REGULAR ARTICLE

blood ICT
immunology & cellular therapy

Varnimcabtagene autoleucel in relapsed or refractory B-cell malignancies

Sharat Damodar,[1] Sunil Bhat,[1] Raja Thirumalairaj,[2] Pankaj Malhotra,[3] Akshatha Nayak,[1] Pooja Mallya,[1] Ravi Joshi,[1] Revathy Raj,[2] Rameez Ahamed,[2] Charanpreet Singh,[3] Deepak MB,[1] Lakshman Vaidhyanathan,[2] Man Updesh Singh Sachdeva,[3] Karthik GA,[1] Sunil HV,[1] Jayaraj Govindaraj,[2] Shelley Simon,[2] Rajender Kumar Basher,[3] Rahul Nahar,[4] Anne Roshan Joseph,[4] Mohammed Manzoor Akheel,[4] Giridhar Chenji,[4] and Anil Kamat[4]

[1]Department of Hematology, Mazumdar Shaw Medical Centre, Narayana Health City, Bengaluru, India; [2]Department of Medical Oncology, Apollo Speciality Hospital, Chennai, India; [3]Department of Clinical Hematology and Medical Oncology, Postgraduate Institute of Medical Education and Research, Chandigarh, India; and [4]Immuneel Therapeutics Private Limited, Bengaluru, India

Key Points

- Varnim-cel is a novel autologous CD19-directed CAR T-cell therapy with a murine A3B1 binder.
- Varnim-cel in a fractionated infusion protocol (10%, 30%, and 60%) yielded durable responses and a favorable safety profile.

Varnimcabtagene autoleucel (varnim-cel), an autologous CD19-directed chimeric antigen receptor (CAR) T-cell therapy, has demonstrated an antitumor activity and toxicity profile consistent with known CAR T-cell–associated adverse effects in patients with relapsed or refractory B-cell malignancies, including B-cell acute lymphoblastic leukemia (B-ALL) and B-cell non-Hodgkin lymphoma (B-NHL). In this phase 2 clinical trial, we evaluated the efficacy and safety of varnim-cel in individuals with relapsed or refractory B-cell malignancies with at least 1 prior line of therapy. Varnim-cel was administered at a dosage range of 0.1×10^6 to 5×10^6 CAR^+ T cells per kg. Primary end points were safety and overall response rate (ORR), defined as complete remission (CR) or CR with incomplete hematologic recovery for B-ALL and CR or partial response for B-NHL. Of the 24 patients treated with varnim-cel, day +28 ORR was 92% (22 of 24 patients). Twenty of 24 patients (ORR, 83%) demonstrated a clinical response at day +90 (primary end point). At a median follow-up of 10.6 months, 10 of the 24 patients (42%) maintained a response. Median progression-free survival was 8.9 months. Common treatment-emergent adverse events were cytopenias (neutropenia, 100%; anemia, 96%; and thrombocytopenia, 92%), cytokine release syndrome in 16 patients (67%), including 1 case (4%) of grade $\geq$3 severity and 1 patient (4%) with grade 1 immune effector cell–associated neurotoxicity syndrome, with no cases of grade $\geq$3. Varnim-cel induced durable responses in relapsed or refractory B-cell malignancies, with a favorable safety profile and low incidence of severe immune-mediated adverse events. This trial was registered at www.ctri.nic.in as CTRI/2022/03/041162.

Introduction

Chimeric antigen receptor (CAR) T-cell therapy can induce sustained responses in relapsed or refractory B-cell cancers.[1] Tisagenlecleucel has been available for children and young adults (aged $\leq$25 years) with relapsed or refractory B-cell acute lymphoblastic leukemia (B-ALL) since 2017 in the United States and since 2018 in Europe.[1-3] Brexucabtagene autoleucel (brexu-cel) has been licensed

Submitted 16 July 2025; accepted 22 November 2025; prepublished online 15 December 2025; final version published online 13 January 2026. https://doi.org/10.1016/j.bict.2025.100024.

Deidentified individual participant data that underlie the reported results can be made available after publication. Proposals for access should be sent to imagine@immuneel.com.

