Notice

• The data and conclusions of the following referenced presentations and/or publications are those of the author(s) and are provided as they were presented and/or published
• Some information contained in this presentation may not be included in the approved Prescribing Information for MONJUVI. This presentation is not intended to offer recommendations for any administration, indication, dosage, or other use for MONJUVI in a manner inconsistent with the approved Prescribing Information

Indications and Usage
• MONJUVI (tafasitamab-cxix), in combination with lenalidomide, is indicated for the treatment of adult patients with relapsed or refractory DLBCL not otherwise specified, including DLBCL arising from low grade lymphoma, and who are not eligible for autologous stem cell transplant (ASCT)
• This indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).
Tafasitamab for the Treatment of Relapsed or Refractory Diffuse Large B-Cell Lymphoma in the US Real-World Setting

Kim Saverno,¹ Kristin M. Zimmerman Savill,² Bruce Feinberg,² John Galvin,¹ Prathamesh Pathak,² Sarah Gordon,² Theresa Amoloja,¹ Narendranath Epperla,³ Loretta J. Nastoupil⁴

¹Incyte Corporation, Wilmington, DE, USA; ²Cardinal Health, Dublin, OH, USA; ³The Ohio State University, Columbus, OH, USA; ⁴The University of Texas MD Anderson Cancer Center, Houston, TX, USA

Presented at the 65th ASH Annual Meeting & Exposition • San Diego, CA, USA • December 9-12, 2023 (Presentation 265)

FOR MEDICAL INFORMATION PURPOSES ONLY. NOT FOR PROMOTIONAL USE. DO NOT COPY, DISTRIBUTE OR OTHERWISE REPRODUCE.
Background

- Approximately 30-40% of patients with DLBCL have disease that relapses or is refractory to first-line treatment\(^1,2\)
- The number of therapies in relapsed or refractory settings has increased significantly in the past few years
- Tafasitamab is a CD19-targeting immunotherapy indicated in combination with lenalidomide for the treatment of adult patients with R/R DLBCL ineligible for ASCT\(^3\)
- The 2020 US Food and Drug Administration–accelerated approval of tafasitamab in this setting was based on findings from L-MIND, a multicenter, open-label, single-arm, phase 2 trial\(^4\)
- Since this approval, there has been a paucity of RWS evaluating the outcomes of patients with R/R DLBCL who received tafasitamab in the community setting
- This study describes patient characteristics, treatment patterns, and real-world outcomes associated with tafasitamab for R/R DLBCL across practice settings in the United States

1. Sarkozy C, Sehn LH. Ann Lymphoma. 2019;3:10. 2. Sehn LH, et al. N Engl J Med. 2021;384:842-58. 3. MONJUVI. Prescribing information. MorphoSys US Inc.; 2020. 4. Salles G, et al. Lancet Oncol. 2020;21:978-88. ASCT, autologous stem cell transplantation; DLBCL, diffuse large B-cell lymphoma; R/R, relapsed or refractory; RWS, real-world studies.
Study Objectives

Primary Objectives

- Among patients who received tafasitamab for the treatment of R/R DLBCL in a real-world setting, describe:
  - Patient demographic and clinical characteristics
  - Treatment patterns since initial DLBCL diagnosis
  - Utilization patterns associated with tafasitamab + lenalidomide

Exploratory Objective

- Clinical effectiveness among patients with R/R DLBCL who received tafasitamab in a real-world setting

DLBCL, diffuse large B-cell lymphoma; R/R, relapsed or refractory.

FOR MEDICAL INFORMATION PURPOSES ONLY. NOT FOR PROMOTIONAL USE. DO NOT COPY, DISTRIBUTE OR OTHERWISE REPRODUCE.
Methods

Study Design

- A retrospective, physician-abstracted, multisite, medical chart review

- Physicians from the Cardinal Health Oncology Provider Extended Network (OPEN) abstracted data for eligible patients into electronic case report forms (eCRFs) between February 22, 2023, and March 29, 2023

Data Source

- Cardinal Health’s OPEN is a community of >7000 private practice and hospital-based oncologists/hematologists across the United States, including approximately 800 composing the real-world research community

- The network is geographically diverse, electronic medical record/group purchasing organization agnostic, and inclusive of multiple settings of community oncology care
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)
- Concomitant use of lenalidomide was not a requirement for study eligibility

**Exclusion Criteria**
- Received tafasitamab as a part of an interventional clinical trial

DLBCL, diffuse large B-cell lymphoma; R/R, relapsed or refractory.
Participating Prescribers

