MONJUVI®
tafasitamab-cxix | 200 mg
for injection, for intravenous use

INDICATIONS & USAGE

MONJUVI (tafasitamab-cxix), in combination with lenalidomide, is indicated 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).

MANAGING TREATMENT WITH MONJUVI

MONJUVI is an outpatient targeted immunotherapy for adult patients with NTE DLBCL in 2L[1]*

NCCN PREFERRED

National Comprehensive Cancer Network® (NCCN®) Preferred Treatment Option

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) recommend tafasitamab-cxix (MONJUVI) in combination with lenalidomide as a preferred second-line or subsequent therapy option (if not previously used) for DLBCL in patients who are not candidates for transplant (Category 2A).[2†]

5 YEAR DATA

The 5-year analysis data from L-MIND have not been submitted to or reviewed by the FDA, and potential inclusion of these data in the final FDA-approved labeling has yet to be determined.

*MONJUVI is a CD19-directed cytolytic monoclonal antibody.[1] †It is unclear if tafasitamab or loncastuximab tesirine or if any other CD-19 directed therapy will have a negative impact on the efficacy of subsequent anti-CD19 CAR T-cell therapy.

NCCN makes no warranties of any kind whatsoever regarding their content, use, or application and disclaims any responsibility for their application or use in any way.

NTE=non-transplant eligible; DLBCL=diffuse large B-cell lymphoma; 2L=second line.

IMPORTANT SAFETY INFORMATION

Contraindications

None.

Warnings and Precautions

Infusion-Related Reactions

MONJUVI can cause infusion-related reactions (IRRs). In L-MIND, infusion-related reactions occurred in 6% of the 81 patients. Eighty percent of infusion-related reactions occurred during cycle 1 or 2. Signs and symptoms included fever, chills, rash, flushing, dyspnea, and hypertension. These reactions were managed with temporary interruption of the infusion and/or with supportive medication. Premedicate patients prior to starting MONJUVI infusion. Monitor patients frequently during infusion. Based on the severity of the infusion-related reaction, interrupt or discontinue MONJUVI. Institute appropriate medical management.

Please see the full Prescribing Information for additional Important Safety Information.

L-MIND: AN OPEN-LABEL, MULTICENTER, SINGLE-ARM, PHASE 2 STUDY WITH 5-YEAR FOLLOW UP[1,3]

L-MIND study design[1,3]

- Efficacy and safety of MONJUVI in combination with lenalidomide followed by MONJUVI monotherapy were evaluated in adults with R/R DLBCL after 1 to 3 prior systemic DLBCL therapies, including a CD20-containing therapy[1]
- Enrolled patients at the time of the trial were not eligible for or refused ASCT[1]
- Efficacy was established in 71 patients with DLBCL, as assessed by an Independent Review Committee using the International Working Group Response Criteria (Cheson 2007)[1]

Primary endpoint[3]
Best overall response rate (ORR) (CR + PR)

Select secondary endpoint[3]
Duration of response (DoR)

EACH CYCLE WAS 28 DAYS[1]

Cycles 1 to 3
MONJUVI
12 mg/kg
on days 1, 4*, 8, 15, 22

Lenalidomide
25 mg/day by mouth on days 1 to 21 for up to 12 cycles

*Loading dose on day 4 is given in cycle 1 only.

Cycles 4 to 12
MONJUVI
12 mg/kg
on days 1 and 15

≥SD

Cycle 13+
MONJUVI
12 mg/kg on days 1 and 15

Until progression or unacceptable toxicity

Administer premedications, including acetaminophen, histamine H_1 receptor antagonists, histamine H_2 receptor antagonists, and/or glucocorticosteroids, 30 minutes to 2 hours prior to starting MONJUVI infusion to minimize infusion-related reactions.

R/R=relapsed/refractory; ASCT=autologous stem cell transplant; CR=complete response rate; PR=partial response rate; SD=stable disease.

IMPORTANT SAFETY INFORMATION

Warnings and Precautions (cont.)

Myelosuppression

MONJUVI can cause serious or severe myelosuppression, including neutropenia, thrombocytopenia, and anemia. In L-MIND, Grade 3 neutropenia occurred in 25% of patients, thrombocytopenia in 12%, and anemia in 7%. Grade 4 neutropenia occurred in 25% and thrombocytopenia in 6%. Neutropenia led to treatment discontinuation in 3.7% of patients.

Monitor complete blood counts (CBC) prior to administration of each treatment cycle and throughout treatment. Monitor patients with neutropenia for signs of infection. Consider granulocyte colony-stimulating factor (G-CSF) administration. Withhold MONJUVI based on the severity of the adverse reaction. Refer to the lenalidomide prescribing information for dosage modifications.

