MONJUVI® (tafasitamab-cxix) in Relapsed/Refractory Diffuse Large B-Cell Lymphoma and Follicular Lymphoma

MSL-TAF-US-0005 6/25

Notice

- 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.

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Indications and Usage[1]

- Monjuvi (tafasitamab-cxix) is a CD19-directed cytolytic antibody indicated:
  - In combination with lenalidomide for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (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)
  - In combination with lenalidomide and rituximab for the treatment of adult patients with relapsed or refractory follicular lymphoma
    - Limitations of Use: Monjuvi is not indicated and is not recommended for the treatment of patients with relapsed or refractory marginal zone lymphoma outside of controlled clinical trials
- Please see the Full Prescribing Information, including Warnings & Precautions, and Patient Information

1. Monjuvi® (tafasitamab-cxix). Prescribing information. Incyte Corporation; June 2025.

Presentation Overview

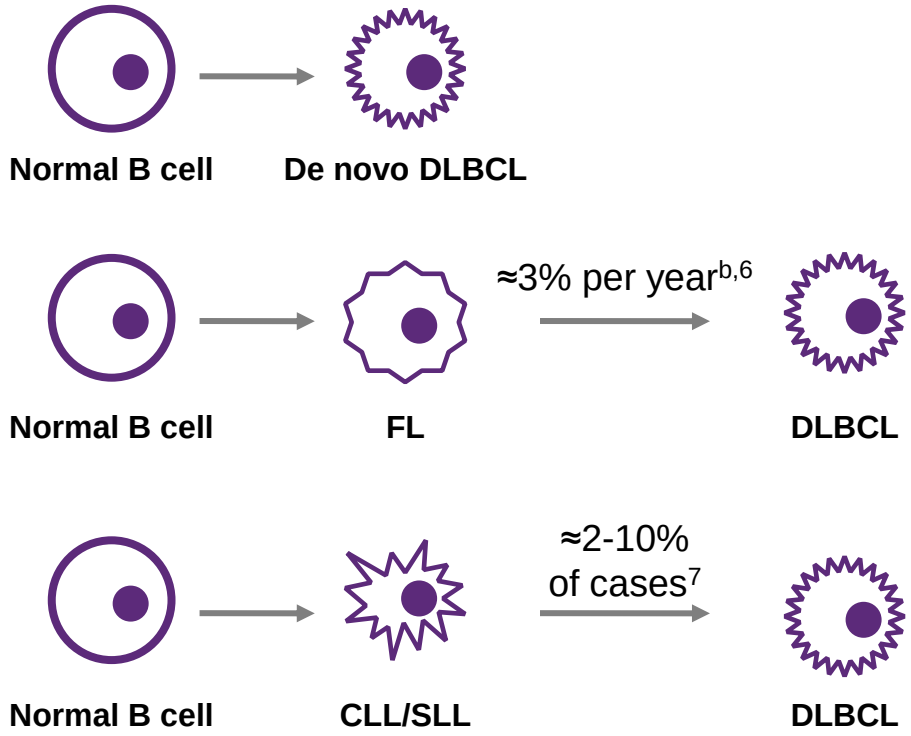
Click the section tab of interest to be taken to the corresponding portion of the deck

DLBCL Disease State Overview

Diffuse Large B-Cell Lymphoma

- DLBCL is the most common type of lymphoma (25% of NHL cases), with approximately 28,000 new cases per year in the US[1,a]
- DLBCL can arise either de novo or from progression or transformation of other types of lymphoma, including CLL/SLL, FL, MZL, and nodal lymphocyte predominant Hodgkin lymphoma[2]
- The CD19 protein, expressed on the surface of B-cell lymphomas, represents a potential therapeutic target for DLBCL[3]
- Without treatment, DLBCL evolves into symptomatic disease that is fatal[4]
- Despite the utility of R-CHOP in the 1L setting, ≈15-25% of patients exhibit primary refractory disease, while an additional 20-30% relapse following initial response to therapy[5]
  - Most relapses occur <2 years after 1L therapy[4]

Examples of DLBCL Development[2]



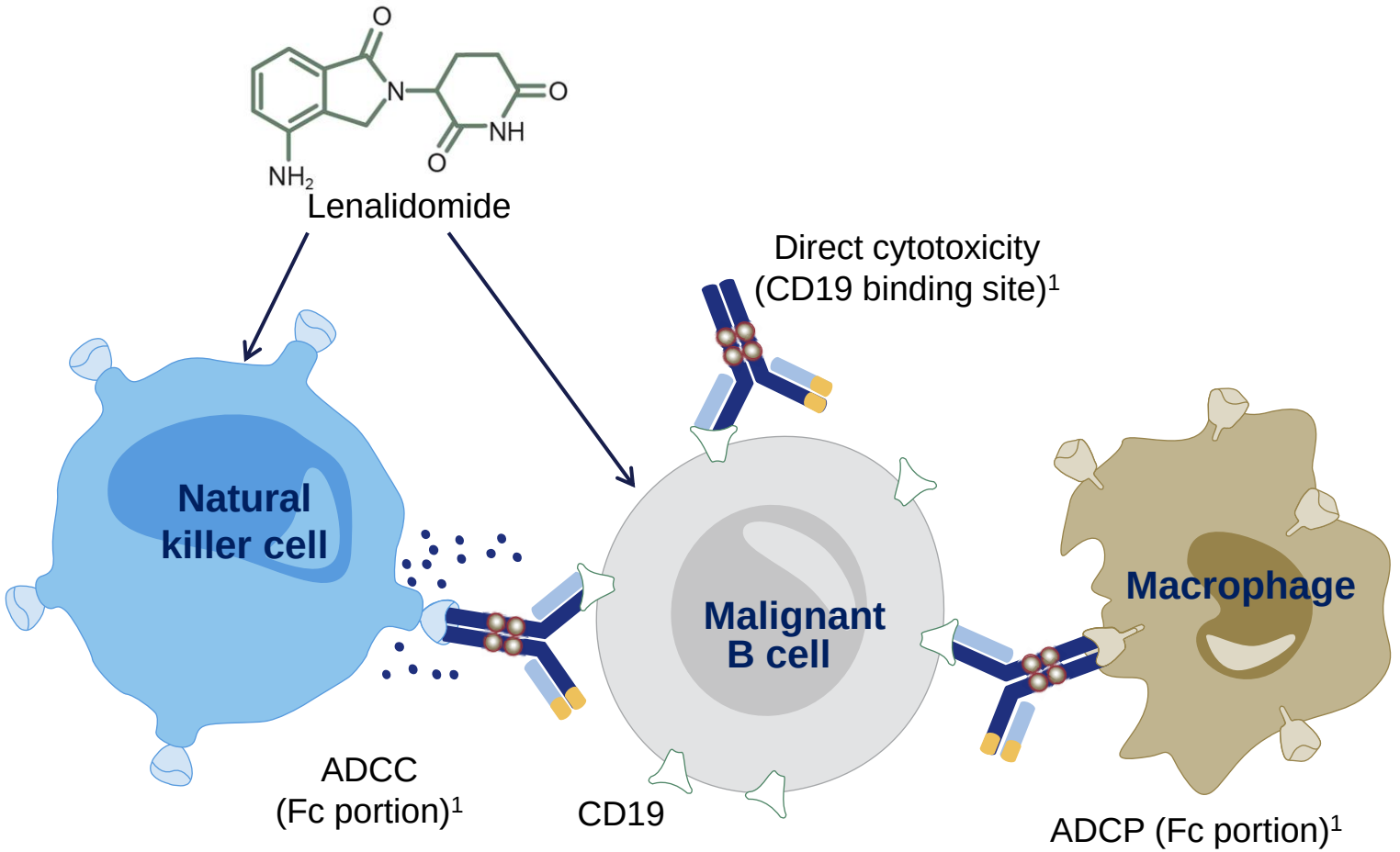
[a] Incidence data from 1995 onward were compiled by the North American Association of Central Cancer Registries from cancer registries that participate in the Centers for Disease Control and Prevention National Program of Cancer Registries or the SEER program. Incidence data from 45 US states and the District of Columbia were used to provide incidence rates during 2011 through 2012 by lymphoma subtype. [b] Cumulative transformation rate.

1L, first-line; R-CHOP, rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone; SLL, small lymphocytic lymphoma.

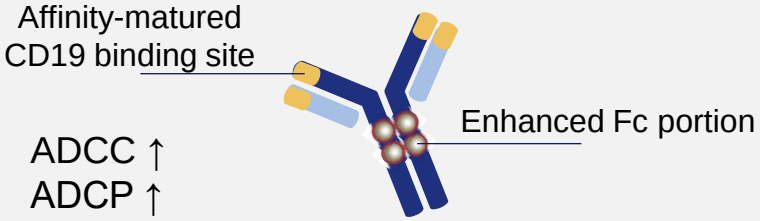
1. Teras LR, et al. *CA Cancer J Clin.* 2016;66:443-459. 2. Martelli M, et al. *Crit Rev Oncol Hematol*. 2013;87:146-171. 3. Horton HM, et al. *Cancer Res.* 2008;68:8049-8057. 4. Sehn L, Gascoyne RD. *Blood.* 2015;125:22-32. 5. Coiffier B, Sarkozy C. *Hematology Am Soc Hematol Educ Program*. 2016(1):366-378. 6. Lossos IS, Gascoyne RD. *Best Pract Res Clin Haematol.* 2011;24:147-163. 7. Jain P, O'Brien S. *Oncology (Williston Park)*. 2012;26(12):1146-1152.