The full-text version of this article contains a data supplement.

for adults aged ≥18 years with relapsed or refractory B-ALL.[4-6] Obecabtagene autoleucel has recently been approved for adults with relapsed or refractory B-ALL.[7]

Varnimcabtagene autoleucel (varnim-cel) is an autologous 4-1BB-ζ anti-CD19 CAR T-cell therapy featuring a murine A3B1 binder. Unlike other CAR T-cell therapies, varnim-cel is administered using a fractionated infusion protocol to reduce toxicities and enhance safety. The preclinical evaluation of varnim-cel (ARI-0001) was conducted in Spain.[8,9] The phase 1 study of varnim-cel (ARI-0001) in Spain included patients with relapsed or refractory B-cell malignancies and demonstrated a high response rate, durable CAR T-cell persistence, and a low incidence of severe immune-related toxicities.[10-12]

Varnim-cel (IMN-003A) was subsequently evaluated in the multicenter phase 2 IMAGINE trial, conducted across clinical sites in India. This study represents the first industry-sponsored phase 2 trial of its kind in the country and was implemented in midst of the COVID-19 pandemic with strict adherence to COVID precautions despite resource limitations. Here, we present the results of the IMAGINE trial, a pivotal, multicenter phase 2 registration study designed to assess the safety and therapeutic efficacy of varnim-cel in patients with relapsed or refractory B-cell malignancies.

Methods

Study design and patients

The IMAGINE study was conducted at 3 clinical trial sites in India. The investigators and sites are listed in the supplemental Appendix. This was a multicenter, phase 2 clinical trial conducted in patients with relapsed or refractory B-cell malignancies in a resource-constrained setting and included both patients with B-ALL and patients with B-cell non-Hodgkin lymphoma (B-NHL). Eligible participants included individuals aged 3 to 45 years with B-ALL, and adults aged ≥18 years with B-NHL. The inclusion criteria were measurable disease, defined as the presence of lymphoid blasts in B-ALL or metabolic tumor burden in B-NHL, with prior exposure to at least 1 line of therapy, documented relapse or refractoriness to the last treatment, an Eastern Cooperative Oncology Group performance status of 0 or 1, and adequate organ function. Demographic and disease characteristics of the patients are described in Table 1. Eligibility is detailed in the supplemental Appendix, and inclusion and exclusion criteria are listed in supplemental Tables 1 and 2 in the supplemental Appendix.

Varnim-cel was manufactured under the current Good Manufacturing Practice compliant conditions. The target varnim-cel dose was 1×10^6 CAR^+ cells per kg for patients with B-ALL and 5×10^6 CAR^+ cells per kg for those with B-NHL (dose range across all patients, 0.1×10^6/kg to 5×10^6/kg). The infusion was administered in a fractionated manner over 3 days (10%, 30%, and 60%), with a minimum 24-hour interval between each dose. Bridging therapy was permitted during the manufacturing period, provided it was discontinued at least 7 to 14 days before varnim-cel infusion and limited to specified drug classes.

Lymphodepletion preparative regimen consisted of fludarabine (30 mg/m^2 per day) and cyclophosphamide (300 mg/m^2 per day), administered over 3 consecutive days, followed by a 2-day rest period before varnim-cel infusion. Patients were monitored for a minimum of 12 months postinfusion and subsequently invited to enroll in a separate long-term follow-up study. Additional methods are provided in the supplemental Appendix.

End points and assessments

The primary end points were overall response rate (ORR), defined as complete remission (CR) or CR with incomplete hematologic recovery (CRi) for B-ALL and CR or partial response (PR) for B-NHL, evaluated at day 90 following the first varnim-cel infusion, along with safety. Disease response was assessed according to the National Comprehensive Cancer Network guidelines for B-ALL and the International Working Group criteria for B-NHL. Minimal residual disease (MRD) in B-ALL was evaluated by flow cytometry with a sensitivity threshold of 10^{-4}, whereas tumor burden in B-NHL was assessed using positron emission tomography–computed tomography. The primary efficacy end points were subject to independent verification to ensure the accuracy and robustness of disease response assessments.

Adverse events were graded using the Common Terminology Criteria for Adverse Events, version 5.0.[13] Cytokine release syndrome (CRS) and immune effector cell–associated neurotoxicity syndrome (ICANS) were assessed according to the American Society for Transplantation and Cellular Therapy consensus grading criteria.[14]

Secondary end points included MRD-negative remission in B-ALL, progression-free survival (PFS), and overall survival (OS). Additional details are available in the supplemental Appendix.

Statistical analysis

The safety and efficacy analyses were conducted in all 24 patients who received varnim-cel. The primary end point was ORR, defined as the proportion of patients achieving either CR or CRi in the B-ALL cohort and CR or PR in the B-NHL cohort.

There was no approved CAR T-cell therapy for this indication in India. Based on the existing literature, the expected ORR for currently available second-line therapies is ~30%, with estimates ranging from 20% to 40%.[15-17] Accordingly, a null hypothesis (H_0: $p = p_0$) was formulated, assuming a historical control ORR (p_0) of 30%. The alternative hypothesis (H_1: $p > p_1$) assumed an ORR of at least 60% (p_1), which was conservatively estimated based on preliminary evidence from the varnim-cel phase 1 study demonstrating an ORR exceeding 70%.[11]

Sample size calculations were based on a 1-sample binomial test, with an α-level of 0.05 (1-sided) and a power of 85%. Under these parameters, a minimum of 18 evaluable patients were required to detect a statistically significant difference from the historical control. However, the IMAGINE phase 2 trial enrolled 24 patients, allowing for both a robust assessment of safety and efficacy and for greater precision in estimating ORR. With the 24 treated patients, the observed ORR could be estimated at 95% exact confidence interval ranging from 34.7% to 81.8%, excluding the null value of 30% and supporting the hypothesis of clinical superiority. Therefore, the study was adequately powered to demonstrate a meaningful treatment effect of varnim-cel compared with historical therapies.