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L-MIND EXAMINED PATIENTS WITH A BROAD RANGE OF CHARACTERISTICS[1,4-8]

Select baseline characteristics (N=71)[1,4,5]		
Time between first DLBCL diagnosis and first documented relapse or progression	≤12 months	17 (23.9%)
	>12 months	53 (74.6%)
	Unknown	1 (1.4%)
IPI score at screening	0–2 (low and low-intermediate risk)	34 (47.9%)
	3–5 (intermediate-high and high risk)	37 (52.1%)
Refractory disease	Primary refractory disease*	14 (19.7%)
	Refractory to last prior therapy	32 (45%)
	Refractory to rituximab	30 (42%)
Prior CD20-containing therapy		100%
Median number of prior therapies		2
Prior lines of therapy	1	49%
	2 to 4	51%
Prior ASCT		9 (13%)
Median age (range)		71 years (41-86 years)
Race†	White	95%
	Asian	3%
Sex, male		55%
ECOG performance status	0	26 (36.6%)
	1	38 (53.5%)
	2	7 (9.9%)
Primary reasons patients were not candidates for ASCT	Age	47%
	Refractory to salvage chemotherapy	27%
	Comorbidities	13%
	Refusal of high-dose chemotherapy/ASCT	13%
Bulky disease‡		14 (20%)
Elevated LDH		40 (56.3%)

ECOG=Eastern Cooperative Oncology Group; IPI=International Prognostic Index; LDH=lactate dehydrogenase.

L-MIND included difficult to treat patients[4,6,7]:

- **24%** of patients had ≤12 months between first diagnosis and first documented relapse or progression
- **52%** of patients had an IPI score of 3-5
- **20%** of patients had primary refractory disease

*Following a protocol amendment, primary refractory DLBCL was defined as no response to or progression/relapse during or within 6 months of frontline therapy. Prior to the amendment, only patients whose disease relapsed within 3 months were defined as primary refractory and excluded. Therefore, patients with disease that relapsed or progressed between 3 and 6 months of frontline therapy were recruited before the protocol amendment.[8]

†Race was collected in 92% of the 71 patients.[1]
‡Data was collected in 70 patients.[5]

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HIGH ORR REACHED, WITH A MAJORITY OF RESPONDERS ACHIEVING CR

1-year primary analysis in patients with R/R DLBCL (N=71)[1]*:

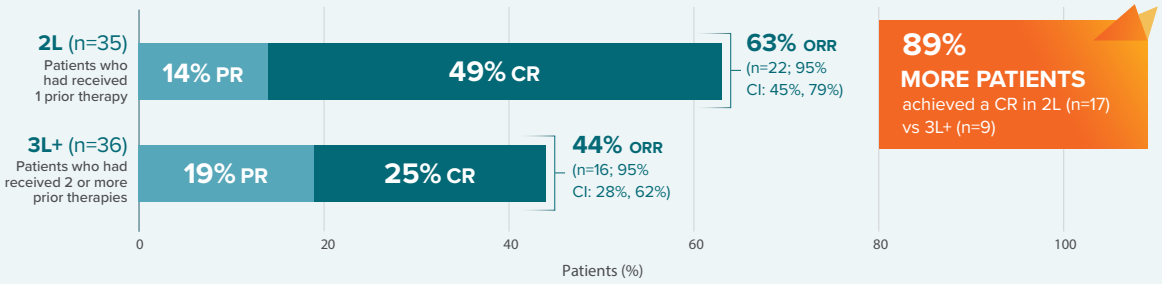
- **Best ORR: 55%** (n=39; 95% CI: 43%, 67%); **CR: 37%; PR: 18%**

MONJUVI, in combination with lenalidomide, was granted accelerated approval based on the 1-year primary analysis of the L-MIND study. The 5-year analysis data from L-MIND have not been submitted to or reviewed by the FDA, and potential inclusion of these data in the final FDA-approved labeling has yet to be determined.

5-year follow-up analysis[9]*:

- **Best ORR: 54%** (n=38; 95% CI: 41%, 66%); **CR: 37%; PR: 17%**

5-year subgroup analysis[9]*



Median time to response[10]

In the L-MIND study (n=71), the median time to response was **2.0 months**

1-year primary analysis in patients with R/R DLBCL (N=71)[1]

- Median time to **CR: 10.9 months** (n=25)[10]
- Median time to **PR: 1.9 months** (n=26)[10]

These analyses are exploratory in nature, and L-MIND was not designed or powered to evaluate and compare multiple subgroups. These results should be interpreted with caution given the small sample size and due to single-arm studies not adequately characterizing time-to-event endpoints, which may lead to estimates that are unstable.

*Assessed by an Independent Review Committee.[1,9]

3L=third line; CI=confidence interval.

The cutoff date for the primary analysis was November 30, 2018, and occurred after the last patient enrolled had completed 12 months of follow-up. The cutoff date for the 5-year follow-up analysis was November 14, 2022, and occurred after the last patient enrolled had completed 5 years of follow-up.[9,11]

IMPORTANT SAFETY INFORMATION

Warnings and Precautions (cont.)

Infections

Fatal and serious infections, including opportunistic infections, occurred in patients during treatment with MONJUVI and following the last dose.

