ABCL-484

A Real-World Study of the Effectiveness and Safety of Post-Tafasitamab Chimeric Antigen Receptor T-Cell (CAR-T) Therapy in Relapsed/Refractory Diffuse Large B-Cell Lymphoma (R/R DLBCL)

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Introduction

- Recent years have seen the expansion of CD19-directed therapies for patients with relapsed/refractory diffuse large B-cell lymphoma (R/R DLBCL)
- Several chimeric antigen receptor T-cell (CAR-T) therapies, including axicabtagene ciloleucel (axi-cel), tisagenlecleucel (tisa-cel), and lisocabtagene maraleucel (liso-cel), have received United States (US) and European Union (EU) regulatory approval for the treatment of lymphoma[1]
- Tafasitamab, a CD19-directed monoclonal antibody, combined with lenalidomide, was approved in the US in 2020 and in the EU in 2021 for the treatment of adult patients with R/R DLBCL who are ineligible for autologous stem cell transplant[2,3]
- As the utilization of CD19-directed therapies increases, the optimal sequencing of these therapies needs to be explored
- There are theoretical concerns that prior exposure to anti-CD19 therapy may compromise the efficacy of subsequent CAR-T treatment due to potential impacts on CD19 antigen availability[4,5]
- Several studies have demonstrated retention of CD19 expression at the cell surface following tafasitamab;[6-8] however, real-world evidence on the effectiveness and safety of sequential use of CAR-T after tafasitamab remains limited[9-11]

Objective

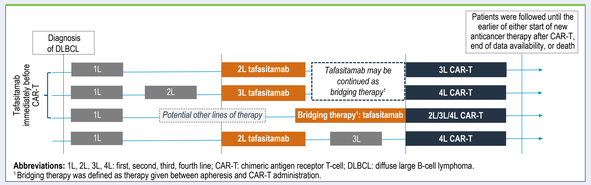
- Assess effectiveness and safety of CAR-T after tafasitamab among adult patients with R/R DLBCL

Methods

Study Design and Population (Figure 1)

- This study was a retrospective panel-based chart review conducted in the US and EU (Spain, Italy, Germany, and Austria)
- Adult patients with R/R DLBCL who received tafasitamab (± lenalidomide) and also subsequent CAR-T therapy were included
  - Patients had to have received tafasitamab (with or without lenalidomide) in second line (2L), 3L, or as bridging therapy for CAR-T
  - Patients had to have received CAR-T therapy in the 2L, 3L, or 4L setting
  - Patients were excluded from the study if they received any CD19-directed therapy other than tafasitamab for R/R DLBCL before CAR-T therapy or if they were enrolled in a clinical trial related to CAR-T therapy
- Patients were required to have at least 6 months of follow-up after CAR-T infusion, except in the event of death
- Data collection took place between October 3, 2025 and January 5, 2026
- Physicians were permitted to submit data for up to 5 eligible patients; a random number generator for patient selection was used to minimize selection bias by participating physicians

Figure 1. Study Design



Abbreviations: 1L, 2L, 3L, 4L: first, second, third, fourth line; CAR-T: chimeric antigen receptor T-cell; DLBCL: diffuse large B-cell lymphoma.
[1] Bridging therapy was defined as therapy given between apheresis and CAR-T administration.

Study Outcomes and Analyses

- Effectiveness was assessed by overall response rate (ORR), defined as the proportion of patients with physician-assessed complete response (CR) or partial response (PR) to CAR-T therapy
- Safety outcomes included the proportion of patients experiencing cytokine release syndrome (CRS) within 6 weeks and immune effector cell-associated neurotoxicity syndrome (ICANS) within 3 months after CAR-T therapy. Results were summarized across all grades and separately for severe events
- Safety outcomes were reported by the treating physician on the study case report form (CRF), without application of standardized grading
- Outcomes were summarized descriptively across all patients. Additionally, ORR was reported by CAR-T line and tafasitamab/CAR-T treatment sequence; safety outcomes were reported by CAR-T line