- 24 physicians/sites across the United States contributed patient data
- Approximately 83% (n=20) of participating physicians were from community oncology practices
- US region of practice included:
  - Northeast (20.8%)
  - Midwest (16.7%)
  - South (41.7%)
  - West (20.8%)
- 79.2% (n=19) of responding physicians had reported having a CAR-T infusion center within 60 miles of their practice

CAR-T, chimeric antigen receptor T cell.
Patient Demographics

| Characteristic                                | All Patients (N=181) | Tafasitamab 2L (n=130) | Tafasitamab 3L (n=43) |
|-----------------------------------------------|----------------------|------------------------|-----------------------|
| Sex at birth, male, n (%)                    | 102 (56.4)           | 68 (52.3)              | 30 (69.8)             |
| Age at tafasitamab initiation, years, median (IQR) | 71.1 (65.0-75.5)     | 72.1 (67.2-77.1)       | 67.7 (62.2-73.9)      |
| Race, n (%)                                   |                      |                        |                       |
| White                                         | 116 (64.1)           | 80 (61.5)              | 29 (67.4)             |
| Black                                         | 40 (22.1)            | 31 (23.8)              | 9 (20.9)              |
| Asian                                         | 11 (6.1)             | 10 (7.7)               | 1 (2.3)               |
| Other*                                        | 3 (1.7)              | 2 (1.5)                | 1 (2.3)               |
| Unknown                                       | 11 (6.1)             | 7 (5.4)                | 3 (7.0)               |
| Ethnicity, n (%)                              |                      |                        |                       |
| Hispanic/Latino/Latina                        | 31 (17.1)            | 20 (15.4)              | 8 (18.6)              |
| Non-Hispanic/Non-Latino/Non-Latina           | 149 (82.3)           | 109 (83.8)             | 35 (81.4)             |
| Unknown                                       | 1 (0.6)              | 1 (0.8)                | 0                     |

- The median follow-up time since initiating tafasitamab for the overall study population was 6.5 (range, 0.9-27.4) months

*Including Native Hawaiian or Other Pacific Islander, American Indian or Alaska Native, or mixed race (Alaska Native + Asian + Black).
2L, second line; 3L, third line; IQR, interquartile range.

FOR MEDICAL INFORMATION PURPOSES ONLY. NOT FOR PROMOTIONAL USE. DO NOT COPY, DISTRIBUTE OR OTHERWISE REPRODUCE.
| Characteristic                                                                 | All Patients (N=181) | Tafasitamab 2L (n=130) | Tafasitamab 3L (n=43) |
|--------------------------------------------------------------------------------|----------------------|------------------------|-----------------------|
| **ECOG PS at tafasitamab initiation, n (%)**                                    |                      |                        |                       |
| 0-1                                                                            | 95 (52.5)            | 69 (53.1)              | 21 (48.8)             |
| ≥2                                                                             | 86 (47.5)            | 61 (46.9)              | 22 (51.2)             |
| **Ann Arbor stage at tafasitamab initiation, n (%)**                           |                      |                        |                       |
| Stage I/II                                                                     | 10 (5.5)             | 9 (6.9)                | 1 (2.3)               |
| Stage III                                                                      | 58 (32.0)            | 50 (38.5)              | 7 (16.3)              |
| Stage IV                                                                       | 111 (61.3)           | 70 (53.8)              | 35 (81.4)             |
| Unknown                                                                        | 2 (1.1)              | 1 (0.8)                | 0                     |
| **R-IPI at tafasitamab initiation, n (% of patients with data available)***     |                      |                        |                       |
| 1-2 (good prognosis)                                                           | 33 (19.5)            | 22 (18.3)              | 8 (19.0)              |
| 3-5 (poor prognosis)                                                           | 136 (80.5)           | 98 (81.7)              | 34 (81.0)             |
| **Double-hit or triple-hit at tafasitamab initiation, n (%)**                  |                      |                        |                       |
| Yes, double-/triple-hit                                                        | 22 (12.2)            | 14 (10.8)              | 8 (18.6)              |
| Tested, found to be negative                                                    | 130 (71.8)           | 103 (79.2)             | 26 (60.5)             |
| Unknown                                                                        | 29 (16.0)            | 13 (10.0)              | 9 (20.9)              |
| **Cell of origin information, n (%)**                                          |                      |                        |                       |
| GCB                                                                            | 81 (44.8)            | 60 (46.2)              | 17 (39.5)             |
| Non-GCB/ABC                                                                    | 39 (21.5)            | 28 (21.5)              | 9 (20.9)              |
| Unknown                                                                        | 61 (33.7)            | 42 (32.3)              | 17 (39.5)             |
| **Refractory to line prior to tafasitamab†**                                   | 59 (32.6)            | 33 (25.4)              | 19 (44.2)             |

*There were no patients with an R-IPI score of 0 (very good prognosis) at tafasitamab initiation. †Defined as disease progression while receiving line of therapy prior to tafasitamab or disease progression occurring ≤8 months after the completion of the line of therapy prior to tafasitamab.