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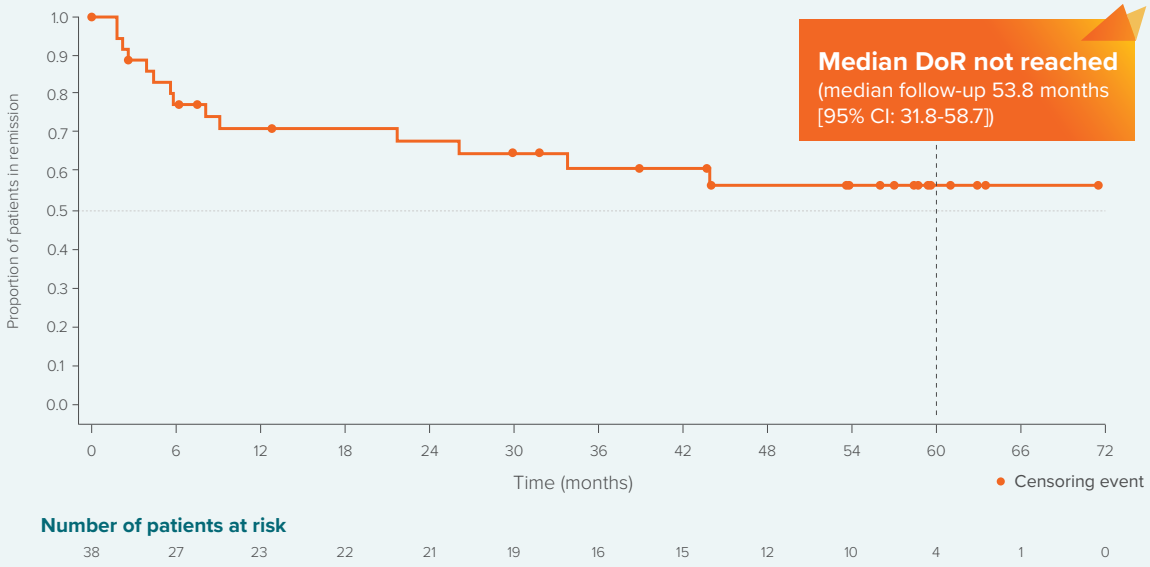
SUSTAINED REMISSION IN PATIENTS WITH R/R DLBCL[1,9]

1-year primary analysis in patients with R/R DLBCL (N=71)[1*†]

- **Median DoR 21.7 months** (range: 0, 24)

MONJUVI, in combination with lenalidomide, was granted accelerated approval based on the 1-year primary analysis of the L-MIND study. The 5-year analysis data from L-MIND have not been submitted to or reviewed by the FDA, and potential inclusion of these data in the final FDA-approved labeling has yet to be determined.

5-year follow-up analysis[9*†]



*Assessed by an Independent Review Committee.[1,9]

†Kaplan-Meier estimates.[1,9]

The cutoff date for the primary analysis was November 30, 2018 and occurred after the last patient enrolled had completed 12 months of follow-up. The cutoff date for the 5-year follow-up analysis was November 14, 2022, and occurred after the last patient enrolled had completed 5 years of follow-up.[9,11]

IMPORTANT SAFETY INFORMATION

Warnings and Precautions (cont.)

Infections (cont.)

In L-MIND, 73% of the 81 patients developed an infection. The most frequent infections were respiratory tract infection (24%), urinary tract infection (17%), bronchitis (16%), nasopharyngitis (10%) and pneumonia (10%). Grade 3 or higher infection occurred in 30% of the 81 patients. The most frequent grade 3 or higher infection was pneumonia (7%). Infection-related deaths were reported in 2.5% of the 81 patients.

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SAFETY AND TOLERABILITY[1]

- Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in clinical trials of a drug cannot be directly compared to rates in other clinical trials of another drug and may not reflect the rates observed in practice

- Serious adverse reactions occurred in 52% of patients who received MONJUVI
  - Serious adverse reactions in ≥6% of patients included infections (26%), including pneumonia (7%) and febrile neutropenia (6%)
- Fatal adverse reactions occurred in 5% of patients who received MONJUVI, including cerebrovascular accident (1.2%), respiratory failure (1.2%), progressive multifocal leukoencephalopathy (1.2%), and sudden death (1.2%)
- Permanent discontinuation of MONJUVI or lenalidomide due to an adverse reaction occurred in 25% of patients and permanent discontinuation of MONJUVI due to an adverse reaction occurred in 15%
  - The most frequent adverse reactions which resulted in permanent discontinuation of MONJUVI were infections (5%), nervous system disorders (2.5%), respiratory, thoracic, and mediastinal disorders (2.5%)
- Dosage interruptions of MONJUVI or lenalidomide due to an adverse reaction occurred in 69% of patients and dosage interruption of MONJUVI due to an adverse reaction occurred in 65%
  - The most frequent adverse reactions which required a dosage interruption of MONJUVI were blood and lymphatic system disorders (41%) and infections (27%)
- The most common adverse reactions (≥20%) were neutropenia (51%), fatigue (38%), anemia (36%), diarrhea (36%), thrombocytopenia (31%), cough (26%), pyrexia (24%), peripheral edema (24%), respiratory tract infection (24%), and decreased appetite (22%)
- Clinically relevant adverse reactions in <10% of patients in L-MIND were:
  - Blood and lymphatic system disorders: lymphopenia (6%)
  - General disorders and administration site conditions: IRR (6%)
  - Infections: sepsis (4.9%)
  - Investigations: weight decreased (4.9%)
  - Musculoskeletal and connective tissue disorders: arthralgia (9%), pain in extremity (9%), musculoskeletal pain (2.5%)
  - Neoplasms benign, malignant, and unspecified: basal cell carcinoma (1.2%)
  - Nervous system disorders: headache (9%), paresthesia (7%), dysgeusia (6%)
  - Respiratory, thoracic, and mediastinal disorders: nasal congestion (4.9%), exacerbation of chronic obstructive pulmonary disease (1.2%)
  - Skin and subcutaneous tissue disorders: erythema (4.9%), alopecia (2.5%), hyperhidrosis (2.5%)