Time-to-event end points, including PFS and duration of response, were analyzed using the Kaplan-Meier method. Patients who

Table 1. Demographic and disease characteristics of the patients before enrollment

Characteristic	B-ALL cohort (n = 12)	B-NHL cohort (n = 12)	Overall (N = 24)
Demographic characteristics			
Age			
Median (range), y	12.0 (4-43)	53.0 (31-66)	32.5 (4-66)
<18 years, n (%)	9 (75)	–	9 (37.5)
≥18 years, n (%)	3 (25)	12 (100)	15 (62.5)
Sex, n (%)			
Male	7 (58.3)	8 (66.7)	15 (62.5)
Female	5 (41.7)	4 (33.3)	9 (37.5)
Previous therapies			
No. of previous lines, median (range)	2 (1-5)	3 (2-5)	3 (1-5)
Refractory disease, n (%)	8 (66.7)	3 (25)	11 (45.8)
Relapsed disease, n (%)			
First relapse	1 (8.3)	–	1 (4.2)
Second plus relapse	3 (25)	9 (75)	12 (50)
Previous use of inotuzumab ozogamicin, n (%)	4 (33.3)	–	4 (16.7)
Previous autologous stem cell transplantation, n (%)	–	1 (8.3)	1 (4.2)
Disease characteristics			
Median percentage of bone marrow blasts (range)	0.34 (0.01-27.2)	–	0.34 (0.01-27.2)
Philadelphia chromosome–positive disease, n (%)	1 (8.3)	–	1 (4.2)
B-NHL subtypes, n (%)			
Large B-cell lymphomas: diffuse large B-cell lymphoma, NOS	–	4 (33.3)	4 (16.7)
Transformations of indolent B-cell lymphomas	–	3 (25)	3 (12.5)
Follicular lymphoma	–	4 (33.3)	4 (16.7)
Mantle cell lymphoma	–	1 (8.3)	1 (4.2)
Bulky disease >7 cm	–	3 (25)	3 (12.5)
TMTV (range), mL	–	67.9 (27.1-1 177)	67.9 (27.1-1 177)
SPD (range), mm^2	–	3 846 (1 001-35 849)	3 846 (1 001-35 849)
ECOG performance status score, n (%)			
0	12 (100)	8 (66.7)	20 (83.3)
1	0	4 (33.3)	4 (16.7)

ECOG, Eastern Cooperative Oncology Group; NOS, not otherwise specified; SPD, sum of the product of the perpendicular diameters for multiple lesions; TMTV, total metabolic tumor volume.

initiated subsequent nonprotocol anticancer therapies, including varnim-cel reinfusions and hematopoietic stem cell transplantation, were censored at the time of treatment initiation for the relevant analyses.

Study oversight

The study was conceptualized and designed collaboratively by the investigators and study sponsor and conducted in compliance with the International Council for Harmonisation guidelines for Good Clinical Practice and the ethical principles outlined in the Declaration of Helsinki. The protocol received approval from the institutional review boards or institutional ethics committees at each participating center. Written informed consent was obtained from all patients before enrollment. The authors confirm the accuracy and integrity of the data presented, as well as the study's adherence to the approved protocol. All manuscript drafts were critically reviewed and revised by the authors. The author contributions are detailed in supplemental Table 3 in the supplemental Appendix. The authors vouch for the completeness and accuracy of the data and for the adherence of the study to the protocol.

Results

Patient disposition

Between 17 March 2022 and 16 May 2023, a total of 25 patients were enrolled and underwent leukapheresis (Figure 1). Of these, 24 (96%) received varnim-cel infusions; however, 1 patient withdrew before the infusion (supplemental Table 7). The median age of the treated patients was 32.5 years (range, 4-66). The patients had received a median of 3 prior lines of therapy (range, 1-5), and 1 patient (4%) had previously undergone autologous hematopoietic stem cell transplantation. Bridging therapy was administered