Results

Patient Characteristics (Table 1)

- A total of 338 patient charts were abstracted by 145 physicians (US: 73 [50.3%]; EU: 72 [49.7%])
  - Across regions, most physicians practiced in academic medical centers (57.2%).
- At the date of last known contact, which may have occurred after the end of follow-up, 247 (73.1%) patients were alive

Table 1. Patient Characteristics

	All patients N = 338
Demographic characteristics	
Age at time of CAR-T infusion, median [IQR] years	61.5 [55.1, 67.4]
Male, n (%)	223 (66.0%)
Region	
US	168 (49.7%)
EU	170 (50.3%)
Clinical characteristics at time of CAR-T infusion	
Ann Arbor stage, n (%)	
Stage I - II	66 (19.5%)
Stage III	103 (30.5%)
Stage IV	162 (47.9%)
Unknown	7 (2.1%)
Bulky disease (≥7.5 cm), n (%)	97 (28.7%)
Extranodal involvement, n (%)	99 (29.3%)
R-IPI score[1], n (%)	
0 (Very good prognosis)	8 (2.4%)
1-2 (Good prognosis)	150 (44.4%)
3-5 (Poor prognosis)	179 (53.0%)
Unknown	1 (0.3%)
Primary refractory to 1L treatment[2], n (%)	246 (72.8%)
Time from DLBCL diagnosis to CAR-T infusion, median [IQR] months	18.2 [12.4, 32.8]
Time from R/R DLBCL diagnosis to CAR-T infusion, median [IQR] months	7.7 [5.1, 13.4]
Follow-up time from CAR-T infusion, median [IQR] months	7.4 [3.3, 10.6]

Abbreviations: 1L: first line; CAR-T: chimeric antigen receptor T-cell; DLBCL: diffuse large B-cell lymphoma; ECOG: Eastern Cooperative Oncology Group; EU: European Union; IQR: interquartile range; LDH: lactate dehydrogenase; PR: partial response; R-IPI: revised International Prognostic Index; R/R: relapsed/refractory; US: United States.
Notes:
[1] R-IPI score was calculated using age, ECOG, LDH levels, Ann Arbor stage, and number of extranodal sites.[12]
[2] Primary refractory status was defined as disease progression during the course of 1L treatment, or showing a response of less than PR (i.e., progressive disease or stable disease) as best response to 1L treatment, or disease progression within ≤ 6 months from the completion of 1L.

Treatment Characteristics (Tables 2a and 2b)

- Median (interquartile range [IQR]) time from last dose of tafasitamab to CAR-T infusion was 1.2 (0.6, 2.3) months

Table 2a. Treatment Characteristics Overall

	All patients N = 338
Duration of tafasitamab treatment across all patients, median [IQR] months	4.2 [2.8, 6.1]
Time from last dose of tafasitamab to CAR-T infusion, median [IQR] months	1.2 [0.6, 2.3]
Patients who received tafasitamab as a line of therapy before CAR-T, n (%)	266 (78.7%)
Tafasitamab ORR, n (%)	179 (67.3%)
CR, n (%)	95 (35.7%)
PR, n (%)	84 (31.6%)

Abbreviations: CAR-T: chimeric antigen receptor T-cell; CR: complete response; IQR: interquartile range; ORR: overall response rate; PR: partial response.

Table 2b. Type of CAR-T Therapy Overall and by CAR-T Line

	Overall N = 338	CAR-T in 2L n = 37	CAR-T in 3L n = 243	CAR-T in 4L n = 58
Type of CAR-T, n (%)				
Axi-cel	220 (65.1%)	25 (67.6%)	153 (63.0%)	42 (72.4%)
Liso-cel	74 (21.9%)	9 (24.3%)	56 (23.0%)	9 (15.5%)
Tisa-cel	44 (13.0%)	3 (8.1%)	34 (14.0%)	7 (12.1%)

Abbreviations: 2L, 3L, 4L: second, third, fourth line; axi-cel: axicabtagene ciloleucel; CAR-T: chimeric antigen receptor T-cell; liso-cel: lisocabtagene maraleucel; tisa-cel: tisagenlecleucel.