IRR=infusion-related reaction.

L-MIND: ADVERSE REACTIONS IN 1-YEAR PRIMARY ANALYSIS[1]

Adverse reactions (≥10%) in patients with R/R DLBCL who received MONJUVI in L-MIND

Adverse Reaction		MONJUVI (N=81)	
		All Grades (%)	Grade 3 or 4 (%)
Blood and lymphatic system disorders	Neutropenia	51	49
	Anemia	36	7
	Thrombocytopenia	31	17
	Febrile neutropenia	12	12
General disorders and administration site conditions	Fatigue*	38	3.7
	Pyrexia	24	1.2
	Peripheral edema	24	0
Gastrointestinal disorders	Diarrhea	36	1.2
	Constipation	17	0
	Abdominal pain†	15	1.2
	Nausea	15	0
	Vomiting	15	0
Respiratory, thoracic, and mediastinal disorders	Cough	26	1.2
	Dyspnea	12	1.2
Infections	Respiratory tract infection‡	24	4.9
	Urinary tract infection§	17	4.9
	Bronchitis	16	1.2
Metabolism and nutrition disorders	Decreased appetite	22	0
	Hypokalemia	19	6
Musculoskeletal and connective tissue disorders	Back pain	19	2.5
	Muscle spasms	15	0
Skin and subcutaneous tissue disorders	Rash‖	15	2.5
	Pruritus	10	1.2

- No new safety signals were observed in the 5-year analysis[5]

*Fatigue includes asthenia and fatigue.

†Abdominal pain includes abdominal pain, abdominal pain lower, and abdominal pain upper.

‡Respiratory tract infection includes: lower respiratory tract infection, upper respiratory tract infection, respiratory tract infection.

§Urinary tract infection includes: urinary tract infection, Escherichia urinary tract infection, urinary tract infection bacterial, urinary tract infection enterococcal.

‖Rash includes rash, rash maculopapular, rash pruritic, rash erythematous, rash pustular.

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L-MIND: LABORATORY ABNORMALITIES IN 1-YEAR PRIMARY ANALYSIS[1]

Select laboratory abnormalities (>20%) worsening from baseline in patients with R/R DLBCL who received MONJUVI in L-MIND

Laboratory Abnormality		MONJUVI*	
		All Grades (%)	Grade 3 or 4 (%)
Chemistry	Glucose increased	49	5
	Calcium decreased	47	1.4
	Gamma glutamyl transferase increased	34	5
	Albumin decreased	26	0
	Magnesium decreased	22	0
	Urate increased	20	7
	Phosphate decreased	20	5
	Creatinine increased	20	1.4
	Aspartate aminotransferase increased	20	0
Coagulation	Activated partial thromboplastin time increased	46	4.1

*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.

