ABCL-207

Real-World Use of Tafasitamab for Relapsed or Refractory Diffuse Large B-Cell Lymphoma in the United States by Primary Refractory Status

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Objective

- The purpose of this analysis was to report characteristics, treatment patterns, and outcomes by primary refractory status, among patients who received tafasitamab for R/R DLBCL identified as part of a previously reported RWS[4]

Conclusions

- **In this RWS, more than a quarter of patients had primary refractory DLBCL**
- **Findings from this RWS show that the response rates to tafasitamab were favorable among patients with primary refractory and nonprimary refractory DLBCL**
- **Longer follow-up is required to evaluate long-term outcomes with tafasitamab among patients with primary refractory DLBCL**

Abbreviations

ASCT, autologous stem cell transplant; CAR-T, chimeric antigen receptor T cell; CI, confidence interval; DLBCL, diffuse large B-cell lymphoma; OPEN, Oncology Provider Extended Network; Q1, first quartile; Q3, third quartile; R/R, relapsed or refractory; RWS, real-world study.

Disclosures

Saverno, Galvin, Amoloja: Employment and stock ownership – *Incyte Corporation.*
Zimmerman Savill: Former employment and stock ownership – *Cardinal Health.*
Feinberg, Pathak: Employment and stock ownership – *Cardinal Health.*
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Introduction

- DLBCL is an aggressive form of lymphoma with highly variable prognoses[1]
  - Patients with primary refractory or early relapsed disease tend to have poor outcomes in second line and beyond
- Tafasitamab is a CD19-targeting immunotherapy, which received accelerated approval by the US Food and Drug Administration in combination with lenalidomide for the treatment of patients with R/R DLBCL ineligible for ASCT[2,3]
- In a recent US RWS of tafasitamab for R/R DLBCL, over 1 in 4 patients receiving tafasitamab had primary refractory disease[4]
  - Here, we report results from this RWS according to patients' primary refractory status

Methods

Study Design and Data Source

- Retrospective, multisite, medical chart review
- Physicians from Cardinal Health's Oncology Provider Extended Network (OPEN) abstracted demographic, clinical, treatment, and outcomes-related data from eligible patients' medical records into electronic case report forms
  - OPEN is a community of >7000 oncologists/hematologists based in private practices and hospitals across the United States
- Data collection occurred between February 22, 2023, and March 29, 2023

Eligibility Criteria

- Patient selection criteria are summarized in **Table 1**

Table 1. Patient Selection Criteria

Inclusion Criteria	• Initiation of tafasitamab for R/R DLBCL on or after October 21, 2020* • Age ≥18 years at tafasitamab initiation • ≥4 months of follow-up since tafasitamab initiation (otherwise eligible patients who died during this 4-month interval were still eligible)
Exclusion Criteria	• Received tafasitamab as part of an interventional clinical trial

*Concomitant use of lenalidomide was not a requirement for study eligibility.

Statistical Analysis

- Results were summarized by patients' primary refractory status using descriptive statistics
  - Primary refractory disease was defined as disease that progressed while receiving or within 6 months after completing first-line therapy
- The Kaplan-Meier method was used to measure time-to-event outcomes (eg, duration of treatment)

Results

Prescriber Characteristics

- The final dataset of 181 patients was contributed by 23 providers across the United States (83% [n=19] from community oncology practices)
  - Twenty-four physicians contributed data on 182 patients; 1 patient received tafasitamab monotherapy only as bridge therapy for CAR-T and was excluded from the study
- The majority of providers were located in urban (48%; n=11) and suburban settings (39%; n=9)

Patient Demographics and Characteristics

- A total of 181 patients initiated tafasitamab treatment for R/R DLBCL
- Patient characteristics by primary refractory status are summarized in **Table 2**

Table 2. Demographic and Clinical Characteristics of Patients Who Received Tafasitamab for R/R DLBCL by Primary Refractory Status

Variable	Primary Refractory (n=47)	Nonprimary Refractory (n=134)
Sex at birth, male, n (%)	24 (51.1)	78 (58.2)
Age at tafasitamab initiation, median (Q1-Q3), year	72.3 (64.0-77.3)	71.1 (65.7-75.2)
Time from diagnosis to tafasitamab initiation, median (Q1-Q3), months	10.2 (7.1-19.7)	23.8 (16.7-45.6)
ECOG PS at tafasitamab initiation, n (%)		
0-1	27 (57.4)	68 (50.7)
≥2	20 (42.6)	66 (49.3)
Ann Arbor stage at tafasitamab initiation, n (%)		
I	0	0
II	2 (4.3)	8 (6.0)
III	13 (27.7)	45 (33.6)
IV	31 (66.0)	80 (59.7)
Unknown	1 (2.1)	1 (0.7)
R-IPI score at tafasitamab initiation, n (% of patients with data available)		
0	0	0
1-2	8 (17.4)	25 (20.3)
3-5	38 (82.6)	98 (79.7)

ECOG PS, Eastern Cooperative Oncology Group performance status; R-IPI, revised International Prognostic Index.