Tafasitamab-cxix Clinical Efficacy and Safety in R/R DLBCL

Tafasitamab-cxix and Lenalidomide Combination



Tafasitamab-cxix (Fc-modified, anti-CD19 mAb)[1–3]



- ADCC ↑
- ADCP ↑
- Direct cell death
- Encouraging single-agent activity in patients with R/R DLBCL and iNHL

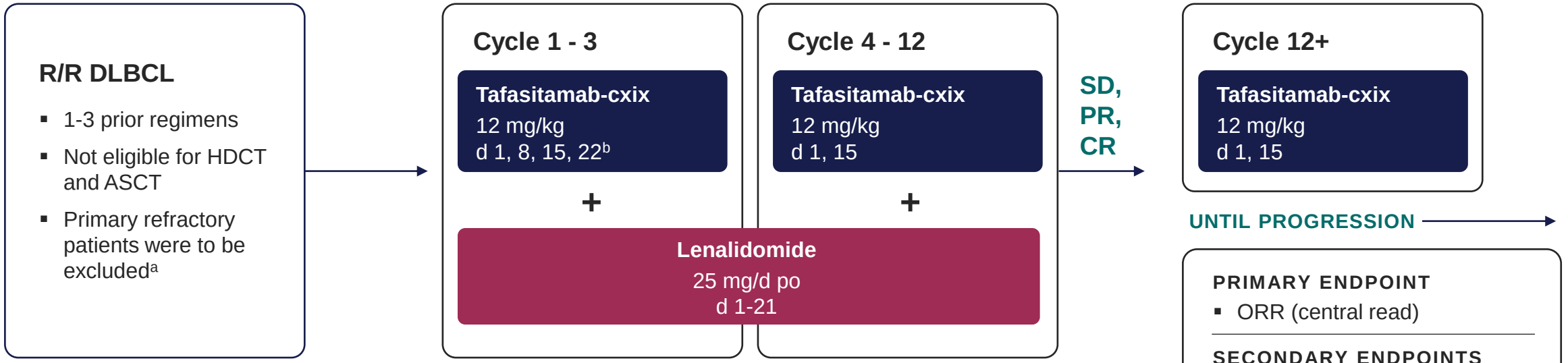
- T-cell and NK-cell activation/expansion
- Direct cell death
- Well-studied as an anti-lymphoma agent, alone or in combination

ADCC, antibody-dependent cellular cytotoxicity; ADCP, antibody-dependent cellular phagocytosis; iNHL, indolent non-Hodgkin's lymphoma.

1. Horton HM et al. *Cancer Res* 2008;68(19):8049–57; 2. Woyach JA et al. *Blood* 2014;124(24):3553–60; 3. Jurczak W et al. *Ann Oncol* 2018;29(5):1266–72; 4. Witzig TE et al. *Ann Oncol* 2015; 26(8):1667–77; 5. Czuczman MS et al. *Clin Cancer Res* 2017;23(15):4127–37.

L-MIND: Study Design

Phase 2, single-arm, open-label, multicenter study (NCT02399085)



Sample size suitable to detect ≥15% absolute increase in ORR for tafasitamab-cxix/LEN combination versus LEN monotherapy at 85% power, 2-sided alpha of 5%

Mature data: primary endpoint analysis with data cut-off of Nov 30, 2018; minimum follow-up for primary endpoint 12 months, median follow-up 13.2 months

PRIMARY ENDPOINT

- ORR (central read)

SECONDARY ENDPOINTS

- PFS
- DoR
- OS
- Safety of the tafasitamab-cxix + LEN combination
- Exploratory and biomarker-based analyses

Response assessment (Cheson 2007 Criteria) was after cycles 2, 4, 6, 9 and 12, thereafter every 3 cycles.

[a] Primary refractory DLBCL was defined as no response to or progression/relapse during or within 6 months of frontline therapy.

[b] A loading dose of tafasitamab-cxix was administered on day 4 of cycle 1

DoR, duration of response; HDCT, high-dose chemotherapy; LEN, lenalidomide; ORR, objective response rate; PFS, progression-free survival; po, per os; SD, stable disease; PR, partial response; CR, complete response.

Salles G, et al. *Lancet Oncol*. 2020;21(7):978-988.

L-MIND: Baseline Characteristics

Baseline Characteristic	Patients (n = 71)
Median age, years (range)	71 (41-86)
Sex, Male	55%
Received previous anti-CD20 therapy	100%
Race (n=65)[a]	
White	95%
Asian	3%
Previous lines of systemic therapy	
Median	2
1	49%
2-4	51%
Refractory Disease, % (n)	
Primary refractory	20% (14)
Refractory to last prior therapy	45% (32)
Refractory to rituximab	42% (30)
Prior ASCT, % (n)	13% (9)
Primary reasons patients were not candidates for ASCT, %:	
Age	47%
Refractoriness to salvage chemotherapy	27%
Comorbidities	13%
Refusal of high dose chemotherapy/ASCT	13%

ASCT, autologous stem cell transplantation.

[a]Race was collected in 92% of patients.

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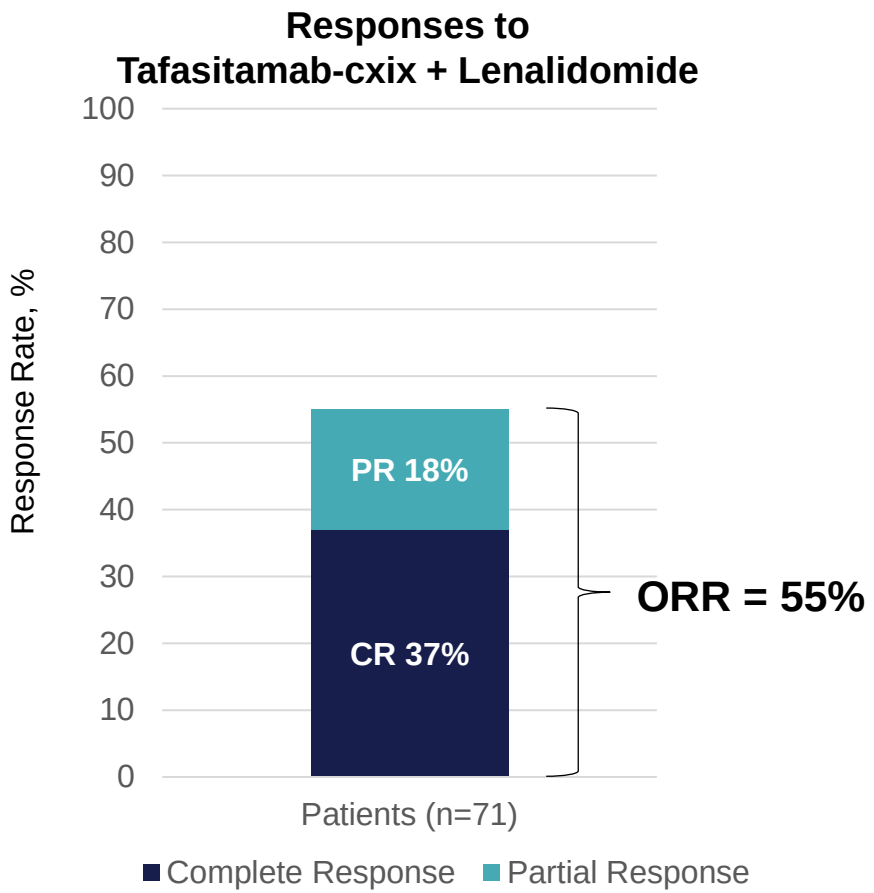
Overall Response Rate and Duration of Response[1]

- Efficacy was established based on best ORR, defined as the proportion of complete and partial responders and DoR, as assessed by an Independent Review Committee (IRC) using IWG Response Criteria[2]



Patients (n = 71)	
Best overall response rate, n (%)	39 (55%)
(95% CI)	(43%, 67%)
Complete response rate	37%
Partial response rate	18%
Duration of Response	
Median (range) in months[a]	21.7 (0, 24)

[a]Kaplan-Meier estimates.

1. Monjuvi® (tafasitamab-cxix). Prescribing information. Incyte Corporation; June 2025 2. Cheson B, et al. J Clin Oncol. 2007;25:579-586.

Safety: Exposure, SAEs, and Fatal Adverse Events

- **Serious adverse events** occurred in 52% of patients
  - SAEs that occurred in ≥6% of patients:
    - Infections (26%), including pneumonia (7%) and febrile neutropenia (6%)
- **Fatal adverse events** occurred in 5% of patients
  - Cerebrovascular accident (1.2%)
  - Respiratory failure (1.2%)
  - PML (1.2%)
  - Sudden death (1.2%)

Tafasitamab-cxix exposure in the L-MIND study (N=81)

57%: 6 months or longer

⇩

42%: > 1 year

⇩

24%: > 2 years

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Safety: Discontinuation and Dosage Interruptions

- **Permanent discontinuation** of tafasitamab-cxix or lenalidomide due to an adverse reaction occurred in 25% of patients
  - Permanent discontinuation of tafasitamab-cxix due to an adverse reaction occurred in 15%
    - Most frequent adverse reactions that resulted in permanent discontinuation
      - Infections and infestations (5%)
      - Nervous system disorders (2.5%)
      - Respiratory, thoracic and mediastinal disorders (2.5%)
- **Dosage interruptions** of tafasitamab-cxix or lenalidomide due to an adverse reaction occurred in 69% of patients
  - Dosage interruption of tafasitamab-cxix due to an adverse reaction occurred in 65%
    - Most frequent adverse reactions requiring dosage interruption:
      - Blood and lymphatic system disorders (41%)
      - Infections and infestations (27%)

