be excluded from the study.
12. Willing and able to comply with scheduled visits, treatment plan, laboratory tests, and other study procedures.

Exclusion criteria

Participants with any of the following characteristics/conditions were not included in the study:

1. Isolated extramedullary relapse (ie, testicular or central nervous system).
2. Burkitt's or mixed phenotype acute leukemia based on the WHO 2008 criteria.6
3. Active CNS leukemia, as defined by unequivocal morphologic evidence of lymphoblasts in the CSF, use of CNS-directed local treatment for active disease within the prior 28 days, symptomatic CNS leukemia (ie, cranial nerve palsies or other significant neurologic dysfunction) within 28 days. Prophylactic intrathecal medication is not a reason for exclusion.
4. Prior chemotherapy within 2 weeks before randomization with the following exceptions:
    a. To reduce the circulating lymphoblast count or palliation: ie, steroids, hydroxyurea or vincristine;
    b. For ALL maintenance: mercaptopurine, methotrexate, vincristine, thioguanine, and/or tyrosine kinase inhibitors.

Patients must have recovered from acute nonhematologic toxicity (to ≤Grade 1) of all previous therapy prior to enrollment.

5. Prior monoclonal antibodies within 6 weeks of randomization, with the exception of rituximab which must be discontinued at least 2 weeks prior to randomization.
6. Prior inotuzumab ozogamicin treatment or other anti-CD22 immunotherapy ≤6 months before randomization.
7. Prior allogeneic HSCT ≤90 days before randomization. Patients must have completed immunosuppression therapy for treatment of GvHD prior to enrollment. At randomization, patients must not have ≥Grade 2 acute GvHD, or extensive chronic GvHD.
8. Peripheral absolute lymphoblast count ≥10,000/μL (treatment with hydroxyurea and/or steroids/vincristine is permitted within 2 weeks of randomization to reduce the WBC count).
9. Known systemic vasculitides (eg, Wegener's granulomatosis, polyarteritis nodosa, systemic lupus erythematosus), primary or secondary immunodeficiency (such as HIV infection or severe inflammatory disease).
10. Active hepatitis B infection as evidenced by hepatitis B surface antigen, active hepatitis C infection (must be anti-hepatitis C antibody negative or hepatitis C ribonucleic acid negative), or known seropositivity for HIV. HIV testing may need to be performed in accordance with local regulations or local practice.
11. Major surgery within ≤4 weeks before randomization.
12. Unstable or severe uncontrolled medical condition (eg, unstable cardiac function or unstable pulmonary condition).
13. Concurrent active malignancy other than nonmelanoma skin cancer, carcinoma in situ of the cervix, or localized prostate cancer that has been definitely treated with radiation or surgery. Patients with previous malignancies are eligible provided that they have been disease free for ≥2 years.
14. Patients with active heart disease or the presence of NYHA stage III or IV congestive heart failure.
15. QTcF >470 msec (based on the average of 3 consecutive ECGs).
16. Myocardial infarction ≤6 months before randomization.
17. History of clinically significant ventricular arrhythmia, or unexplained syncope not believed to be vasovagal in nature, or chronic bradycardic states such as sinoatrial block or higher degrees of AV block unless a permanent pacemaker has been implanted.
18. Uncontrolled electrolyte disorders that can compound the effects of a QTc prolonging drug (eg, hypokalemia, hypocalcemia, hypomagnesemia).
19. Prior confirmed or ongoing SOS, or other serious or current ongoing liver disease such as cirrhosis or nodular regenerative hyperplasia.
20. Total serum bilirubin >1.5 x ULN unless the patient has documented Gilbert syndrome, and AST and ALT ≥2.5 x
21. Administration of live vaccine ≤6 weeks before randomization.
22. Evidence of uncontrolled current serious active infection (including sepsis, bacteremia, fungemia) or patients with a recent history (within 4 months) of deep tissue infections such as fasciitis or osteomyelitis.
23. Patients who have had a severe allergic reaction or anaphylactic reaction to any humanized monoclonal antibodies.
24. Pregnant female subjects; breastfeeding female subjects; fertile male subjects and female subjects of childbearing potential who are unwilling or unable to use highly effective contraception as outlined in this protocol for the duration of the study and for a minimum of 8 months (females) and 5 months (males) after the last dose of investigational product.

