MONJUVI®
tafasitamab-cxix | 200mg
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).

NOW WITH 3-YEAR FOLLOW-UP DATA

SECURE RESPONSE IN SECOND LINE[1]

MONJUVI is the first and only FDA-approved treatment for adult patients with DLBCL who have received at least 1 prior therapy, in combination with lenalidomide[1]

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

DLBCL=diffuse large B-cell lymphoma; NCCN=National Comprehensive Cancer Network.

*It is unclear if tafasitamab or loncastuximab tesirine or if any other CD-19 directed therapy would 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.

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.

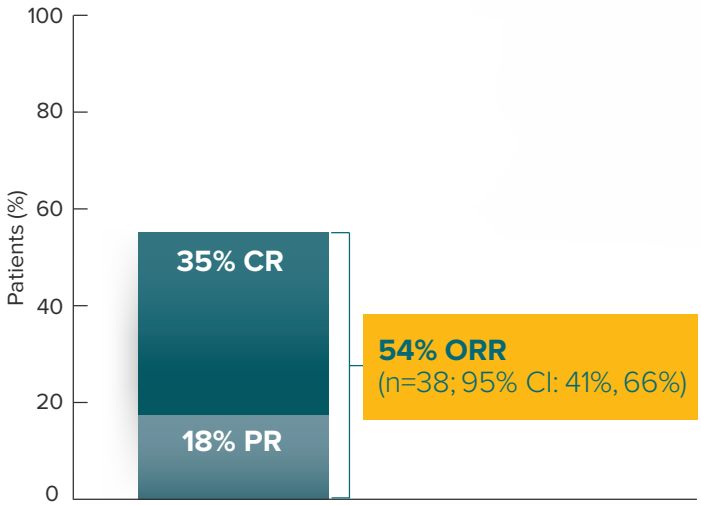
HIGH ORR REACHED, WITH A MAJORITY OF RESPONDERS ACHIEVING CR[1]

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

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

3-YEAR ORR[3]

Follow-up analysis in patients with R/R DLBCL (N=71)[3*]



CI=confidence interval.

*Assessed by an Independent Review Committee.[1,3]

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 3-year follow-up analysis was October 30, 2020 and occurred after the last patient enrolled had completed 35 months of follow-up.[3,4]

L-MIND Study Design

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 (confirmed by central laboratory). Efficacy was established in 71 patients based on best ORR (CR + PR) and DoR, as assessed by an Independent Review Committee using the International Working Group Response Criteria (Cheson 2007).[1]

The time between first DLBCL diagnosis and first documented relapse or progression was ≤12 months for 23.9% (n=17) and >12 months for 74.6% (n=53) of patients. 19.7% of patients (n=14) had primary refractory disease. For 45% of patients (n=32), disease was refractory to their last prior therapy. IPI scores ranged from 3 to 5 for 52.1% (n=37) and 0 to 2 for 47.9% (n=34) of patients.[1,5]

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.

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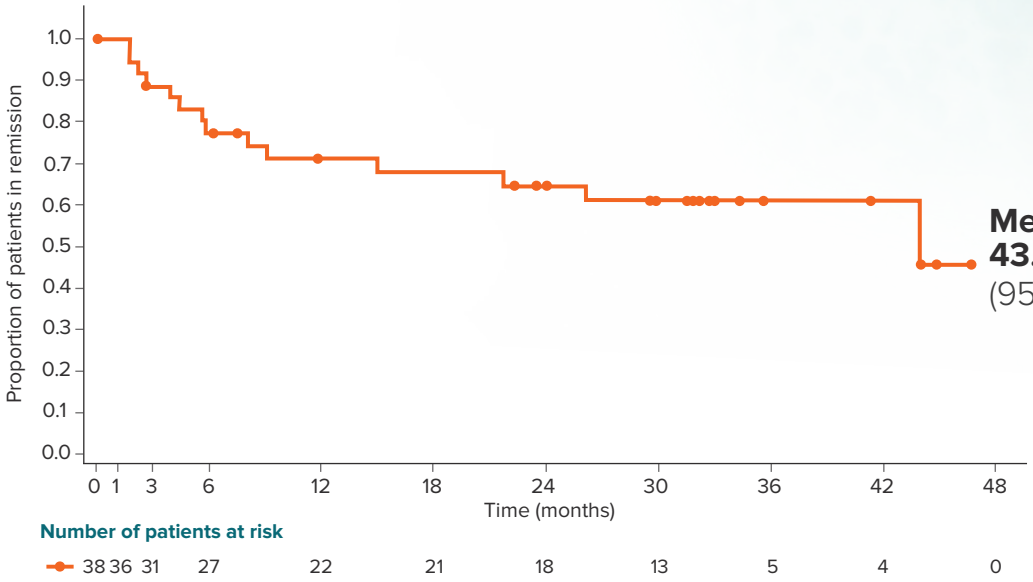
RESPONSE SUSTAINED IN PATIENTS WITH R/R DLBCL[1]

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

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

3-YEAR MEDIAN DOR[3]

Follow-up analysis in patients with R/R DLBCL (N=71)[3*†]



Median DoR: 43.9 months
(95% CI: 15.0, NR)

*Assessed by an Independent Review Committee.[1,3]

†Kaplan-Meier estimates.[1,3]

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 3-year follow-up analysis was October 30, 2020 and occurred after the last patient enrolled had completed 35 months of follow-up.[3,4]

IMPORTANT SAFETY INFORMATION

Warnings and Precautions (cont'd)

Myelosuppression (cont'd)

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.

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IMPORTANT SAFETY INFORMATION

Warnings and Precautions (cont'd)

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

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%).

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.

▶ To learn more, visit MonjuviHCP.com

▶ For information about patient assistance, visit MyMissionSupport.com

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

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.4.2021. © National Comprehensive Cancer Network, Inc. 2021. All rights reserved. Accessed May 6, 2021. To view the most recent and complete version of the guideline, go online to NCCN.org. **3.** Data on file. 3-year follow-up analysis. MorphoSys. Boston, MA. **4.** Data on file. CSR. MorphoSys. Boston, MA. **5.** Data on file. Primary analysis ad hoc tables. MorphoSys. Boston, MA.

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