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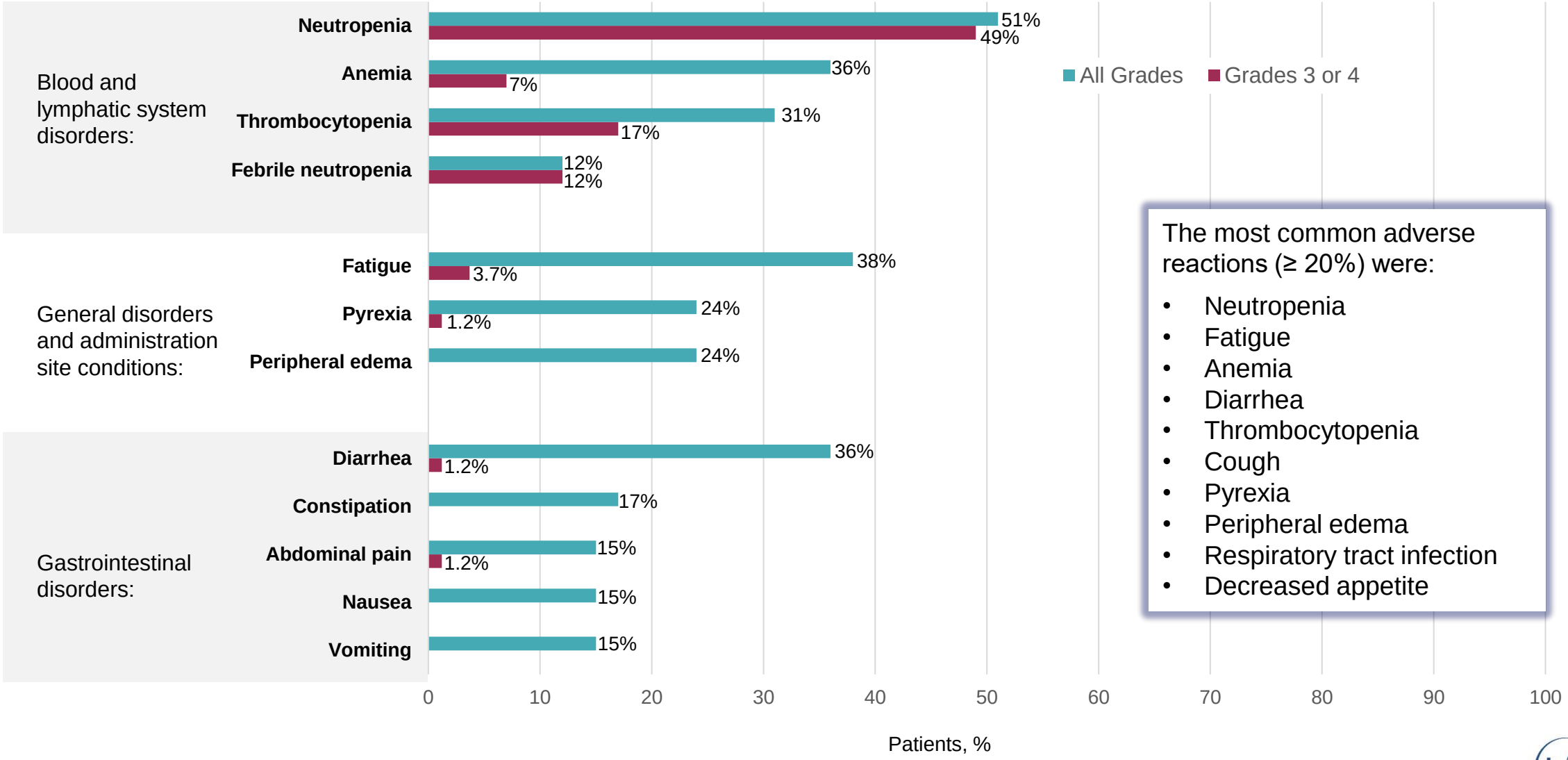
Adverse Reactions in ≥10% of Patients Who Received Tafasitamab-cxix in L-MIND (N=81)

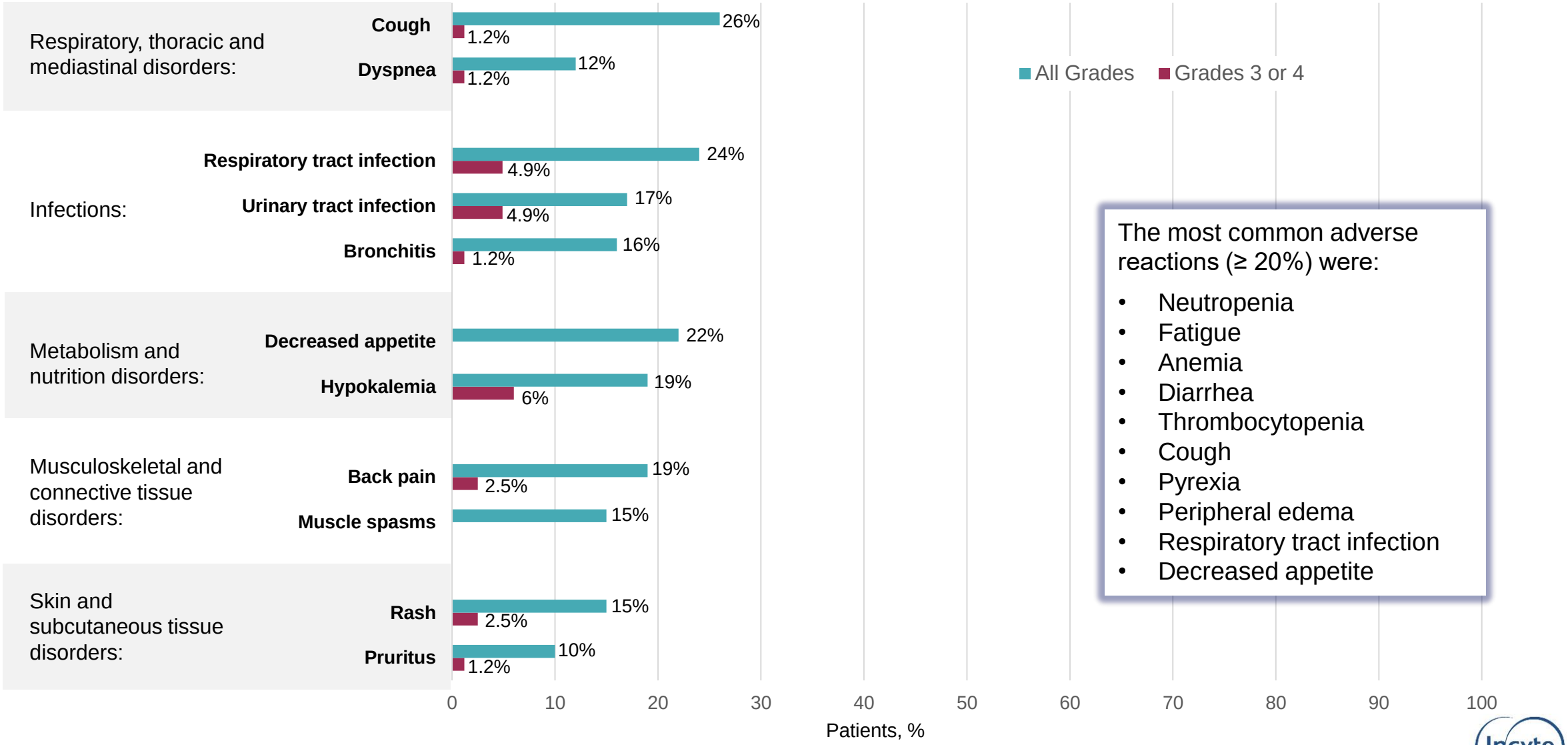


The most common adverse reactions (≥ 20%) were:

- Neutropenia
- Fatigue
- Anemia
- Diarrhea
- Thrombocytopenia
- Cough
- Pyrexia
- Peripheral edema
- Respiratory tract infection
- Decreased appetite

Monjuvi® (tafasitamab-cxix). Prescribing information. Incyte Corporation; June 2025

Adverse Reactions in ≥10% of Patients Who Received Tafasitamab-cxix in L-MIND (N=81)