25. Investigative site staff members directly involved in the conduct of the study and their family members, site staff members otherwise supervised by the Investigator, or subjects who are Pfizer employees, including their family members, directly involved in the conduct of the study.
26. Participation in other studies involving investigational drug(s) within 2 weeks prior to study entry and/or during study participation (up through the end of treatment visit).
27. Other acute or chronic medical or psychiatric condition including recent (within the past year) or active suicidal ideation or behavior or laboratory abnormality that may increase the risk associated with study participation or investigational product administration or may interfere with the interpretation of study results and, in the judgment of the Investigator, would make the subject inappropriate for entry into this study.

ALL=acute lymphoblastic leukemia; ALT=alanine aminotransferase; AST=aspartate aminotransferase; AV=atrioventricular; CNS=central nervous system; CSF=cerebrospinal fluid; ECG=electrocardiogram; ECOG=Eastern Cooperative Oncology Group; FSH=follicle-stimulating hormone; GvHD=graft vs host disease; HSCT=hematopoietic stem cell transplantation; NYHA=New York Heart Association; Ph+=Philadelphia chromosome–positive; SOS=sinusoidal obstruction syndrome; ULN=upper limit of normal; WBC=white blood cell.

Supplementary Table S2. Association of baseline characteristics at time of HSCT with post-HSCT SOS. Treatment group: Total (N=43) univariate analysis

	Subsets N	Estimate	SE	Odds ratio	95% CI	p-value
Age (<55 years, ≥55 years)	35, 8	0.89	1.14	2.423	0.261, 22.493	0.436
Salvage status (1, ≥2)	17, 26	-1.20	0.86	0.300	0.055, 1.633	0.164
Prior HSCT (Yes, No)	8, 35	0.12	0.91	1.125	0.189, 6.699	0.897
Prior history of liver disease/hepatitis (Yes, No)	16,27	-1.08	0.87	0.339	0.062, 1.850	0.212
Number of treatment cycles received (continuous)	43	-0.17	0.47	0.843	0.335, 2.123	0.717
Dual alkylator conditioning (Yes, No)	8, 35	0.12	0.91	1.125	0.189, 6.699	0.897
Last bilirubin prior to follow-up HSCT (<ULN, ≥ULN)	40, 3	11.52	318.03	>999.999	<0.001, >999.999	0.971
Time from InO to transplant (days) (continuous)	43	-0.00	0.01	0.996	0.977, 1.016	0.711
Cumulative dose (mg) (continuous)	43	-0.15	0.38	0.857	0.408, 1.801	0.685
Region (Asia, EU/NA)	24, 19	0.22	0.73	1.250	0.297, 5.269	0.761

EU=European Union; HSCT=hematopoietic stem cell transplantation; InO=inotuzumab ozogamicin; NA=North America; SOS=sinusoidal obstruction syndrome; ULN=upper limit of normal.

Supplementary Table S3. Summary of rate of follow-up HSCT.

Number of patients who received follow-up HSCT, n	Starting dose of InO and trial phase				
	1.2 mg/m^2/cycle (run-in) n=10	1.2 mg/m^2/cycle (randomized) n=21	1.2 mg/m^2/cycle (run-in + randomized) n=31	1.8 mg/m^2/cycle (randomized) n=12	Total n=43
Number of participants received HSCT post InO treatment directly without new induction therapy	10 (100.0)	21 (100.0)	31 (100.0)	11 (91.7)	42 (97.7)
Time of transplant relative to last InO dose					
<2 months after last dose of InO	9 (90.0)	17 (81.0)	26 (83.9)	11 (91.7)	37 (86.0)
≥2 months after last dose of InO	1 (10.0)	4 (19.0)	5 (16.1)	1 (8.3)	6 (14.0)
Type of transplant					
Allogeneic	9 (90.0)	21 (100.0)	30 (96.8)	12 (100)	42 (97.7)
Unknown	1 (10.0)	0	1 (3.2)	0	1 (2.3)
Hla compatibility					
Hla-haploidentical	1 (10.0)	3 (14.3)	4 (12.9)	0	4 (9.3)
Hla-matched	7 (70.0)	15 (71.4)	22 (71.0)	11 (91.7)	33 (76.7)
Hla-unmatched	0	2 (9.5)	2 (6.5)	0	2 (4.7)
Unknown	2 (20.0)	1 (4.8)	3 (9.7)	1 (8.3)	4 (9.3)
Stem cell source					
Bone marrow	1 (10.0)	0	1 (3.2)	2 (16.7)	3 (7.0)
Cord blood	0	1 (4.8)	1 (3.2)	0	1 (2.3)
Peripheral blood	8 (80.0)	19 (90.5)	27 (87.1)	9 (75.0)	36 (83.7)
Unknown	1 (10.0)	1 (4.8)	2 (6.5)	1 (8.3)	3 (7.0)
Type of conditioning					
Myeloablative	7 (70.0)	13 (61.9)	20 (64.5)	5 (41.7)	25 (58.1)
Reduced intensity	3 (30.0)	6 (28.6)	9 (29.0)	6 (50.0)	15 (34.9)
Unknown	0	2 (9.5)	2 (6.5)	1 (8.3)	3 (7.0)