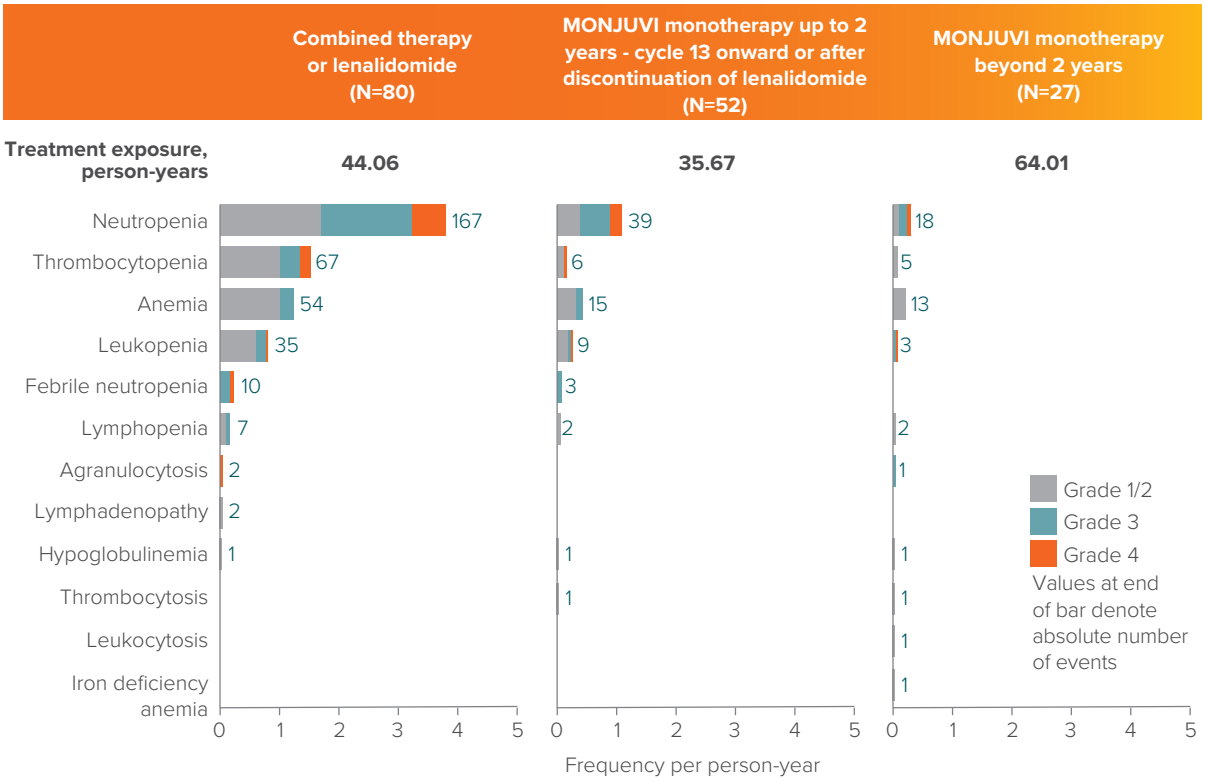
Immunogenicity

As with all therapeutic proteins, there is the potential for immunogenicity. The detection of antibody formation is highly dependent on the sensitivity and specificity of the assays. Additionally, the observed incidence of antibody (including neutralizing antibody) positivity in an assay may be influenced by several factors, including assay methodology, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of the incidence of antibodies in the studies described in the Prescribing Information with the incidence of antibodies in other studies or to other tafasitamab products may be misleading.

Overall, no treatment-emergent or treatment-boosted anti-tafasitamab antibodies were observed. No clinically meaningful differences in the pharmacokinetics, efficacy, or safety profile of tafasitamab-cxix were observed in 2.5% of 81 patients with relapsed or refractory DLBCL with pre-existing anti-tafasitamab antibodies in L-MIND.

SAFETY BY TREATMENT PHASE

HEMATOLOGICAL TREATMENT-EMERGENT ADVERSE EVENTS (EXPOSURE-ADJUSTED)[5]



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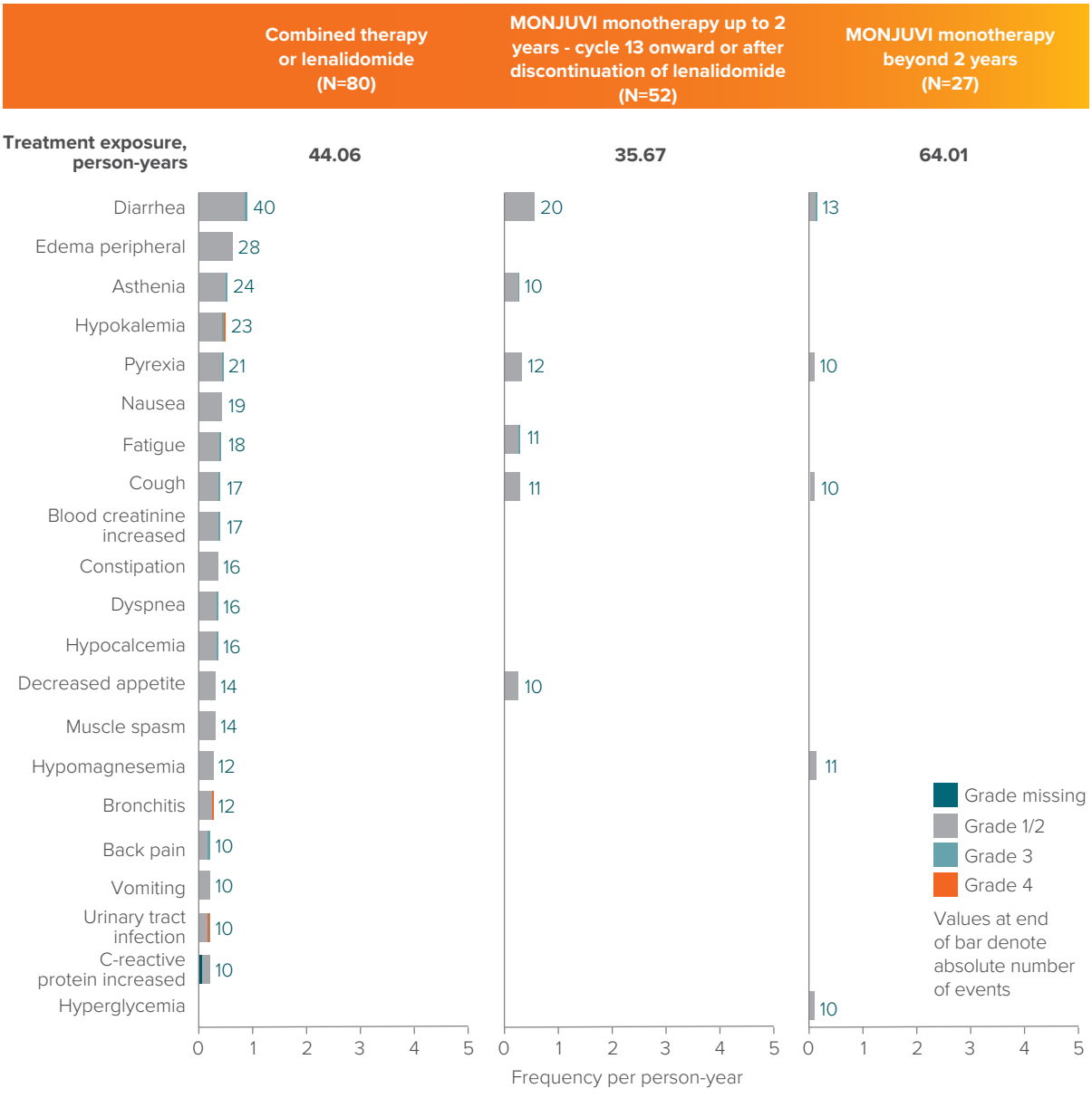
SAFETY BY TREATMENT PHASE