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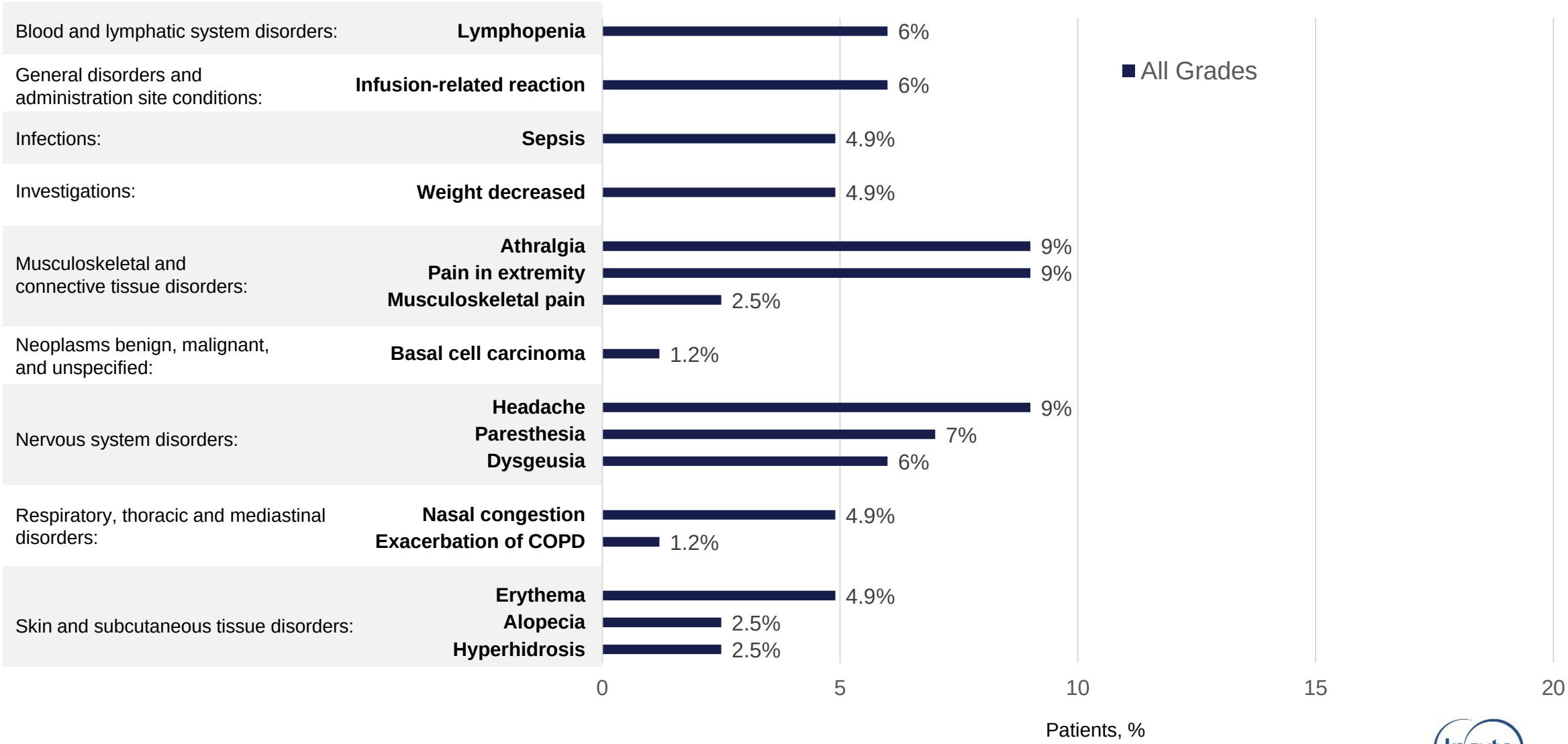
- Pyrexia
- Peripheral edema
- Respiratory tract infection
- Decreased appetite

Monjuvi® (tafasitamab-cxix). Prescribing information. Incyte Corporation; June 2025

Clinically Relevant Adverse Reactions in <10% Patients Who Received Tafasitamab-cxix (N=81)



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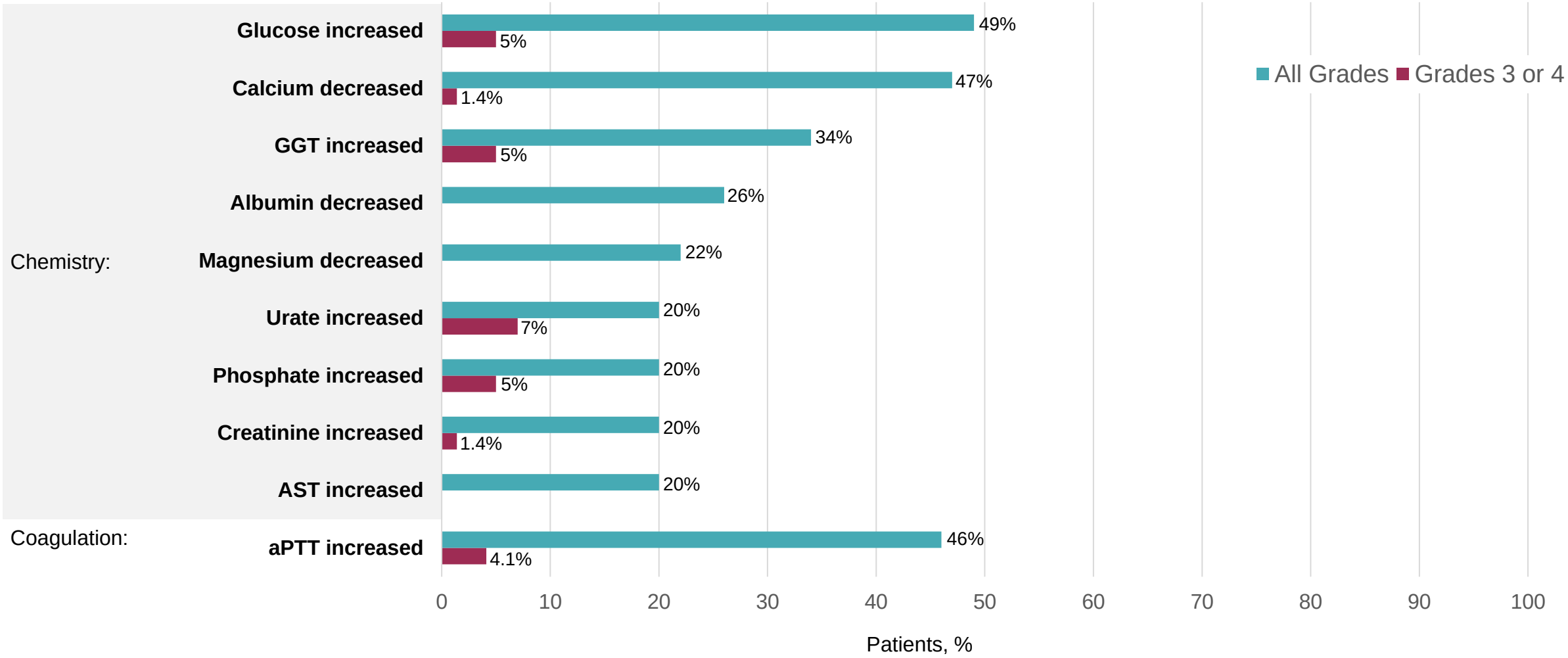
Select Laboratory Abnormalities (>20%) Worsening from Baseline (n=74)[a]



GGT, gamma glutamyl transferase; AST, aspartate aminotransferase; aPTT, activated partial thromboplastin time.

[a]The denominator used to calculate the rate was 74 based on the number of patients with a baseline value and at least one post-treatment value.

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L-MIND Data Summary

- In the single-cohort, open-label L-MIND study, 81 patients with relapsed/refractory DLBCL were treated with tafasitamab-cxix and lenalidomide
  - Among patients who received tafasitamab-cxix, 57% were exposed for 6 months or longer, 42% were exposed for greater than one year, and 24% were exposed for greater than two years
  - In total, 71 patients were confirmed by central laboratory to have DLBCL
- Efficacy for patients centrally confirmed to have R/R DLBCL (n=71):
  - Best overall response rate: 55%
    - CR, 37%; PR, 18%
  - Median (range) duration of response was 21.7 months (range: 0, 24)
- Safety (N=81)
  - SAEs occurred in 52% of patients, including infections (26%)
  - Fatal AEs occurred in 5% of patients (1 patient each: CVA, respiratory failure, PML, sudden death)
  - Permanent discontinuation of tafasitamab-cxix or lenalidomide due to an adverse reaction occurred in 25% of patients
    - Permanent discontinuation of tafasitamab-cxix due to an adverse reaction occurred in 15%
  - Dosage interruptions of tafasitamab-cxix or lenalidomide due to an adverse reaction occurred in 69% of patients
    - Dosage interruption of tafasitamab-cxix due to an adverse reaction occurred in 65%

Monjuvi® (tafasitamab-cxix). Prescribing information. Incyte Corporation; June 2025

Tafasitamab-cxix Dosage in R/R DLBCL

Recommended Dosage

- The recommended dosage of tafasitamab-cxix is 12 mg/kg based on actual body weight administered as an intravenous infusion according to the following dosing schedule:

Cycle[a]	Dosing Schedule
Cycle 1	Days 1, 4, 8, 15, and 22
Cycles 2 and 3	Days 1, 8, 15, and 22
Cycle 4 and beyond	Days 1 and 15

- Administer tafasitamab-cxix in combination with daily, oral lenalidomide 25 mg for a maximum of 12 cycles, then continue tafasitamab-cxix as monotherapy until disease progression or unacceptable toxicity
  - Refer to the Prescribing Information for lenalidomide for dosage recommendations

