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).

SECURE RESPONSE IN SECOND LINE[1]

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

MONJUVI is the only outpatient targeted immunotherapy for adult NTE patients with R/R DLBCL in 2L with 5-year data[1,2]*

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

5-year follow-up analysis[2†]:

- **Best ORR: 54%** (n=38; 95% CI: 41%, 66%); **CR: 37%; PR: 17%**
- **Median DoR: not reached** after a median follow-up of 53.8 months‡

- L-MIND was an open-label, multicenter, single-arm, Phase 2 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[1,3]
- Enrolled patients at the time of the trial were not eligible for or refused ASCT[1]
- 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, as assessed by an Independent Review Committee using the International Working Group Response Criteria (Cheson 2007)[1]

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.

*MONJUVI is a CD19-directed cytolytic monoclonal antibody.[1] †Assessed by an Independent Review Committee.[1,2] ‡Kaplan-Meier estimates.[1,2]

NTE=non-transplant eligible; R/R=relapsed/refractory; DLBCL=diffuse large B-cell lymphoma; 2L=second line; ORR=overall response rate; CI=confidence interval; CR=complete response rate; PR=partial response rate; DoR=duration of response; ASCT=autologous stem cell transplant.

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.

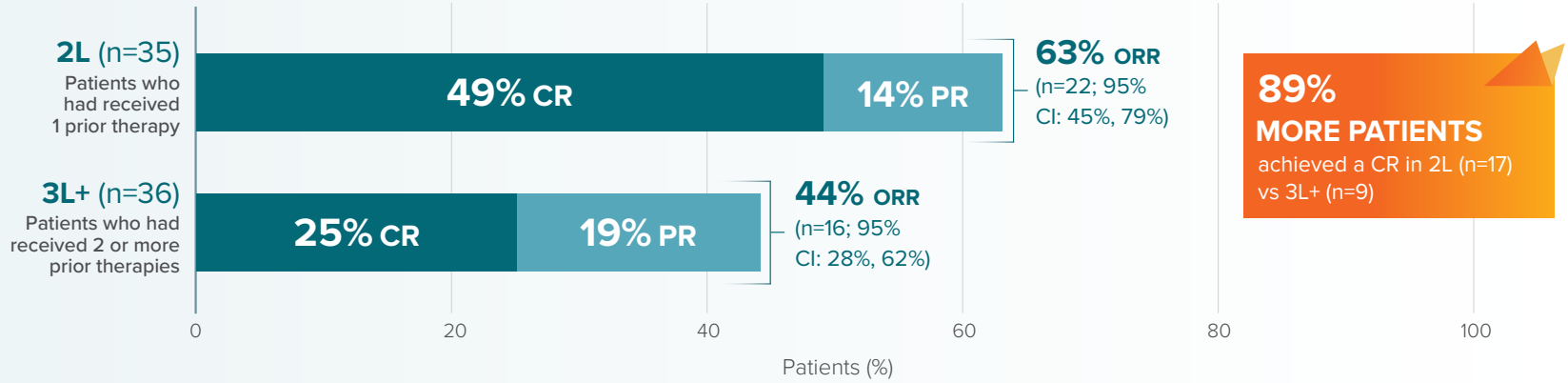
HIGH ORR REACHED, WITH A MAJORITY OF RESPONDERS ACHIEVING CR[1]

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[2]*: best ORR: 54% (n=38; 95% CI: 41%, 66%); CR: 37%; PR: 17%

5-year subgroup analysis[2]*



This analysis is 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, which may lead to estimates that are unstable.

Patients received MONJUVI 12 mg/kg intravenously in combination with lenalidomide (25 mg orally on days 1 to 21 of each 28-day cycle) for a maximum of 12 cycles, followed by MONJUVI as monotherapy until disease progression or unacceptable toxicity.[1]

*Assessed by an Independent Review Committee.[1,2]

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.[2,4]

3L=third line.