Treatment and Utilization Patterns

- The median (Q1-Q3) follow-up time from tafasitamab initiation to data collection for the overall study population was 6.5 (5.0-8.6) months
- Treatment and utilization patterns are summarized in **Table 3**

Table 3. Treatment Patterns in Patients Who Received Tafasitamab for R/R DLBCL by Primary Refractory Status

Variable	Primary Refractory (n=47)	Nonprimary Refractory (n=134)
Line of therapy in which tafasitamab was received, n (%)		
2	33 (70.2)	97 (72.4)
3	13 (27.7)	30 (22.4)
4+	1 (2.1)	7 (5.2)
Received ASCT prior to tafasitamab, n (%)	4 (8.5)	17 (12.7)
Received CAR-T therapy prior to tafasitamab, n (%)	3 (6.4)	3 (2.2)
Duration of tafasitamab treatment, median (95% CI), months	11.0 (5.8-14.1)	11.9 (10.5-16.8)
Duration of follow-up from tafasitamab initiation, median (Q1-Q3), months	5.7 (4.6-7.6)	6.5 (5.1-9.2)

- Most patients (96%) received tafasitamab in combination with lenalidomide
- At the time of data abstraction, 74% of patients (n=35) with primary refractory disease and 81% (n=109) with nonprimary refractory disease were still alive, of whom 77% (n=27) and 86% (n=94) were still receiving tafasitamab, respectively
- Of the patients who had discontinued tafasitamab treatment at the time of data abstraction, 65% (n=13) with primary refractory and 68% (n=27) with nonprimary refractory disease did so due to disease progression (confirmed by scan or defined clinically)

Treatment Outcomes

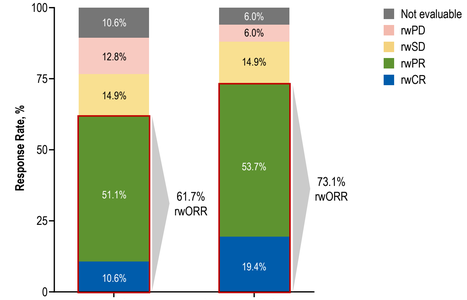
- Real-world overall response rate (95% CI) among patients is presented in **Table 4** and **Figure 1**

Table 4. Treatment Outcomes in Patients Who Received Tafasitamab for R/R DLBCL by Primary Refractory Status

Variable	Primary Refractory (n=47)	Nonprimary Refractory (n=134)
Disease response		
rwORR (95% CI), %	61.7 (47.8-75.6)	73.1 (65.6-80.6)
rwCR (95% CI), %	10.6 (1.8-19.5)	19.4 (12.7-26.1)
Response criteria utilized for best response (n, % among those with best response available)*		
Cheson 2007	15 (35.7)	30 (23.8)
Lugano	26 (61.9)	96 (76.2)
Other	1 (2.4)	0

*Categories not mutually exclusive, and thus may not total to 100%.
rwCR, real-world complete response; rwORR, real-world overall response rate.

Figure 1. Real-World Best Responses Among Patients Who Received Tafasitamab for R/R DLBCL by Primary Refractory Status



rwCR, real-world complete response; rwORR, real-world overall response rate; rwPD, real-world progressive disease; rwPR, real-world partial response; rwSD, real-world stable disease.

Study Limitations

- RWS analyses are susceptible to biases introduced by missing/underreporting data (eg, events that happened outside of the clinical setting may not have been reported, loss to follow-up)
- The median follow-up time was relatively short (6.5 months), and many patients were still on tafasitamab at time of data collection
- The observed treatment patterns may not be reflective of all oncology care centers or physicians managing patients with DLBCL
- Source document verification was not conducted; however, all physicians were required to submit to data validation checks
- Study findings may have been impacted by the lack of uniform assessment criteria for variables such as disease response