[a]Each treatment cycle is 28 days

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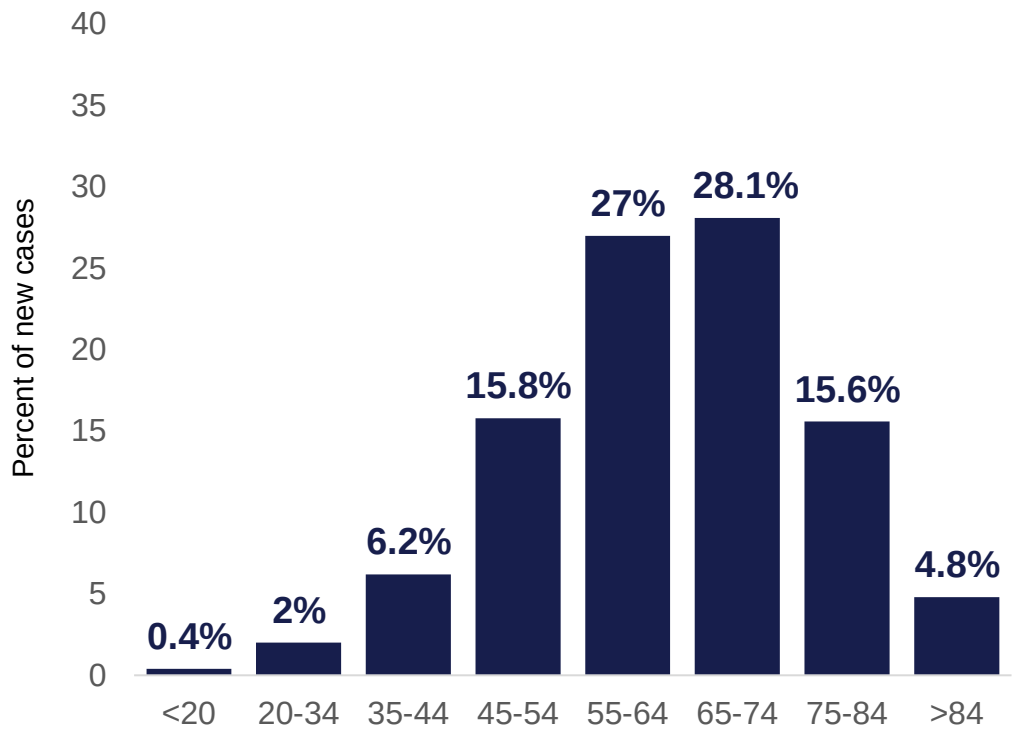
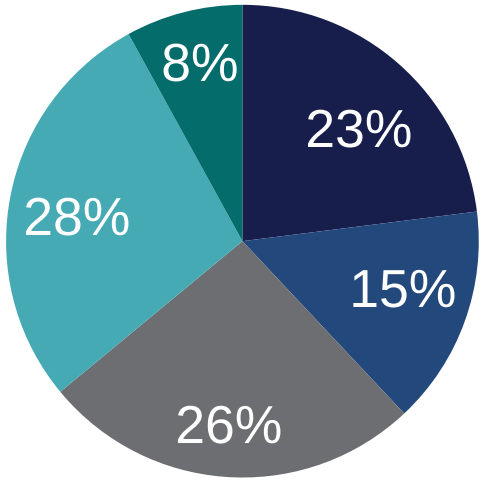
FL Disease State Overview

FL in the United States

New FL Cases by Age Group[a]



Prevalence of FL Cases by Stage[b]



Stage I	Confined to Single Region
Stage II	Involving Multiple Regions
Stage III	Spread to Both Sides of Diaphragm
Stage IV	Diffuse or Disseminated Involvement
Unknown	Unstaged

- The rate of new cases of FL is **2.5 per 100,000** people per year[a]
- The median age at diagnosis is **64 years**[a]
- The 5-year relative survival is **89.9%**[b]

[a] Based on 2017–2021 cases. [b] Based on 2014–2020 cases.
National Cancer Institute. Accessed Jan 2025. https://seer.cancer.gov/statfacts/html/follicular.html

FL Initial Management and Treatment Approaches

- Early-stage FL (stages I-II) may initially be treated with:[1,2]
  - Watch-and-wait approach (observation)
  - Radiation therapy
  - Immunotherapy alone
  - Immunotherapy with chemotherapy

- For advanced-stage FL (stages III-IV), 1L treatment is based on symptoms, histologic grade, and tumor burden; treatment options include:[1,2]
  - Watch-and-wait approach
  - Immunotherapy alone
  - Immunotherapy with chemotherapy (with or without maintenance therapy)

1. Carbone A, et al. *Nat Rev Dis Primers*. 2019;5(1):83. 2. Gupta G, et al. *Am J Blood Res*. 2022;12(4):105-124.

Burden of Disease in FL

- FL is a largely incurable, indolent disease associated with high rates of long-term survival (10-year OS rates of 72%–85%); however, lymphoma remains a leading cause of death for patients with FL[1-4]
  - In approximately 20%–30% of patients with FL, relapse occurs within 2 years of initial systemic treatment (POD24), which is associated with inferior survival[5]
  - Patients with shorter response durations on 1L therapy (including POD24), have shorter 2L and 3L response durations and may receive more lines of therapy[5,6]
- Patients with FL have a high QoL burden (eg, physical functioning) and symptom burden (eg, fatigue, pain), which increases among patients who receive additional lines of therapy[7,8]

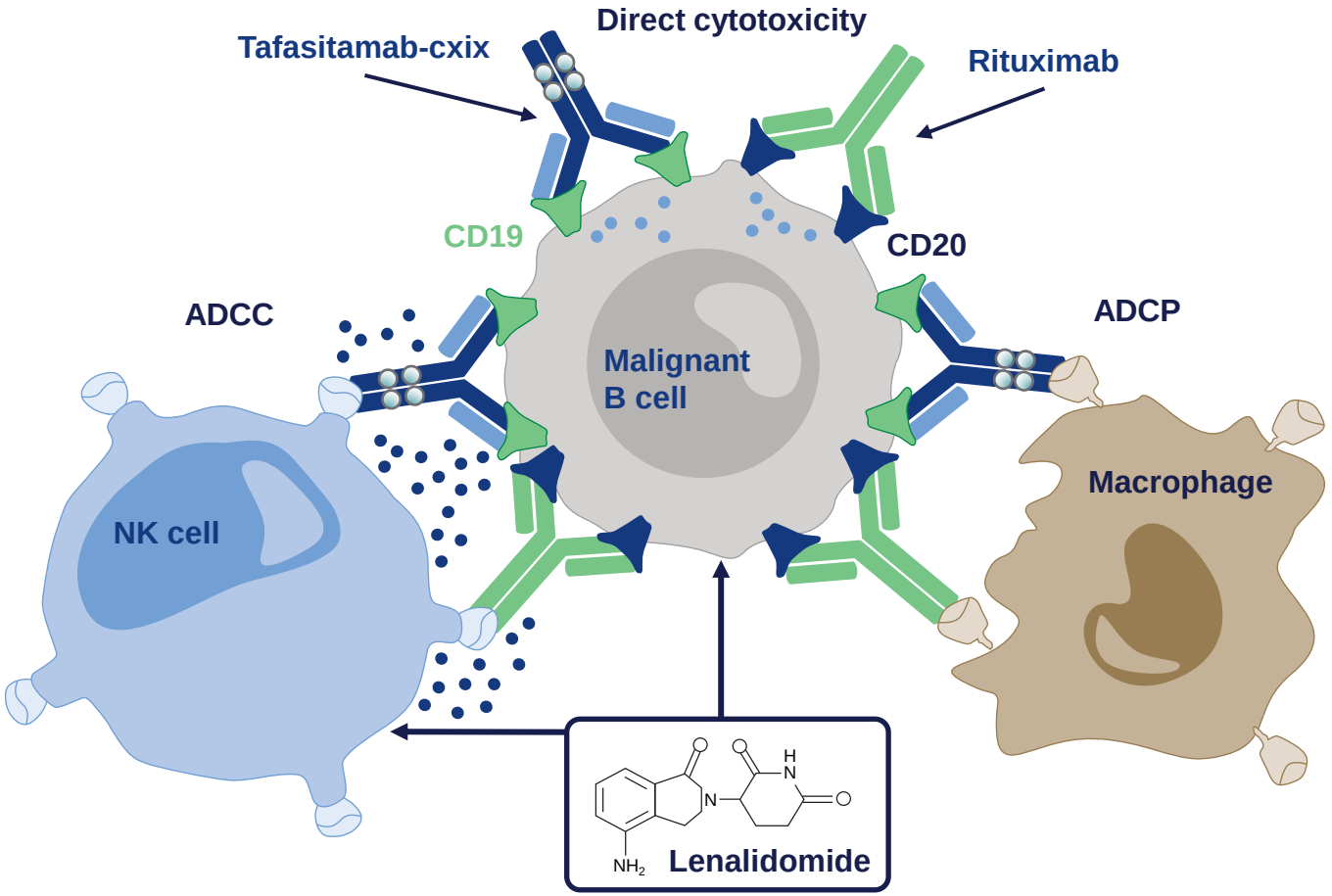
Prognosis for patients with FL has been shown to worsen with anti-CD20–refractory disease and each subsequent relapse/line of therapy[12,13]

QoL, quality of life.

1. Dinnessen MAW, et al. *Leukemia.* 2022;36(5):1416-1420. 2. Mozas P, et al. *Blood Cancer J*. 2020;10(3):31 3. Sarkozy C, et al. *J Clin Oncol*. 2019;37(2):144-152. 4. Watanabe T, et al. *Br J Haematol.* 2024;204(3):849-860. 5. Wästerlid T, et al. *eJHaem.* 2024;5:516-526. 6. Rivas-Delgado A, et al. *Br J Haematol*. 2019;184(5):753-759. 7. Johnsen AT, et al. *Eur J Haematol*. 2009;83(2):139-148. 8. Johnson PC, et al. *Adv Ther*. 2024;41(8):3342-3361.