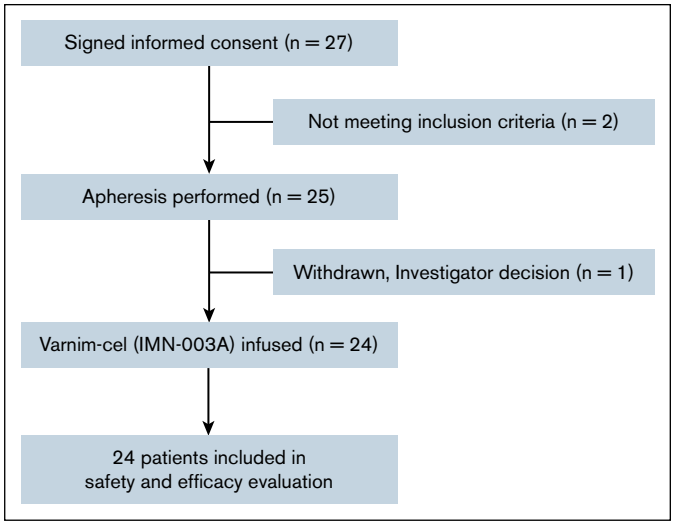


Figure 1. Screening, enrollment, and infusion.

to 12 patients (50%) during the manufacturing phase. Manufacturing feasibility is detailed in the supplemental Results of the supplemental Appendix.

Efficacy

Patients received varnim-cel at target doses of 1×10^6 CAR^+ T cells per kg for B-ALL and 5×10^6 CAR^+ T cells per kg for B-NHL (dose range across all patients, 0.1×10^6/kg to 5×10^6/kg).

At the day +28 evaluation, 22 of the 24 patients (92%) demonstrated a clinical response (11/12 patients each in B-ALL and B-NHL cohorts). Twenty of 24 patients (83%) demonstrated a clinical response (10/12 patients each in B-ALL and B-NHL cohorts) at day +90 (primary end point). In the B-ALL cohort, MRD negativity, defined as $<10^{-4}$ nucleated cells, was achieved in 9 of the 10 responders (90%). In the B-NHL cohort, the CR rate among responders was 70%. Of 3 patients (30% of responders) with PR at day +90, 2 patients lost response and 1 patient remained in PR at day +365. At a median follow-up of 10.6 months, 10 of the 24 patients (42%) maintained a response, including 9 patients (38%) with a CR. Table 2 summarizes the response according to cohort and in all patients who received varnim-cel.

The median time to initial response was 28 days (range, 28-33). The median duration of response was 7.9 months (range, 0 to not reached [NR]; B-ALL, 6.6 months [range, 0 to NR]; B-NHL, NR [range, 0 to NR]). Median PFS was 8.9 months (range, 0.4 to NR), whereas the median OS was NR (range, 0.4 months to NR). Survival curves are shown in Figures 2 and 3.

Following disease progression, 4 patients received a second infusion of varnim-cel; 2 of these patients (50%) achieved a subsequent response. All were redosed with the same cell dose as during their initial infusion.

Safety

Adverse events, including immunotoxicity, cytopenia, and infections, are summarized in Table 3.

CRS

CRS of all grades occurred in 16 of 24 patients (67%; 58% in B-ALL and 75% in B-NHL [aggressive, 42%; indolent, 33%; P = not significant]). One patient (4%) experienced grade ≥3 CRS. The median time to CRS onset was 5 days postinfusion (range, 1-9), and the median duration was 3 days (range, 1-7). Management included tocilizumab in 9 patients (37%), anakinra in 1 patient (4%), and corticosteroids in 2 patients (8%).

ICANS

ICANS of grade 1 was observed in 1 patient (4%) with B-ALL, with no events exceeding grade 2 severity. The onset occurred 10 days postinfusion and lasted 3 days. Treatment included anakinra and corticosteroids. No other patient experienced ICANS or neurotoxicity.

Cytopenias

All patients (100%) developed neutropenia, with 92% experiencing grade ≥3 severity. Anemia was reported in 23 patients (96%), with grade ≥3 in 8 (33%). Thrombocytopenia was observed in 22 patients (92%), with 5 cases (21%) being grade ≥3. B-cell aplasia was observed in all patients. Posttreatment hypogammaglobulinemia occurred in 11 patients (46%), and 18 patients (75%) received IV immunoglobulin, including prophylactic administration.

Intensive care unit admission

Only 1 patient (4%) required intensive care unit admission for 2 days, related to the management of grade ≥3 CRS.