CAR-T Effectiveness Outcomes (Table 3 and Figure 2)

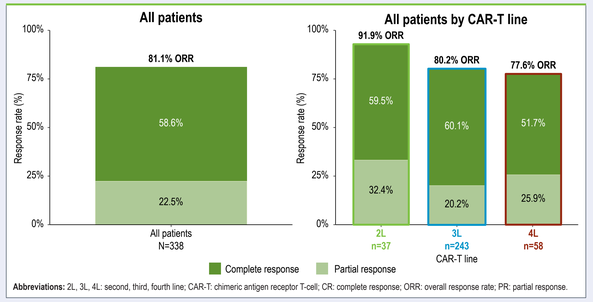
- The ORR for CAR-T after tafasitamab was 81.1% (CR: 58.6%, PR: 22.5%) overall; ORR gradually decreased with advancing lines
- Response was evaluated using PET scan and/or CT scan among 93.5% patients

Table 3. ORR to CAR-T by CAR-T Line and Treatment Sequence

	N	ORR, n (%)	CR, n (%)	PR, n (%)
Overall	**338**	274 (81.1%)	198 (58.6%)	76 (22.5%)
2L CAR-T (tafasitamab as bridging therapy)[1]	**37 (10.9%)**	**34 (91.9%)**	**22 (59.5%)**	**12 (32.4%)**
3L CAR-T	**243 (71.9%)**	**195 (80.2%)**	**146 (60.1%)**	**49 (20.2%)**
2L tafasitamab	178 (52.7%)	142 (79.8%)	112 (62.9%)	30 (16.9%)
Tafasitamab as bridging therapy	32 (9.5%)	27 (84.4%)	16 (50.0%)	11 (34.4%)
2L tafasitamab + bridging therapy[2]	33 (9.8%)	26 (78.8%)	18 (54.5%)	8 (24.2%)
4L CAR-T	**58 (17.2%)**	**45 (77.6%)**	**30 (51.7%)**	**15 (25.9%)**
2L tafasitamab	31 (9.2%)	23 (74.2%)	16 (51.6%)	7 (22.6%)
3L tafasitamab	14 (4.1%)	13 (92.9%)	8 (57.1%)	5 (35.7%)
Tafasitamab as bridging therapy	3 (0.9%)	1 (33.3%)	0 (0.0%)	1 (33.3%)
3L tafasitamab + bridging therapy[2]	10 (3.0%)	8 (80.0%)	6 (60.0%)	2 (20.0%)

Abbreviations: 2L, 3L, 4L: second, third, fourth line; CAR-T: chimeric antigen receptor T-cell; CR: complete response; ORR: overall response rate; PR: partial response.
Notes:
[1] All patients received tafasitamab as bridging therapy to CAR-T.
[2] Tafasitamab was used as both a line of therapy and as bridging therapy to CAR-T.

Figure 2. ORR to CAR-T Overall and by CAR-T Line

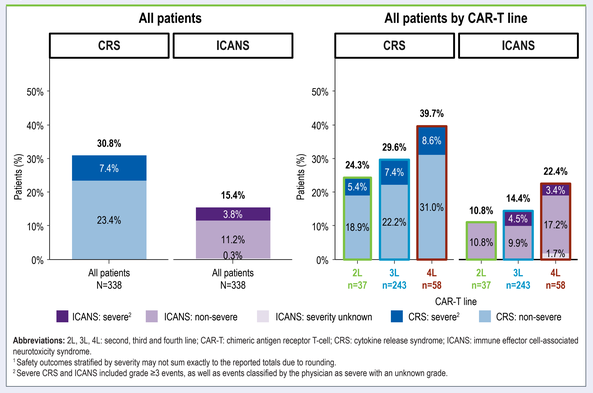


Abbreviations: 2L, 3L, 4L: second, third, fourth line; CAR-T: chimeric antigen receptor T-cell; CR: complete response; ORR: overall response rate; PR: partial response.