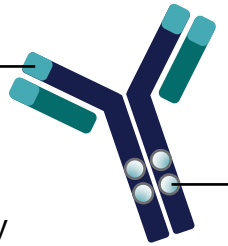
Tafasitamab-cxix Clinical Efficacy and Safety in R/R FL

Targeting CD19 and CD20 Together with Lenalidomide Immunomodulation



Tafasitamab (Fc-Modified, Anti-CD19 mAb)

Affinity-matured CD19-binding site

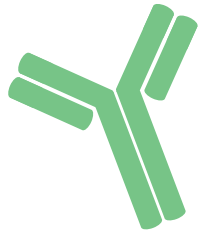


Modified Fc portion

- ADCC
- ADCP
- Direct cytotoxicity

Rituximab (Anti-CD20 mAb)

- ADCC
- ADCP
- Direct cytotoxicity
- CDC

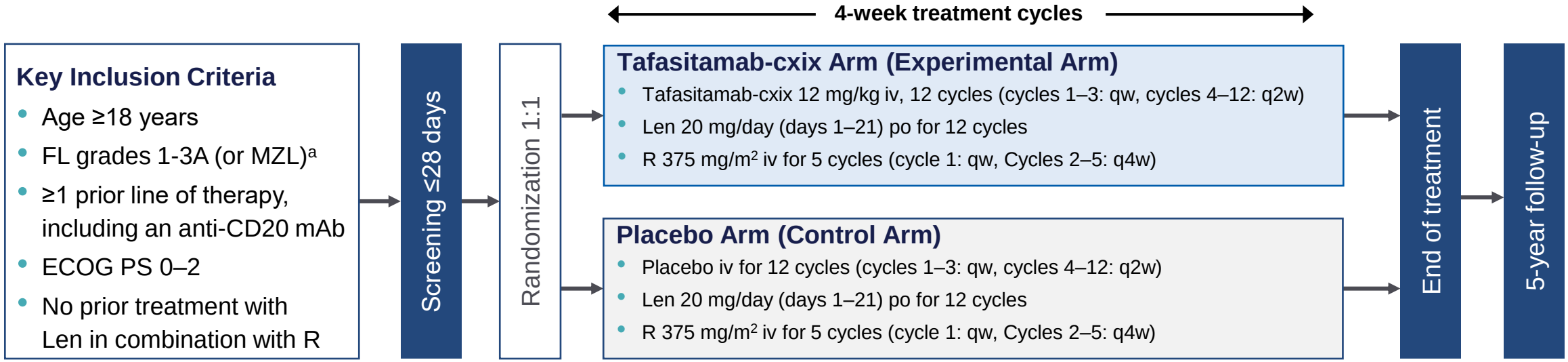


Modified from Patra M, et al. Presented at: 62nd Annual Meeting of the American Society Hematology (Poster 2095) (*Blood.* 2020;136[suppl 1]:44-45; doi:10.1182/blood-2020-140381) and Cheson BD, et al. *Blood Cancer J*. 2021;11:68.

ADCC, antibody-dependent cellular cytotoxicity; ADCP, antibody-dependent cellular phagocytosis; CDC, complement-dependent cytotoxicity; FL, follicular lymphoma; Len, lenalidomide; mAb, monoclonal antibody; MZL, marginal zone lymphoma; NK, natural killer; R, rituximab; R/R, relapsed or refractory.

Trneny et al. EHA 2025. Abstract #S230.

inMIND: Phase 3, Double-Blind, Placebo-Controlled, International, Multicenter Randomized Study



Stratification Factors (Patients With FL)

- POD24
- Refractoriness to prior anti-CD20 mAb therapy
- Number of prior lines of therapy (1 or ≥2)

Study Endpoints in FL Population (Investigator Assessed Unless Specified)

- **Primary study endpoint:** PFS
- **Key secondary:** PET-CR rate in the FDG-avid population, OS
- **Select other secondary**: PFS by IRC, ORR, DOR, safety, QoL, MRD
- **Exploratory:** TTNT, B-cell recovery, Ig levels, CD19 expression

- Powered to assess PFS in the FL population, triggered when 174 investigator-assessed events occurred
- OS analysis planned after 5 years of follow-up

[a] Limited number of patients with MZL were enrolled, but the study was not powered for this population; data for patients with MZL will be presented separately.
DOR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; FDG, fluorodeoxyglucose; Ig, immunoglobulin; IRC, independent review committee; iv, intravenous; MRD, minimal residual disease; ORR, overall response rate; PET-CR, positron emission tomography-complete response; po, orally; qw, weekly; q2w, every 2 weeks; q4w, every 4 weeks; TTNT, time to next treatment.
Sehn LH, et al. ASH 2024. Abstract LBA-1.

inMIND: Baseline Characteristics

Variable	Total FL Patients (N=548)
Median age, years (range)	64 (31-88)
≥75, %	109 (20)
Male sex, %	55
Race, %	
White	80
Asian	15
Black	0.2
Median Prior Lines of Therapy, n (range)	1 (1-7)
1, %	55%
2, %	25%
3+, %	20%
POD24, %	32%
Refractory to Prior CD20-Directed Therapy	43%

POD24, progression of disease within 24 months after initial diagnosis.

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Efficacy Results in Patients with R/R FL in inMIND

Outcome per Investigator	Tafasitamab-cxix + Len + R	Placebo + Len + R
Patients, n	273	275
Progression-free Survival	273	275
Patients with events, n (%)	75 (27.5)	131 (47.6)
Disease progression	67 (24.5)	124 (45.1)
Death	8 (2.9)	7(2.5)
Median PFS (95% CI), months	22.4 (19.2, NE)	13.9 (11.5, 16.4)
Hazard ratio[b] (95% CI)	0.43 (0.32, 0.58)	
p-value	< 0.0001	
Overall response rate, n (%) (95% CI)	224 (84) (79, 88)	199 (72) (66.7-77.6)

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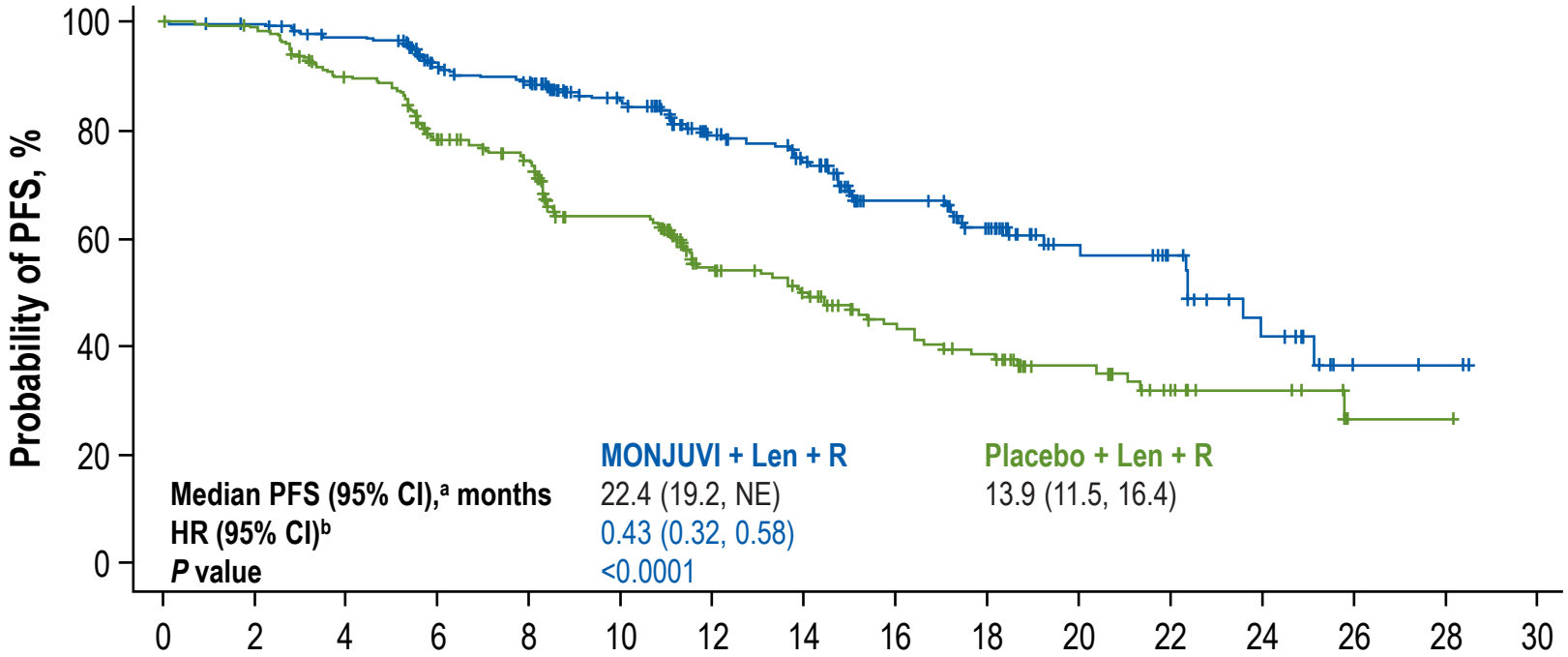
Investigator-Assessed Progression-free Survival



Median follow-up time: 14.1 months

No. at Risk

Tafasitamab-cxix + Len + R	273	261	250	212	200	164	119	103	71	57	30	22	12	3	2	0
Placebo + Len + R	275	265	235	192	173	126	82	70	48	40	26	16	10	2	2	0

- At the time of PFS analysis, median OS had not been reached in either arm with a total of 38 deaths: 15 deaths (5.5%) in the MONJUVI arm and 23 deaths (8.4%) in the placebo arm

[a]Kaplan-Meier estimate; [b]Hazard ratio based on a stratified Cox proportional hazard model.

Len, lenalidomide; R, rituximab.