NON-HEMATOLOGICAL TREATMENT-EMERGENT ADVERSE EVENTS (EXPOSURE-ADJUSTED)[5]



- Chart depicts treatment-emergent adverse events with at least 10 events in any treatment period

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DOSAGE AND ADMINISTRATION OF MONJUVI + LENALIDOMIDE

- MONJUVI should be administered by a healthcare professional with immediate access to emergency equipment and appropriate medical support to manage IRRs[1]

The cycle length for MONJUVI is 28 days[1]

Cycle 1

DAYS	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28
MONJUVI 12 mg/kg	■			■				■							■							■						
Lenalidomide 25 mg daily	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●							

Cycles 2 and 3

DAYS	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28
MONJUVI 12 mg/kg	■							■							■							■						
Lenalidomide 25 mg daily	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●							

Cycles 4 to 12

DAYS	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28
MONJUVI 12 mg/kg	■														■													
Lenalidomide 25 mg daily	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●							

After 12 cycles, continue MONJUVI monotherapy until disease progression or unacceptable toxicity

DAYS	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28
MONJUVI 12 mg/kg	■														■													

- Refer to the lenalidomide prescribing information for lenalidomide dosage recommendation[1]
- MONJUVI may be administered in a local office or clinic or at an outpatient center

IMPORTANT SAFETY INFORMATION

Warnings and Precautions (cont.)

Infections (cont.)

Monitor patients for signs and symptoms of infection and manage infections as appropriate.

Embryo-Fetal Toxicity

Based on its mechanism of action, MONJUVI may cause fetal B-cell depletion when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Advise women of reproductive potential to use effective contraception during treatment with MONJUVI and for at least 3 months after the last dose.

MONJUVI is initially administered in combination with lenalidomide. The combination of MONJUVI with lenalidomide is contraindicated in pregnant women because lenalidomide can cause birth defects and death of the unborn child. Refer to the lenalidomide prescribing information on use during pregnancy.

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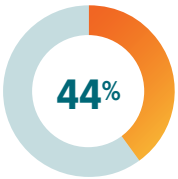
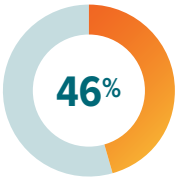
L-MIND: HEMATOLOGIC TOXICITIES MANAGEMENT AND DOSING MODIFICATIONS[1,8,11]

Administer MONJUVI in combination with lenalidomide 25 mg orally for a maximum of 12 cycles, then continue MONJUVI as monotherapy until disease progression or unacceptable toxicity[1]

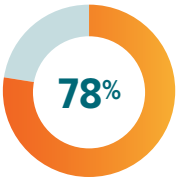
Refer to the lenalidomide prescribing information for lenalidomide dosing recommendations.[1]



44% of patients in L-MIND received concomitant granulocyte-colony stimulating factor[8]



46% of patients (37/80) had at least one dose reduction of lenalidomide[8*]



78% of patients (62/80) were able to receive a lenalidomide dose of ≥20 mg/day over the duration of their treatment[11*]

- Permanent discontinuation of MONJUVI or lenalidomide due to an adverse reaction occurred in 25% of patients and permanent discontinuation of MONJUVI due to an adverse reaction occurred in 15%[1]
- Dosage interruptions of MONJUVI or lenalidomide due to an adverse reaction occurred in 69% of patients and dosage interruption of MONJUVI due to an adverse reaction occurred in 65%[1]

*81 patients were enrolled; 80 patients received MONJUVI plus lenalidomide and 1 received MONJUVI alone.[8]

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RECOMMENDED PREMEDICATIONS[1]

Administer premedications 30 minutes to 2 hours prior to starting MONJUVI infusion to minimize IRRs. Premedications may include acetaminophen, histamine H_1 receptor antagonists, histamine H_2 receptor antagonists, and/or glucocorticosteroids.