Mortality

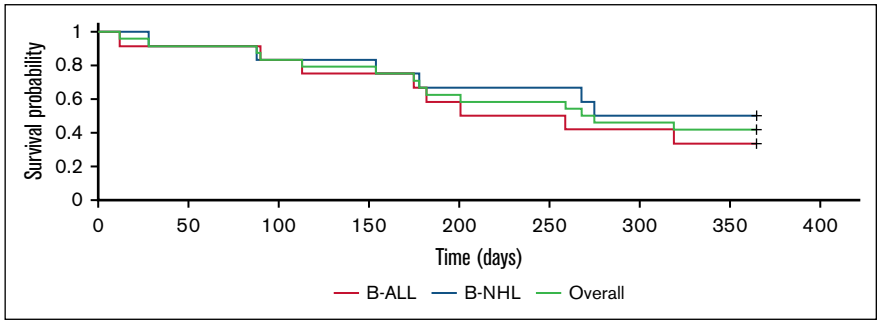
One patient with B-ALL died because of CRS with tumor lysis syndrome, an event attributed to varnim-cel. In total, 5 patients

Table 2. Response according to the cohorts and among all patients who received varnim-cel

	B-ALL cohort (n = 12)			B-NHL cohort (n = 12)			Overall (N = 24)		
Response, n (%)	**D +28**	**D +90**	**D +365**	**D +28**	**D +90**	**D +365**	**D +28**	**D +90**	**D +365**
ORR	11 (92)	10 (83)	4 (33)	11 (92)	10 (83)	6 (50)	22 (92)	20 (83)	10 (42)
MRD-negative*	10 (91)	9 (90)	2 (50)	–	–	–	–	–	–
CR*	11 (92)	10 (83)	4 (33)	7 (64)	7 (70)	5 (83)	–	–	–
PR*	–	–	–	4 (36)	3 (30)	1 (17)	–	–	–

D, day.
*Responses among responders.

Figure 2. **PFS.**



(21%) died during the study period, with all remaining deaths attributed by the investigator to underlying disease progression. Additional details are provided in supplemental Tables 10 and 11 in the supplemental Appendix.

Cellular pharmacokinetics

The median peak CAR T-cell concentration in all the patients who received varnim-cel infusion was 125 242 copies per microgram of genomic DNA (range, 18 256-413 968). The median time to peak CAR T-cell concentration was 10 days (range, 7-28) after varnim-cel infusion. The median duration of CAR T-cell persistence in peripheral blood as assessed by droplet digital polymerase chain reaction assay was 56 days (10 to NR). Additional details are provided in the supplemental Appendix.

Replication competent lentivirus assay results were negative for all patients at baseline and up to 1 year after varnim-cel infusion.

Discussion

In this phase 2 study, varnim-cel was administered to 24 patients with relapsed or refractory B-cell malignancies. Formal hypothesis testing was conducted for the primary end point of ORR, defined as CR or CRi in B-ALL and CR or PR in B-NHL along with safety outcomes.

At the day +28 evaluation, 22 of the 24 patients (92%) demonstrated a clinical response (11/12 patients each in the B-ALL and B-NHL cohorts). At day 90 postinfusion, the ORR was 83% (primary end point). The median time to first response was 28 days (range, 28-33), with a median duration of response of 7.9 months (range, 0 to NR). Median PFS was 8.9 months (range, 0.4 to NR), and the median OS was NR at the time of data cutoff. Importantly, varnim-cel exhibited a favorable safety profile, with only 1 case of grade ≥3 CRS and no cases of grade ≥3 neurotoxicity.

Current therapeutic agents such as blinatumomab and inotuzumab ozogamicin have demonstrated improved response rates in relapsed or refractory B-ALL but typically require consolidation with allogeneic hematopoietic stem cell transplantation to achieve durable remission.[18,19] Brexu-cel, a CD28-ζ–based CD19 CAR T-cell product, is approved for adults with relapsed or refractory B-ALL and has demonstrated an ORR of 71%.[4-6] Brexu-cel is associated with higher rates of grade ≥3 CRS (24%-26%) and ICANS (25%-35%) than other CD19 CAR T-cell products, such as obecabtagene autoleucel, for which reported incidences of grade ≥3 CRS and ICANS are 2.4% and 7.1%, respectively.[6,7,20] In contrast, in this study, varnim-cel was not associated with any grade ≥3 ICANS or neurotoxicity events, and only 1 patient developed grade ≥3 CRS.

This study represents a landmark in India's advancement in cellular immunotherapy, being the first industry-sponsored, multicenter phase 2 trial of a CAR T-cell therapy conducted in the country. Varnim-cel, a personalized autologous CAR T-cell product with a unique A3B1 binder (non-FMC63) and a 4-1BB costimulatory domain, was manufactured in India's first integrated cell and gene therapy research, development, and manufacturing facility. The trial was executed during the COVID-19 pandemic without any COVID-related mortality, underscoring the resilience of the infrastructure, COVID prevention, and patient care protocols. Varnim-cel was administered using a fractionated dosing schedule and demonstrated a favorable safety profile, with a particularly low incidence of severe neurotoxicity, supporting its potential for