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Adverse Reactions (≥10%) in Patients with R/R FL in inMIND

	Tafasitamab-cxix + Len + R (n=274)		Placebo + Len + R (n=272)	
Adverse Reaction	**All Grades (%)**	**Grade 3 or 4 (%)**	**All Grades (%)**	**Grades 3 or 4 (%)**
Infections				
Respiratory tract infection	56	18	56	9
COVID-19 infection[a]	34[e]	10	24[e]	2.9
Pneumonia[b]	18	14	11[f]	7
Upper respiratory tract infection[c]	17	1.1	22	0.4
Gastrointestinal disorders				
Diarrhea	38	0.7	28	1.8
Constipation	29	0.7	25	0
Nausea	18	0.4	14	0.4
Abdominal pain	13	0	18	2.2
Skin and subcutaneous tissue disorders				
Rash[d]	37	3.6	33	1.5
Pruritus	16	0.4	10	0
General disorders				
Fatigue[g]	34	2.9	25	0.7
Pyrexia	19	1.8	16	2.2
Mucositis[h]	17	0.4	11	0
Edema[i]	11	0.7	17	1.1

[a]Includes COVID-19, COVID-19 pneumonia, and coronavirus test positive.; [b]Includes pneumonia, COVID-19 pneumonia, pneumonia fungal, Pneumocystis jirovecii pneumonia, and other types of pneumonia.; [c]Includes upper respiratory tract infection, nasopharyngitis, sinusitis, laryngitis, and related terms; [d]Includes rash, urticaria, dermatitis, drug eruption, and related terms; [e]Includes 2 cases in each arm with fatal outcome; [f]Includes 3 cases with fatal outcome, including 2 reported under COVID-19 infection; [g]Includes fatigue and asthenia; [h]Includes oropharyngeal pain, stomatitis, mucosal inflammation, mouth ulceration, odynophagia, aphthous ulcer, esophageal pain, and related terms. [i]Includes edema, peripheral edema, pulmonary edema, generalized edema, and related terms.

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Adverse Reactions (≥10%) in Patients with R/R FL in inMIND cont'd

	Tafasitamab-cxix + Len + R (n=274)		Placebo + Len + R (n=272)	
Adverse Reaction	**All Grades (%)**	**Grade 3 or 4 (%)**	**All Grades (%)**	**Grades 3 or 4 (%)**
Musculoskeletal and connective tissue disorders				
Musculoskeletal pain[a]	24	0.4	16	0.4
Muscle contracture[b]	18	0	19	0
Respiratory, thoracic and mediastinal disorders				
Cough	21	0	19	0
Procedural complications				
Infusion-related reaction[c]	16	0.7	16	0.4
Nervous system disorders				
Peripheral neuropathy[d]	12	0	11	0.4
Headache	10	0.4	7	0
Metabolism and nutrition disorders				
Decreased appetite	10	0	9	0.7
Pruritus	16	0.4	10	0

[a]Includes back pain, pain in extremity, myalgia, bone pain, neck pain, spinal pain, limb discomfort, musculoskeletal chest pain, musculoskeletal discomfort, and sacral pain; [b]Includes muscle spasms and muscle contractions involuntary; [c]Includes infusion-related reaction and cytokine release syndrome; [d]Includes peripheral neuropathy, paresthesia, peripheral sensory neuropathy, neuralgia, dysesthesia, hyperesthesia, and peripheral motor neuropathy.

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Select Laboratory Abnormalities (>20%) Worsening from Baseline in Patients with R/R FL in inMIND

	Tafasitamab-cxix + Len + R (n=274)[a]		Placebo + Len + R (n=272)[a]	
Laboratory Abnormality	**All Grades (%)**	**Grade 3 or 4 (%)**	**All Grades (%)**	**Grades 3 or 4 (%)**
Hematology				
Neutrophils decreased	75	48	71	44
Hemoglobin decreased	60	9	54	7
Lymphocytes decreased	57	22	51	19
Platelets decreased	40	8	43	9
Chemistry				
Alanine aminotransferase increased	47	1.5	42	1.5
Alkaline phosphatase increased	33	0	27	0
Creatinine increased	29	1.5	30	0.7
Aspartate aminotransferase increased	29	0	31	0.4
Glucose increased	28	0.4	28	1.1
Potassium decreased	24	3.3	24	3
Sodium decreased	24	1.5	22	0.4

[a] The denominator used to calculate the rate varied from 268 - 274 based on the number of patients with a baseline value and at least 1 post-treatment value.

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Tafasitamab-cxix Dosage in R/R FL

Tafasitamab-cxix Dosing for R/R FL

Dosing Schedule[1]

Cycles[a]

	1	2	3	4	5	6	7	8	9	10	11	12
Tafasitamab-cxix 12 mg/kg iv	Days 1, 8, 15, 22			Days 1 and 15								
Rituximab 375 mg/m^2 iv[b]	qw			q4w								
Lenalidomide 20 mg po	Days 1-21											

[a] Each treatment cycle is 28 days; [b]In inMIND, rituximab was administered approximately 30 minutes after the tafasitamab-cxix/placebo infusion was completed but no less than 15 minutes.[2]

1. Monjuvi® (tafasitamab-cxix). Prescribing information. Incyte Corporation; June 2025 2. Data on file, Incyte Corporation.

Premedications, Preparation and Administration, and Dosage Modifications

Recommended Premedications and Prophylactic Medication

- Administer premedications 30 minutes to 2 hours prior to starting tafasitamab-cxix infusion to minimize infusion-related reactions
- Premedications may include:
  - Acetaminophen
  - Histamine H_1 receptor antagonists
  - Histamine H_2 receptor antagonists
  - Glucocorticosteroids
- For patients not experiencing infusion-related reactions during the first 3 infusions, premedication is optional for subsequent infusions
- If a patient experiences an infusion-related reaction, administer premedications before each subsequent infusion

- Thromboprophylaxis
  - Refer to the lenalidomide prescribing information for recommendations on prophylaxis for venous and arterial thrombotic events

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Preparation and Administration

Reconstitution

1. Calculate the dose (mg) and determine the number of vials needed.
2. Reconstitute each 200 mg tafasitamab-cxix vial with 5 mL Sterile Water for Injection, USP with the stream directed toward the wall of each vial to obtain a final concentration of 40 mg/mL tafasitamab-cxix.
3. Gently swirl the vial(s) until completely dissolved. Do not shake or swirl vigorously. Complete dissolution may take up to 5 minutes.
4. Visually inspect the reconstituted solution for particulate matter or discoloration. The reconstituted solution should appear as a colorless to slightly yellow solution. Discard the vial(s) if the solution is cloudy, discolored, or contains visible particles.
5. Use the reconstituted tafasitamab-cxix solution immediately. If needed, store the reconstituted solution in the vial for a maximum of 12 hours either refrigerated at 36°F to 46°F (2°C to 8°C) or room temperature at 68°F to 77°F (20°C to 25°C) before dilution. Protect from light during storage.

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Preparation and Administration (cont'd)

Dilution

1. Determine the volume (mL) of the 40 mg/mL reconstituted MONJUVI solution needed based on the required dose.
2. Remove a volume equal to the required MONJUVI solution from a 250 mL 0.9% Sodium Chloride Injection, USP infusion bag and discard it.
3. Withdraw the necessary amount of MONJUVI and slowly dilute in the infusion bag that contains the 0.9% Sodium Chloride Injection, USP to a final concentration of 2 mg/mL to 8 mg/mL. Discard any unused portion of MONJUVI remaining in the vial.
4. Gently mix the intravenous bag by slowly inverting the bag. *Do not shake*. Visually inspect the infusion bag with the diluted MONJUVI infusion solution for particulate matter and discoloration prior to administration.
5. If not used immediately, store the diluted MONJUVI infusion solution refrigerated for up to 18 hours at 36°F to 46°F (2°C to 8°C) and/or at room temperature for up to 12 hours at 68°F to 77°F (20°C to 25°C). The room temperature storage includes time for infusion. Protect from light during storage.

Do not shake or freeze the reconstituted or diluted infusion solutions.

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Preparation and Administration (cont'd)

Administration

1. Administer tafasitamab-cxix as an intravenous infusion.
   - For the first infusion, use an infusion rate of 70 mL/h for the first 30 minutes, then, increase the rate so that the infusion is administered within 1.5 to 2.5 hours
   - Administer all subsequent infusions within 1.5 to 2 hours
2. Infuse the entire contents of the bag containing tafasitamab-cxix.
3. Do not co-administer other drugs through the same infusion line.
4. No incompatibilities have been observed between tafasitamab-cxix with infusion containers made of polypropylene (PP), polyvinylchloride (PVC), polyethylene (PE), polyethylenterephthalate (PET), or glass and infusion sets made of polyurethane (PUR) or PVC.

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Dosage Modifications for Adverse Reactions: Infusion-Related Reactions

Infusion-Related Reactions[a]	
Severity	**Dosage Modification**
Grade 2 (moderate)	• Interrupt infusion immediately and manage signs and symptoms • Once signs and symptoms resolve or reduce to grade 1, resume infusion at no more than 50% of the rate at which the reaction occurred. If the patient does not experience further reaction within 1 hour and vital signs are stable, the infusion rate may be increased every 30 minutes as tolerated to the rate at which the reaction occurred
Grade 3 (severe)	• Interrupt infusion immediately and manage signs and symptoms • Once signs and symptoms resolve or reduce to grade 1, resume infusion at no more than 25% of the rate at which the reaction occurred. If the patient does not experience further reaction within 1 hour and vital signs are stable, the infusion rate may be increased every 30 minutes as tolerated to a maximum of 50% of the rate at which the reaction occurred • If Grade 3 reaction returns, stop the infusion immediately and permanently discontinue tafasitamab-cxix.
Grade 4 (life-threatening)	• Stop the infusion immediately and permanently discontinue tafasitamab-cxix

[a]Ensure premedications administered before subsequent infusions.