2L, second line; 3L, third line; ABC, activated B cell; GCB, germinal center B cell; ECOG PS, Eastern Cooperative Oncology Group performance status; R-IPI, revised International Prognostic Index.

FOR MEDICAL INFORMATION PURPOSES ONLY. NOT FOR PROMOTIONAL USE. DO NOT COPY, DISTRIBUTE OR OTHERWISE REPRODUCE.
Primary Refractory* and Early Relapse† Status

*Defined as disease progression while receiving first-line therapy or disease progression occurring ≤6 months after the completion of first-line therapy.

†Defined as disease progression while receiving first-line therapy or disease progression occurring ≤12 months after the completion of first-line therapy.

2L, second line; 3L, third line.

FOR MEDICAL INFORMATION PURPOSES ONLY. NOT FOR PROMOTIONAL USE. DO NOT COPY, DISTRIBUTE OR OTHERWISE REPRODUCE.
Treatment and Utilization Patterns

- At data collection (median follow-up time of 6.5 months), 80% (n=144) of patients were still alive, of whom 84% (n=121) were still receiving tafasitamab

- Among the 60 patients who discontinued tafasitamab, reasons for discontinuation included progression confirmed by scan (50%), progression defined clinically (17%), toxicity (15%), patient/caregiver request (3%), complete response (2%), and other reasons (13%)

|                          | All Patients (N=181) |
|--------------------------|----------------------|
| Prior ASCT therapy, n (%)| 21 (11.6)            |
| Prior CAR-T therapy, n (%)| 6 (3.3)              |
| Subsequent CAR-T therapy, n (%)| 5 (2.8)            |
During treatment, 33 patients (19%) had ≥1 lenalidomide dose reduction

- The most common reasons for any dose reductions were neutropenia (73%), thrombocytopenia (33%), performance status/patient frailty (27%), and renal dysfunction (18%)
Real-World Best Response

- Response criteria used for assessing best response (% among those with best response available) included: Cheson 2007 (26.8%), Lugano (72.6%), and other (0.6%)

*Patient denominators represent those with available best disease response data.
2L, second line; 3L, third line; 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.

FOR MEDICAL INFORMATION PURPOSES ONLY. NOT FOR PROMOTIONAL USE. DO NOT COPY, DISTRIBUTE OR OTHERWISE REPRODUCE.
Real-World Progression-Free Survival (rwPFS)

### Probability of rwPFS at Various Time Points From Time of Tafasitamab Initiation

|                      | All Patients (N=181) | Tafasitamab 2L (n=130) | Tafasitamab 3L (n=43) |
|----------------------|----------------------|------------------------|-----------------------|
| **3-month rwPFS probability** |                      |                        |                       |
| Point-estimate       | 0.93                 | 0.92                   | 0.95                  |
| (lower 95%-upper 95%) | (0.88-0.96)           | (0.86-0.96)            | (0.83-0.99)           |
| **6-month rwPFS probability** |                      |                        |                       |
| Point-estimate       | 0.80                 | 0.83                   | 0.72                  |
| (lower 95%-upper 95%) | (0.73-0.85)           | (0.75-0.89)            | (0.54-0.84)           |
Study Limitations

- The median follow-up time was relatively short (6.5 months), and many patients were still on tafasitamab at time of data collection.
- As with any RWS, this study may be limited by unobserved data and missing data bias.
- Source document verification was not conducted; however, all physicians were required to submit to data validation checks.
- The study included data abstracted by a limited number of oncologists (n=24).
  - Treatment patterns may not reflect those of all oncologists managing patients with DLBCL.
- Findings from this study may be impacted by a lack of uniform assessment criteria for certain variables such as disease response.

DLBCL, diffuse large B-cell lymphoma; RWS, real-world study.
Authors’ Conclusions

- Findings from this real-world analysis support the clinical benefit of tafasitamab when used in early lines of treatment of R/R DLBCL, as demonstrated in L-MIND\textsuperscript{1,2}
- The study included a racially and ethnically diverse patient population; nearly one-third of patients were from typically underrepresented racial groups and approximately one-sixth were of Hispanic ethnicity
- Patients were treated predominantly at community oncology settings, where most treatment for DLBCL is administered in the United States
- Most patients were still on tafasitamab at the time of data collection and follow-up was limited in duration
- Longer follow-up of these patients is warranted to better understand long-term outcomes of tafasitamab and treatment sequencing among this diverse patient population