CAR-T Safety Outcomes (Figure 3)

- CRS occurred in 30.8% of patients, with 7.4% experiencing severe (grade ≥3) CRS. CRS occurrence was unknown in 4.7% of patients
- ICANS occurred in 15.4% of patients, with 3.8% experiencing severe (grade ≥3) ICANS. ICANS occurrence was unknown in 5.3% of patients
- Rates of CRS and ICANS for the overall study population and by CAR-T line of therapy are provided in **Figure 3**

Figure 3. CAR-T Safety Outcomes Overall and by CAR-T Line[1]



Abbreviations: 2L, 3L, 4L: second, third and fourth line; CAR-T: chimeric antigen receptor T-cell; CRS: cytokine release syndrome; ICANS: immune effector cell-associated neurotoxicity syndrome.
[1] Safety outcomes stratified by severity may not sum exactly to the reported totals due to rounding.
[2] Severe CRS and ICANS included grade ≥3 events, as well as events classified by the physician as severe with an unknown grade.

Sensitivity Analysis

- Abstracting physicians characterized 72 patients as having received tafasitamab (± lenalidomide) as bridging therapy to CAR-T
- The median (IQR) duration of tafasitamab among these patients was 3.3 (1.8, 4.2) months
- A sensitivity analysis was conducted to address the heterogeneity in treatment duration observed among these patients. Those with an apheresis date occurring after bridging initiation or those with a duration of treatment with tafasitamab of >45 days were reclassified as having received tafasitamab as a line of therapy
- Among the 72 patients originally classified as having received tafasitamab as bridging therapy, 54 (75%) were re-classified due to their CAR-T apheresis date occurring after the start of bridging therapy (40 [55.6%]) or because of tafasitamab treatment duration >45 days (14 [19.4%])
- After reclassification, the distribution of CAR-T received by line of therapy was: 2L, 9 (2.7%); 3L, 247 (73.1%); 4L, 80 (23.7%); and 5L, 2 (0.6%)
- ORR and safety outcomes for the sensitivity analysis were consistent with the results reported for the original analysis

Limitations

- This study was subject to methodological limitations which are typical for studies using real-world data:
  - There may have been missing data and gaps in the available records in patient charts. In particular, data from patient encounters with providers outside of the physicians' center may not have been comprehensively captured
- Source document verification was not conducted; however, logic and consistency checks were built into the CRF to minimize data entry errors
- Results may be impacted by lack of uniform assessment criteria for effectiveness and safety outcomes
- Results may not be generalizable to the broader DLBCL population since the physicians included in the study were not randomly selected
- Patient chart selection was susceptible to selection bias, as the inclusion of patient charts depended on record availability and site-specific documentation practices
- Follow-up duration was limited, precluding robust evaluation of longitudinal outcomes such as progression-free survival and duration of response
- Although safety and effectiveness profiles may differ across CAR-T products, outcomes were not analyzed by product

Conclusions

- **In this large, global, real-world study, prior exposure to tafasitamab did not appear to compromise the effectiveness or safety of subsequent CAR-T therapy in patients with R/R DLBCL. Outcomes for CAR-T therapy were largely comparable with prior real-world evidence**[13,14]
- **These findings are particularly relevant in the context of the evolving DLBCL treatment landscape, including emerging front-line tafasitamab data and the potential impact of prior tafasitamab exposure on later-line treatment sequencing**[15]
- **While these real-world results should be interpreted in the context of an observational cohort, these data support tafasitamab followed by CAR-T therapy as a viable treatment sequencing strategy in clinical practice**

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Conflicts of Interest

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