Figure 3. **OS.**

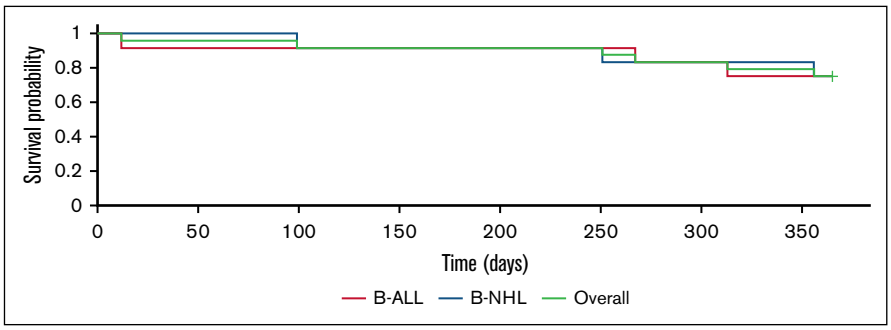


Table 3. Summary of adverse events of special interest

Event, n (%)	Any grade	Grade ≥3
CRS	16 (66.7)	1 (4.2)
ICANS	1 (4.2)	0
B-cell aplasia	24 (100)	–
Hypogammaglobulinemia	11 (45.8)	–
Neutropenia	24 (100)	22 (91.7)
Anemia	23 (95.8)	8 (33.3)
Thrombocytopenia	22 (91.7)	5 (20.8)

treatment in a low-resource setting. The study also established critical operational capabilities, including ultracold chain logistics for individualized therapy (first-in-India for a personalized treatment), marking India's entry into the global CAR T-cell therapy domain with high manufacturing and clinical standards. An interim analysis of this study has been published previously.[21-38]

Overall, the IMAGINE trial demonstrated that varnim-cel is associated with a high rate of durable responses and a low incidence of severe immune-mediated toxicities in patients with relapsed or refractory B-ALL and B-NHL. These results suggest that varnim-cel offers a favorable safety profile compared with other CD19 CAR T-cell therapies, with a potential for achieving long-term efficacy in patients with B-cell malignancies and especially relevant for use in low- and middle-income countries with a huge unmet need.

Acknowledgment

This study received funding support from the Biotechnology Industry Research Assistance Council (BIRAC), Government of India (Grant-in-Aid BT/BIPP1386/51/20).

Authorship

Contribution: S.D., S.B., and A.K. conceptualized the project idea and designed the study methodology; M.M.A. and A.K. were responsible for designing the electronic patient data capture system and statistical analyses; R.N., M.M.A., and A.K. were responsible for the formal statistical analysis and verification of data; S.D., S.B., R.T., P. Malhotra, A.N., P. Mallya, R.J., R.R., R.A., and C.S. cared for the patients included in the study and helped provide data for analysis; M.M.A. and A.K. wrote the original draft; and all authors were responsible for the editing and review of the manuscript.

Conflict-of-interest disclosure: R.N., A.R.J., G.C., M.M.A., and A.K. are employees or consultants for Immuneel Therapeutics. The remaining authors declare no competing financial interests.

ORCID profiles: P.M., 0000-0003-1198-8491; R.J., 0000-0002-2922-4177; R.A., 0000-0002-7885-8627; S.H., 0009-0004-1767-5909; R.K.B., 0000-0001-5098-5707.

Correspondence: Anil Kamat, Immuneel Therapeutics Private Limited, 29/P2, 8th Floor, Narayana Health City, Hosur Rd, Bommasandra Industrial Area, Bengaluru 560099, India; email: anilvkamat@hotmail.com.

