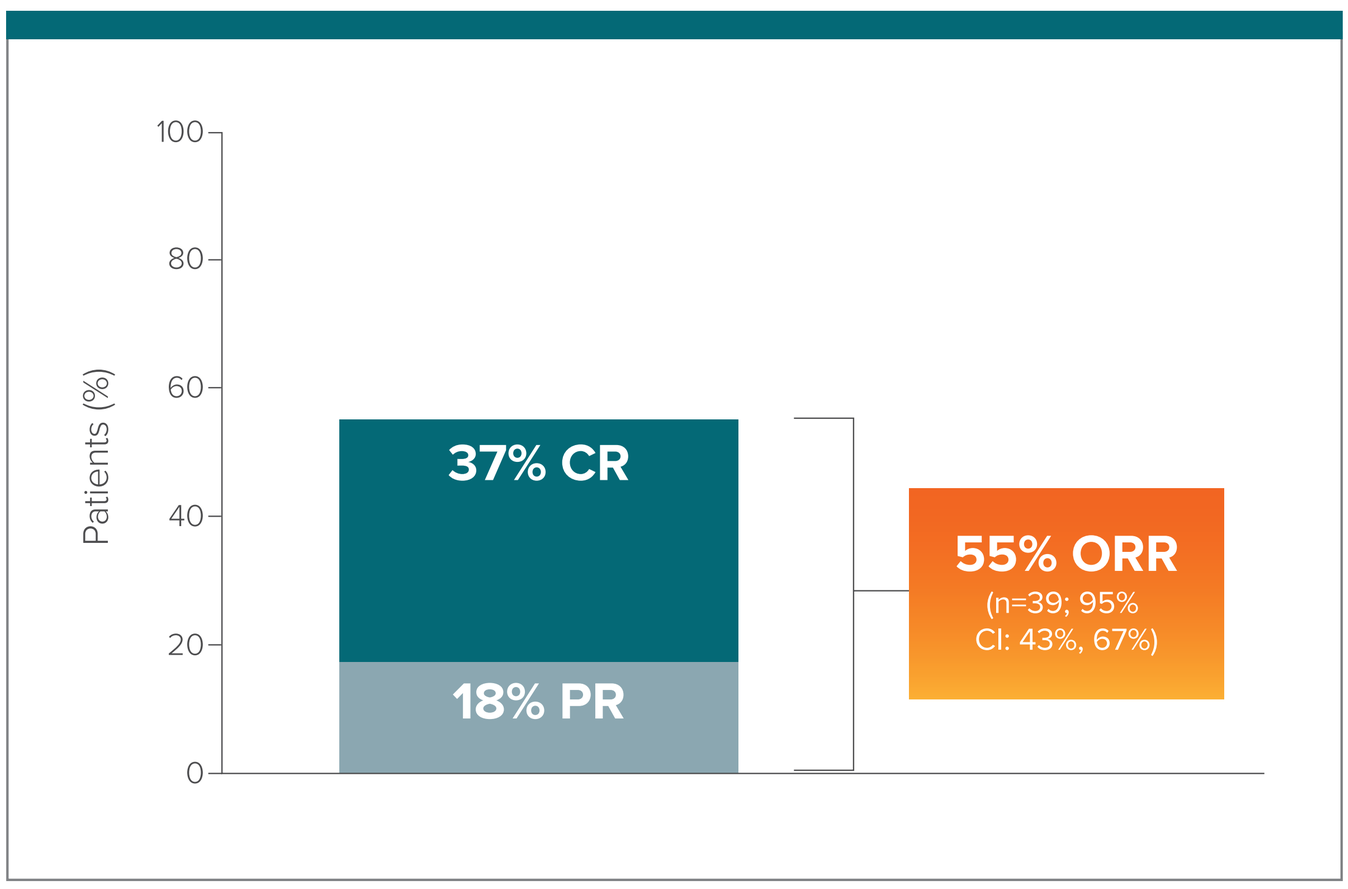
MONJUVI®
tafasitamab-cxix | 200 mg
for injection, for intravenous use

NOW APPROVED

➤ **FDA-approved monoclonal antibody in combination with lenalidomide for adult patients with R/R DLBCL who have received at least one prior therapy[1]**

L-MIND: BEST OVERALL RESPONSE RATE IN PATIENTS WITH R/R DLBCL (N=71)[1]*



R/R DLBCL=relapsed/refractory diffuse large B-cell lymphoma; CR=complete response rate; PR=partial response rate; ORR=overall response rate; CI=confidence interval; ASCT=autologous stem cell transplant; DoR=duration of response.
*Assessed by an Independent Review Committee.

L-MIND STUDY DESIGN[1]

- L-MIND was an open-label, multicenter, single-arm study that evaluated the efficacy and safety of MONJUVI in combination with lenalidomide followed by MONJUVI monotherapy in adult patients with R/R DLBCL after 1 to 3 prior systemic DLBCL therapies, including a CD20-containing therapy. The median number of prior therapies was 2
- Enrolled patients at the time of the trial were not eligible for or refused ASCT
- Efficacy was established in 71 patients with DLBCL (confirmed by central laboratory) based on best ORR (defined as the proportion of complete and partial responders) and DoR

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).

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 chills, 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 available at this booth for additional Important Safety Information.

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L-MIND: DURATION OF RESPONSE (DoR) IN PATIENTS WITH R/R DLBCL[1*]

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

*Assessed by an Independent Review Committee.
†Kaplan-Meier estimates.

IMPORTANT SAFETY INFORMATION

Warnings and Precautions (cont'd)

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.

Infections

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

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.

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.

Adverse Reactions

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

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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REFERENCE: 1. MONJUVI Prescribing Information. Boston, MA: MorphoSys.

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L-MIND: SAFETY PROFILE[1]

ADVERSE REACTIONS[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
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

*Fatigue includes asthenia and fatigue.

†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.

LABORATORY ABNORMALITIES[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.

- 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%)

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