For patients not experiencing IRRs during the first 3 infusions, premedication is optional for subsequent infusions.

If a patient experiences an IRR, administer premedications before each subsequent infusion.

PREPARATION AND ADMINISTRATION OF MONJUVI

Reconstitute and dilute MONJUVI prior to infusion[1]

RECONSTITUTION[1]

1. Calculate the dose (mg) and determine the number of vials needed.
2. Reconstitute each 200 mg MONJUVI 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 MONJUVI 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.

DILUTION[1]

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 OF MONJUVI (CONT.)

ADMINISTRATION

1. Administer MONJUVI as an intravenous infusion.[1]
   - 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[1]
     - —In the L-MIND study, after the first 30 minutes, the rate of infusion was increased to 125 mL/h over a 2-hour period[8]
   - Administer all subsequent infusions within 1.5 to 2 hours[1]
   - In the L-MIND study, vital signs were measured immediately prior to infusion, at 15 minutes (+/- 5 minutes), 30 minutes (+/- 10 minutes), every 60 minutes (+/- 15 minutes), and at the end of the infusion (+/- 20 minutes)[8]
2. Infuse the entire contents of the bag containing MONJUVI.[1]
3. Do not co-administer other drugs through the same infusion line.[1]
4. No incompatibilities have been observed between MONJUVI with infusion containers made of polypropylene (PP), polyvinylchloride (PVC), polyethylene (PE), polyethylenterephthalate (PET), or glass and infusion sets made of polyurethane (PUR) or PVC.[1]

HOW MONJUVI IS SUPPLIED[1]

- MONJUVI for injection is a sterile, preservative-free, white to slightly yellowish lyophilized powder for reconstitution, supplied as a 200-mg, single-dose vial
- Each 200-mg vial is individually packaged in a carton (NDC 73535-208-01)

STORAGE AND HANDLING OF MONJUVI[1]

- Store refrigerated at 36 °F to 46 °F (2 °C to 8 °C) in the original carton to protect from light
- Do not shake
- Do not freeze

IMPORTANT SAFETY INFORMATION

Adverse Reactions

Serious adverse reactions occurred in 52% of patients who received MONJUVI. Serious adverse reactions in ≥6% of patients included infections (26%), including pneumonia (7%), and febrile neutropenia (6%). Fatal adverse reactions occurred in 5% of patients who received MONJUVI, including cerebrovascular accident (1.2%), respiratory failure (1.2%), progressive multifocal leukoencephalopathy (1.2%) and sudden death (1.2%).

Please see the full Prescribing Information for additional Important Safety Information.

MONJUVI®
tafasitamab-cxix | 200 mg
for injection, for intravenous use

DOSAGE MODIFICATIONS FOR ADVERSE REACTIONS[1]

- In the L-MIND study, IRRs occurred in 6% of the 81 patients. 80% of IRRs occurred during cycle 1 or 2

Management guidelines for IRRs and myelosuppression

Infusion-related reactions (IRRs)	
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 after rechallenge the reaction returns, stop the infusion immediately.
Grade 4 (life-threatening)	Stop the infusion immediately and permanently discontinue MONJUVI.

IMPORTANT SAFETY INFORMATION

Adverse Reactions (cont.)

Permanent discontinuation of MONJUVI or lenalidomide due to an adverse reaction occurred in 25% of patients and permanent discontinuation of MONJUVI due to an adverse reaction occurred in 15%. The most frequent adverse reactions which resulted in permanent discontinuation of MONJUVI were infections (5%), nervous system disorders (2.5%), respiratory, thoracic and mediastinal disorders (2.5%).

Dosage interruptions of MONJUVI or lenalidomide due to an adverse reaction occurred in 69% of patients and dosage interruption of MONJUVI due to an adverse reaction occurred in 65%. The most frequent adverse reactions which required a dosage interruption of MONJUVI were blood and lymphatic system disorders (41%), and infections (27%).

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DOSAGE MODIFICATIONS FOR ADVERSE REACTIONS (CONT.)[1]

Management guidelines for IRRs and myelosuppression (cont.)

Myelosuppression	
Severity	**Dosage Modification**
Platelet count of 50,000/mcL or less	Withhold MONJUVI and lenalidomide and monitor CBC weekly until platelet count is 50,000/mcL or higher. Resume MONJUVI at the same dose and lenalidomide at a reduced dose. Refer to lenalidomide prescribing information 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 MONJUVI and lenalidomide and monitor CBC weekly until neutrophil count is 1,000/mcL or higher. Resume MONJUVI at the same dose and lenalidomide at a reduced dose. Refer to the lenalidomide prescribing information for dosage modifications.

CBC=complete blood count.

Refer to the lenalidomide Prescribing Information for lenalidomide dosage recommendations.

IMPORTANT SAFETY INFORMATION

Adverse Reactions

The most common adverse reactions (≥20%) were neutropenia (51%), fatigue (38%), anemia (36%), diarrhea (36%), thrombocytopenia (31%), cough (26%), pyrexia (24%), peripheral edema (24%), respiratory tract infection (24%), and decreased appetite (22%).