References

1. Maude SL, Laetsch TW, Buechner J, et al. Tisagenlecleucel in children and young adults with B-cell lymphoblastic leukemia. *N Engl J Med*. 2018;378(5):439-448.
2. US Food and Drug Administration. Kymriah Prescribing Information. Accessed 16 December 2025. https://www.fda.gov/media/107296/download?attachment
3. European Medicines Agency. Summary of Product Characteristics: Kymriah (Tisagenlecleucel). Accessed 16 December 2025. https://www.ema.europa.eu/en/documents/product-information/kymriah-epar-product-information_en.pdf
4. Tecartus. Prescribing Information. Kite Pharma. June 2025. Accessed 16 December 2025. https://www.fda.gov/media/140409/download?attachment
5. European Medicines Agency. Summary of Product Characteristics: Tecartus (Brexucabtagene Autoleucel). Accessed 16 December 2025. https://www.ema.europa.eu/en/documents/product-information/tecartus-epar-product-information_en.pdf
6. Shah BD, Ghobadi A, Oluwole OO, et al. KTE-X19 for relapsed or refractory adult B-cell acute lymphoblastic leukaemia: phase 2 results of the single-arm, open-label, multicentre ZUMA-3 study. *Lancet*. 2021;398(10299):491-502.
7. Roddie C, Sandhu KS, Tholouli E, et al. Obecabtagene autoleucel in adults with B-cell acute lymphoblastic leukemia. *N Engl J Med*. 2024;391(23):2219-2230.
8. Castella M, Boronat A, Martín-Ibáñez R, et al. Development of a novel anti-CD19 chimeric antigen receptor: a paradigm for an affordable CAR T cell production at academic institutions. *Mol Ther Methods Clin Dev*. 2019;12:134-144.
9. Castella M, Caballero-Baños M, Ortiz-Maldonado V, et al. Point-of-care CAR T-cell production (ARI-0001) using a closed semi-automatic bioreactor: experience from an academic phase I clinical trial. *Front Immunol*. 2020;11:482.
10. Delgado J, Caballero-Baños M, Ortiz-Maldonado V, et al. Chimeric antigen receptor T cells targeting CD19 and ibrutinib for chronic lymphocytic leukemia. *HemaSphere*. 2019;3(2):e174.
11. Ortíz-Maldonado V, Rives S, Castellà M, et al. CART19-BE-01: a multicenter trial of ARI-0001 cell therapy in patients with CD19+ relapsed/refractory malignancies. *Mol Ther*. 2021;29(2):636-644.
12. Ortiz-Maldonado V, Alonso-Saladrigues A, Español-Rego M, et al. Results of ARI-0001 CART19 cell therapy in patients with relapsed/refractory CD19 -positive acute lymphoblastic leukemia with isolated extramedullary disease. *Am J Hematol*. 2022;97(6):731-739.