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Dosage Modifications for Adverse Reactions: Myelosuppression

Myelosuppression	
Severity	**Dosage Modification**
Platelet count of 50,000/mcL or less	• Withhold tafasitamab-cxix and lenalidomide and monitor CBC weekly until platelet count is 50,000/mcL or higher • Resume tafasitamab-cxix at the same dose and lenalidomide at a reduced dose. Refer to the Prescribing Information for lenalidomide for dosage modifications
Neutrophil count of 1,000/mcL or less for at least 7 days **OR** **Neutrophil count of 1,000/mcL or less with an increase of body temperature to 100.4°F (38°C) or higher** **OR** **Neutrophil count less than 500/mcL**	• Withhold tafasitamab-cxix and lenalidomide and monitor CBC weekly until neutrophil count is 1,000/mcL or higher • Resume tafasitamab-cxix at the same dose and lenalidomide at a reduced dose. Refer to the Prescribing Information for lenalidomide for dosage modifications

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Warnings, Precautions, and Use in Specific Populations

Summary of Warnings and Precautions

Infusion-Related Reactions

- Tafasitamab-cxix can cause infusion-related reactions
- In L-MIND, IRRs occurred in 6% of 81 patients with DLBCL
  - 80% of IRRs occurred during Cycle 1 or 2
- In inMIND, IRRs occurred in 16% of the 274 patients with FL who received tafasitamab-cxix + lenalidomide + rituximab
- Signs and symptoms included fever, chills, rash, flushing, dyspnea, and hypertension
  - These reactions were generally managed with temporary interruption of the infusion and/or with supportive medication

- Premedicate patients prior to starting tafasitamab-cxix infusion and monitor patients frequently during infusion
- Based on the severity of the IRR, interrupt or discontinue tafasitamab-cxix
  - Institute appropriate medical management

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Summary of Warnings and Precautions

Myelosuppresion

- Tafasitamab-cxix can cause serious or severe myelosuppression, including neutropenia, lymphopenia, thrombocytopenia, and anemia
- In L-MIND, among 81 patients with DLBCL, Grade 3 adverse reactions occurred as follows:
  - Neutropenia (25%)
  - Thrombocytopenia (12%)
  - Anemia (7%)
- In L-MIND, Grade 4 adverse reactions:
  - Neutropenia (25%)
    - Neutropenia led to treatment discontinuation in 3.7% of patients
    - Febrile neutropenia occurred in 12%
  - Thrombocytopenia (6%)
- In inMIND, among 274 patients with FL, Grade 3 or 4 adverse reactions occurred as follows:
  - Grade 3 Neutropenia (48%), Grade 4 neutropenia (19%)
  - Grade 3 lymphopenia (22%), Grade 4 lymphopenia (1.8%)
  - Grade 3 anemia (9%), Grade 4 anemia (0%)
  - Grade 3 thrombocytopenia (8%), Grade 4 thrombocytopenia (4%)
    - Febrile neutropenia occurred in 4.4%

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Summary of Warnings and Precautions

Myelosuppresion Cont'd

- Monitor CBC prior to administration of each treatment cycle and throughout treatment
- Monitor patients with neutropenia for signs of infection
- Consider G-CSF administration
- Withhold tafasitamab-cxix based on the severity of the adverse reaction
- Refer to the Prescribing Information for lenalidomide for dosage modifications

CBC, complete blood counts; G-CSF, granulocyte colony stimulating factor.

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Summary of Warnings and Precautions

Infections

- Fatal and/or serious infections including opportunistic infections occurred in patients during treatment with tafasitamab-cxix and following the last dose
- In L-MIND, 73% of the 81 patients with DLBCL developed an infection
  - Grade 3 or higher infection occurred in 30% of patients
  - Infection-related deaths occurred in 2.5% of patients, including a case of PML
  - The most frequent Grade 3 or higher infection was pneumonia (7%)
  - The most frequent infection of any grade were respiratory tract infections (51%, including pneumonias) and urinary tract infections (17%)
- In inMIND, 24% of 274 patients with FL developed a Grade 3 or higher infection
  - Fatal infections occurred in 1.1%
  - The most frequent Grade ≥ 3 infections were respiratory tract infections (19%), including Grade 3 or higher pneumonia (14%) and COVID-19 infection (11%)
  - Opportunistic infections of any grade occurred in 6%, including herpes simplex or zoster infection (5%), fungal pneumonia (1.1%, including *pneumocytis jirovecii* pneumonia (0.4%) and cytomegalovirus reactivation (0.4%)

- Monitor patients for signs and symptoms of infection and manage infections as appropriate
- Consider infection prophylaxis per institutional guidelines
- Consider treatment with subcutaneous or IVIG as appropriate

IVIG, intravenous immunoglobulin; PML, progressive multifocal leukoencephalopathy.

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Summary of Warnings and Precautions

Embryo-Fetal Toxicity

- Based on its mechanism of action, tafasitamab-cxix may cause fetal B-cell depletion when administered to a pregnant person
- Advise pregnant people of the potential risk to a fetus
- Advise people of reproductive potential to use effective contraception during treatment with tafasitamab-cxix and for 3 months after the last dose

- The combination of tafasitamab-cxix with lenalidomide and of tafasitamab-cxix with lenalidomide and rituximab is contraindicated in pregnant people because lenalidomide can cause birth defects and death of the unborn child
- Refer to the Prescribing Information for lenalidomide for use during pregnancy

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Use in Specific Populations

Pregnancy

- Based on its MOA, MONJUVI may cause fetal B-cell depletion when administered to a pregnant person.
- There are no available data on MONJUVI use in pregnant people to evaluate for a drug-associated risk.
- Defer administering live vaccines to neonates and infants exposed to tafasitamab-cxix in utero until a hematology evaluation is completed

People of Reproductive Potential

- Advise females to use effective contraception during treatment with MONJUVI and for 3 months after last dose
- For males and females, refer to lenalidomide PI for recommendations

Pediatric Use

- Safety and efficacy has not been established in pediatric patients

Lactation

- Advise people not to breastfeed during treatment with MONJUVI and for 3 months after the last dose

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Use in Specific Populations Cont'd

Geriatric Use in R/R DLBCL

- In L-MIND, among the 81 patients, 72% were ≥ 65 years, while 38% were ≥ 75 years
- L-MIND did not include sufficient patients ≥ 65 to determine if efficacy differs from that of younger patients
- Patients ≥ 65 years old had more SAEs (57%) than younger patients (39%)

Geriatric Use in R/R FL

- In inMIND, among the 274 patients, 50% were ≥ 65 years and 20% were ≥ 75 years
- No clinically meaningful differences in safety or effectiveness were observed between these patients and younger patients

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Appendix

- Pharmacodynamics
- Pharmacokinetics
- Immunogenicity

Click on bulleted text to access corresponding back up slides.

Pharmacodynamics

- Tafasitamab-cxix reduced peripheral blood B-cell counts by 97% after 8 days of treatment in patients with relapsed or refractory DLBCL
  - Nadir with a reduction to undetectable levels (<1 cell/mL) was reached within 16 weeks of treatment
- Circulating B-cells decreased to undetectable levels (< 1 cell/mL) by Cycle 1 Day 15 after administration of the recommended dosage of tafasitamab-cxix in patients with FL who had detectable B-cells at treatment initiation and the depletion was sustained while patients remained on treatment
- Tafasitamab-cxix maximum concentration is achieved at the end of weekly dosing (i.e., end of Cycle 3)

[a]Tafasitamab-cxix 12 mg/kg on Days 1, 8, 15, 22 (plus an additional dose on Cycle 1 Day 4), [b]Tafasitamab-cxix 12 mg/kg on Days 1 and 15.

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Pharmacokinetics

- PK parameters are presented as geometric mean (CV%) unless otherwise specified

	C_{avg} (mcg/mL)[a]	C_{max} (mcg/mL)[a]	C_{trough} (mcg/mL)[a]
End of weekly dosing (end of Cycle 3) (N = 367)	315 (30.3%)	489 (22.8%)	226 (38.5%)
Steady state[b] with every 2-week dosing (N = 285)	185 (32.5%)	375 (20.8%)	112 (44.8%)

- Tafasitamab-cxix estimated elimination half-life was 13.4 days (31.7%) with an apparent clearance of 0.44 L/day (29.2%)
- Body weight (37.6 to 163 kg) has a significant effect on the PK of tafasitamab cxix, with higher clearance and volume of distribution expected with higher body weight
- No clinically meaningful differences in the PK of tafasitamab-cxix were observed based on age, sex, race, mild to severe renal impairment (creatinine clearance [CLcr] 15 to < 90 mL/min), and mild to moderate hepatic impairment (total bilirubin ≤ ULN and AST > ULN, or total bilirubin 1 to 3.0 times ULN and any AST)
- The effect of end-stage renal disease (CLcr < 15 mL/min) and severe hepatic impairment (total bilirubin > 3.0 times ULN and any AST) on the PK of tafasitamab-cxix are unknown

[a] Values are geometric mean with geometric CV%; [b] Steady state values are approximated at Cycle 6

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Immunogenicity

- The observed incidence of ADA is highly dependent on the sensitivity and specificity of the assay
- Differences in assay methods preclude clinically meaningful comparisons of the incidence of ADA in the L-MIND and inMIND studies with the incidence of ADA in other studies, including those of tafasitamab-cxix or other tasfasitamab products
- Following tafasitamab-cxix treatment, anti-tafasitamab-cxix antibodies developed in
  - 2.5% (2/81) of patients with DLBCL in L-MIND (up to 23 cycles)
  - 0.9% (3/327) of patients with FL in inMIND (up to 12 cycles)
- Because of the low occurrence of ADA, the effect of these antibodies on the pharmacokinetics, pharmacodynamics, safety, and effectiveness of tasfasitamab products is unknown

ADA, anti-drug antibodies.

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