You may report side effects to the FDA at (800) FDA-1088 or www.fda.gov/medwatch. You may also report side effects to MORPHOSYS US INC. at (844) 667-1992.

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COUNSELING YOUR PATIENTS[1]

Advise the patient to read the FDA-approved patient labeling (Patient Information). Advise your patients to contact their healthcare provider if they experience signs and symptoms of:

Infusion-related reactions

- Advise patients to contact their healthcare provider if they experience signs and symptoms of infusion-related reactions

Myelosuppression

- Fever of 100.4 °F (38 °C) or greater, or bruising or bleeding should be reported immediately
- Advise patients of the need for periodic monitoring of blood counts

Infections

- Fever of 100.4 °F (38 °C) or greater or signs or symptoms of infection should be reported immediately

Embryo-fetal toxicity

- Advise pregnant women of the potential risk to a fetus. Women of reproductive potential should inform their healthcare provider of a known or suspected pregnancy
- Advise women of reproductive potential to use effective contraception during treatment with MONJUVI and for at least 3 months after the last dose
- Advise patients that lenalidomide has the potential to cause fetal harm and has specific requirements regarding contraception, pregnancy testing, blood and sperm donation, and transmission in sperm. Lenalidomide is only available through a REMS program

Lactation

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

REFERENCES: 1. MONJUVI Prescribing Information. Boston, MA: MorphoSys. 6/2021. **2.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for B-Cell Lymphomas V.5.2023. © National Comprehensive Cancer Network, Inc. 2023. All rights reserved. Accessed July 7, 2023. To view the most recent and complete version of the guideline, go online to NCCN.org. **3.** ClinicalTrials.gov. A study to evaluate the safety and efficacy of lenalidomide with MOR00208 in patients with R-R DLBCL (L-MIND). https://clinicaltrials. gov/study/NCT02399085. Accessed June 27, 2023. **4.** Data on file. L-MIND primary analysis. MorphoSys. Boston, MA. **5.** Data on file. 5-year subgroup and safety analyses. MorphoSys. Boston, MA. **6.** 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. **7.** McMillan AK, Phillips EH, Kirkwood AA, et al. Favourable outcomes for high-risk diffuse large B-cell lymphoma (IPI 3-5) treated with front-line R-CODOX-M/R-IVAC chemotherapy: results of a phase 2 UK NCRI trial. *Ann Oncol.* 2020;31(9):1251-1259. **8.** Salles G, Duell J, Gonzáles Barca E, et al. Tafasitamab plus lenalidomide in relapsed or refractory diffuse large B-cell lymphoma (L-MIND): a multicentre, prospective, single-arm, phase 2 study. *Lancet Oncol.* 2020;21(7):978-988. doi:10.1016/S1470-2045(20)30225-4 **9.** Data on file. 5-year follow-up analysis. MorphoSys. Boston, MA. **10.** Data on file. Time to response tables. MorphoSys. Boston, MA. **11.** Data on file. CSR. MorphoSys. Boston, MA.

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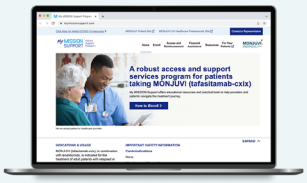
MONJUVI IS AN OUTPATIENT TARGETED IMMUNOTHERAPY FOR ADULT PATIENTS WITH NTE DLBCL IN 2L[1]

INDICATIONS & USAGE

MONJUVI (tafasitamab-cxix), in combination with lenalidomide, is indicated 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).



My MISSION SUPPORT Patient Support Program™

Enroll patients in My MISSION Support today by calling 855-421-6172 or visiting our website at MyMISSIONSupport.com.

My MISSION Support can help you understand health insurance coverage requirements, answer billing and coding questions, and enroll eligible patients in all program services, including financial assistance programs, helping to secure appropriate access to MONJUVI for eligible patients.

RESOURCES FOR YOU AND YOUR PATIENTS

Create customized infusion schedules for your patients ›

Download educational materials for healthcare professionals ›

Find information and resources for your patients ›

SELECT SAFETY INFORMATION

MONJUVI can cause serious adverse reactions including:

- **Infusion-Related Reactions:** Monitor patients frequently during infusion. Interrupt or discontinue infusion based on severity
- **Myelosuppression:** MONJUVI can cause serious or severe myelosuppression, including neutropenia, thrombocytopenia, and anemia. Monitor complete blood counts. Manage using dose modifications and growth factor support. Interrupt or discontinue MONJUVI based on severity
- **Infections:** Fatal and serious infections, including opportunistic infections, occurred in patients during treatment with MONJUVI and following the last dose. Bacterial, fungal, and viral infections can occur during and following MONJUVI. Monitor patients for infections and manage as appropriate
- **Embryo-Fetal Toxicity:** May cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus and use of effective contraception

Please see related and other Important Safety Information discussed throughout this brochure.

Please see the full Prescribing Information for additional Important Safety Information.

Morphosys | Incyte