13. *Common Terminology Criteria for Adverse Events (CTCAE) v 5.0*. National Institutes of Health, National Cancer Institute; 2017.
14. Lee DW, Santomasso BD, Locke FL, et al. ASTCT consensus grading for cytokine release syndrome and neurologic toxicity associated with immune effector cells. *Biol Blood Marrow Transpl*. 2019;25(4):625-638.
15. Fielding AK, Richards SM, Chopra R, et al. Outcome of 609 adults after relapse of acute lymphoblastic leukemia (ALL); an MRC UKALL12/ECOG 2993 study. *Blood*. 2007;109(3):944-950.
16. Arya LS. Acute lymphoblastic leukemia: current treatment concepts. *Indian Pediatr*. 2000;37(4):397-406.
17. Crump M, Neelapu SS, Farooq U, et al. Outcomes in refractory diffuse large B-cell lymphoma: results from the international SCHOLAR-1 study. *Blood*. 2017;130(16):1800-1808.
18. Kantarjian H, Stein A, Gökbuget N, et al. Blinatumomab versus chemotherapy for advanced acute lymphoblastic leukemia. *N Engl J Med*. 2017; 376(9):836-847.
19. Kantarjian HM, DeAngelo DJ, Stelljes M, et al. Inotuzumab ozogamicin versus standard therapy for acute lymphoblastic leukemia. *N Engl J Med*. 2016; 375(8):740-753.
20. Bouchkouj N, Lin X, Wang X, et al. FDA approval summary: brexucabtagene autoleucel for treatment of adults with relapsed or refractory B-cell precursor acute lymphoblastic leukemia. *Oncologist*. 2022;27(10):892-899.
21. Bhat S, Damodar S, Mallya P, et al. Response, peak and persistence of varnimcabtagene autoleucel (IMN-003A), first-in-India industry CD19-directed CAR-T cell therapy, with fractionated infusions for patients with relapsed and/or refractory B cell malignancies: early results (IMAGINE study) [abstract]. *Blood*. 2022;140(suppl 1):7478-7479.
22. Bhat S, Damodar S, Thirumalairaj R, et al. Varnimcabtagene autoleucel (IMN-003A): pharmacokinetic profile with predominant naïve and central memory phenotype demonstrates sustained in vivo persistence and durable responses in a first-in-India industry phase-2 study (IMAGINE) [abstract]. *Blood*. 2023;142(suppl 1):6876.
23. Bhat S, Damodar S, Thirumalairaj R, et al. Modified endothelial activation and stress index (mEASIX) score and immune effector cell associated haematotoxicity (ICAHT) following varnimcabtagene autoleucel (IMN-003A), a CD19-directed chimeric antigen receptor T (CAR-T) cell therapy, in the phase-2 study (IMAGINE) [abstract]. *Blood*. 2023;142(suppl 1):6856.
24. Bhat S, Damodar S, Thirumalairaj R, et al. Varnimcabtagene autoleucel (IMN-003A): differences in T cell subset phenotype in B-ALL and B-NHL cohorts did not influence efficacy outcomes in the phase-2 study (IMAGINE) [abstract]. *Blood*. 2023;142(suppl 1):6881.
25. Bhat S, Damodar S, Thirumalairaj R, et al. Immunotherapy: IMAGINE study: interim translational outcomes of varnimcabtagene autoleucel (IMN-003A) from first-in-India phase 2 trial for anti CD19-CAR-T cell therapy for patients with relapsed/refractory B cell malignancies. *Cytotherapy*. 2023;25(6): S242-S243.
26. Bhat S, Thirumalairaj R, Raj R. Phase-2 first-in-India industry study of varnimcabtagene autoleucel (IMN-003A) in relapsed refractory B cell malignancies: B-ALL pediatric subanalysis (IMAGINE Study). *Pediatr Blood Cancer*. 2023;70(S8):e30748.
27. Damodar S, Bhat S, Nayak A, et al. Early results from a phase-2 study of varnimcabtagene autoleucel (IMN-003A), a first-in-India industry CD19-directed CAR-T cell therapy with fractionated infusions for patients with relapsed and/or refractory B cell malignancies (IMAGINE study) [abstract]. *Blood*. 2022;140(suppl 1):10343-10344.
28. Damodar S, Bhat S, Thirumalairaj R, et al. Primary analysis of varnimcabtagene autoleucel (IMN-003A) in phase 2 study (IMAGINE), a first-in-India industry CD19-directed CAR-T cell therapy for patients with relapsed refractory B cell malignancies [abstract]. *Blood*. 2023;142(suppl 1): 2104.
29. Damodar S, Thirumalairaj R, Nayak A, et al. Reinfusion of varnimcabtagene autoleucel (IMN-003A) in patients with relapsed refractory B cell malignancies is feasible with sustained responses [abstract]. *Blood*. 2023;142(suppl 1):6858.
30. Damodar S, Bhat S, Thirumalairaj R, et al. Cytokine profile following varnimcabtagene autoleucel (IMN-003A) in patients with relapsed refractory B cell malignancies in the first-in-India industry phase-2 study (IMAGINE) [abstract]. *Blood*. 2023;142(suppl 1):6862.
31. Damodar S, Bhat S, Thirumalairaj R, et al. Factors associated with refractoriness or relapse after varnimcabtagene autoleucel (IMN-003A) in patients with relapsed refractory B cell malignancies: phase 2 first-in-India industry (IMAGINE) study [abstract]. *Blood*. 2023;142(suppl 1):6879.
32. Damodar S, Bhat S, Thirumalairaj R, et al. Hypogammaglobulinemia and infection risk in relapsed refractory B cell malignancy patients treated with varnimcabtagene autoleucel (IMN-003A), a CD19-directed chimeric antigen receptor T (CAR-T) cell therapy, in the phase-2 study (IMAGINE) [abstract]. *Blood*. 2023;142(suppl 1):6853.
33. Damodar S, Thirumalairaj R, Malhotra P, et al. Phase-2 first-in-India industry study of varnimcabtagene autoleucel (IMN-003A) in relapsed refractory B cell malignancies: imagine study B-NHL subanalysis. *Hematological Oncol*. 2023;41(S2):783-784.
34. Damodar S, Bhat S, Thirumalairaj R, et al. Long-term safety and efficacy outcomes of varnimcabtagene autoleucel in relapsed refractory B cell malignancies: India phase 2 imagine study. *Transplant Cell Ther*. 2025;31(2):S228-S229.
35. Kamat A, Damodar S, Bhat S, et al. The Bengaluru Score - a prognostic predictive score for clinical efficacy outcomes based on discovery cohort of patients treated with varnimcabtagene autoleucel (IMN-003A) in the phase-2 (IMAGINE) study [abstract]. *Blood*. 2023;142(suppl 1): 6859.
36. Malhotra P, Bhat S, Damodar S, et al. Pharmacokinetic profile of varnimcabtagene autoleucel (IMN-003A), first-in-India industry CD19-directed CAR-T cell therapy for patients with relapsed/refractory B cell malignancies (IMAGINE study) [abstract]. *HemaSphere*. 2023;7(S3):e2798752. Abstract P1364.

37. Malhotra P, Damodar S, Bhat S, et al. Phase-2 study of varnimcabtagene autoleucel (IMN-003A) first-in-India industry Cd19-directed CAR-T with fractionated infusions for patients with relapsed refractory B cell malignancies: IMAGINE study [abstract]. *HemaSphere*. 2023;7(S3):e03326b2. Abstract P1409.

38. Damodar S, Bhat S, Thirumalairaj R, et al. Varnimcabtagene autoleucel demonstrates significant, sustained improvements as a first-in-India patient-reported Quality of Life outcomes in relapsed/refractory B-cell malignancies (IMAGINE Study). Milan, Italy: Paper presented at: European Hematology Association Annual Meeting; 12 June 2025.