Disease risk at transplant					
Disease in remission	8 (80.0)	17 (81.0)	25 (80.6)	10 (83.3)	35 (81.4)
Disease not in remission	2 (20.0)	4 (19.0)	6 (19.4)	2 (16.7)	8 (18.6)

HSCT, hematopoietic stem cell transplant; Hla, human leukocyte antigen; InO, inotuzumab ozogamicin.

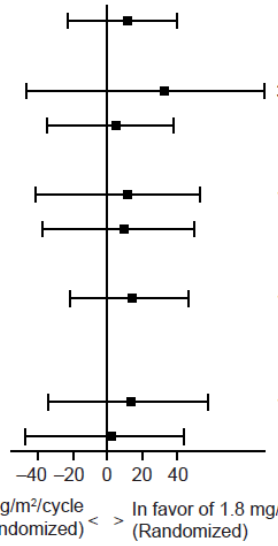
Supplementary Table S4. Association of baseline characteristics at time of HSCT with NRM. Treatment group: Total (N=43) univariate analysis.

	Subsets N	Estimate	SE	Odds ratio	95% CI	p-value
Age (<55 years, ≥55 years)	35,8	1.04	1.10	2.832	0.329, 24.353	0.343
Salvage status (1, ≥2)	17, 26	0.56	0.53	1.748	0.624, 4.895	0.288
Prior HSCT (Yes, No)	8, 35	0.96	0.51	2.621	0.964, 7.128	0.059
Prior history of liver disease/hepatitis (Yes, No)	16, 27	0.64	0.52	1.901	0.691, 5.233	0.213
Number of treatment cycles received (continuous)	43	-0.17	0.47	0.843	0.335, 2.123	0.717
Dual alkylator conditioning (Yes, No)	8, 35	-0.39	0.77	0.678	0.149, 3.081	0.615
Last bilirubin prior to follow-up HSCT (<ULN, ≥ULN)	40, 3	-0.12	1.15	0.884	0.093, 8.368	0.914
Time from InO to transplant (days) (continuous)	43	-0.00	0.01	0.996	0.977, 1.016	0.711
Cumulative dose (mg) (continuous)	43	-0.15	0.38	0.857	0.408, 1.801	0.685
Region (Asia, EU/NA)	24, 19	1.22	0.65	3.380	0.947, 12.063	0.061

EU, European Union, HSCT, hematopoietic stem cell transplant; InO, inotuzumab ozogamicin; NA, not applicable; ULN, upper limit of normal.

Supplementary Figure S1. Forest plot of SOS rate by SOS risk factors - HSCT safety analysis set

Subgroup	Arm 2 (n)	Arm 1 (n)	VOD rate Arm 2	VOD rate Arm 1	Rate diff	[95% CI]	P value
All Participants	21 (6)	12 (2)	28.6	16.7	11.9	[–22.3, 40.1]	0.6776
Prior HSCT							
Yes	3 (1)	3 (0)	33.3	0.0	33.3	[–46.2, 90.6]	1.0000
No	18 (5)	9 (2)	27.8	22.2	5.6	[–34.7, 37.9]	1.0000
Salvage Treatment							
Salvage 1	8 (1)	5 (0)	12.5	0.0	12.5	[–41.1, 53.7]	1.0000
Salvage ≥2	13 (5)	7 (2)	38.5	28.6	9.9	[–37.9, 50.1]	1.0000
Age							
<55 Years	16 (5)	12 (2)	31.3	16.7	14.6	[–21.4, 47.3]	0.6618
≥55 Years	5 (1)	0	20.0	0	NA	[NA, NA]	NA
Ongoing or Prior Heptic Disease							
Yes	7 (1)	6 (0)	14.3	0.0	14.3	[–34.2, 57.9]	1.0000
No	14 (5)	6 (2)	35.7	33.3	2.4	[–47.3, 44.0]	1.0000



Note: n is number of participants with VOD. Arm 2 is 1.2 mg/m²/cycle (randomized) and Arm 1 is 1.8 mg/m²/cycle (randomized).
P values calculated using the exact method.
HSCT=hematopoietic stem cell transplant; SOS=sinusoidal obstruction syndrome; VOD=veno-occlusive disease.