IMPORTANT SAFETY INFORMATION (cont'd)

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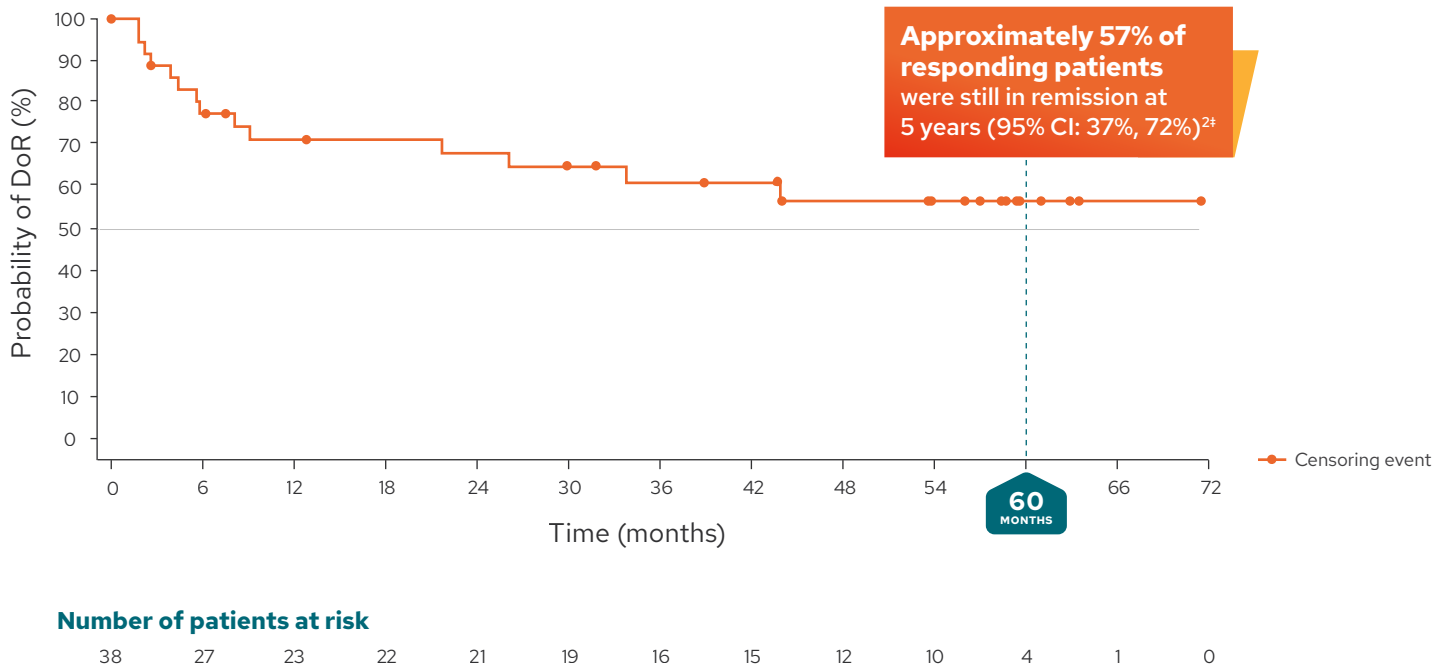
MONJUVI® tafasitamab-cxix | 200mg for injection, for intravenous use

SUSTAINED REMISSION IN PATIENTS WITH R/R DLBCL[1,2]

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: median DoR not reached
(median follow-up 53.8 months [95% CI: 31.8–58.7])[2*†]



*Assessed by an Independent Review Committee.[1,2]

†Kaplan-Meier estimates.[1,2]

‡DoR rate at 5 years is a Kaplan-Meier estimate and should be interpreted with caution due to the small sample size and the number of censored patients.

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 analysis was November 14, 2022, and occurred after the last patient enrolled had completed 5 years of follow-up.[2,4]

IMPORTANT SAFETY INFORMATION (cont'd)

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.

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DURATION OF RESPONSE BY PATIENT[2]

DoR by patient from time of initial response[2]

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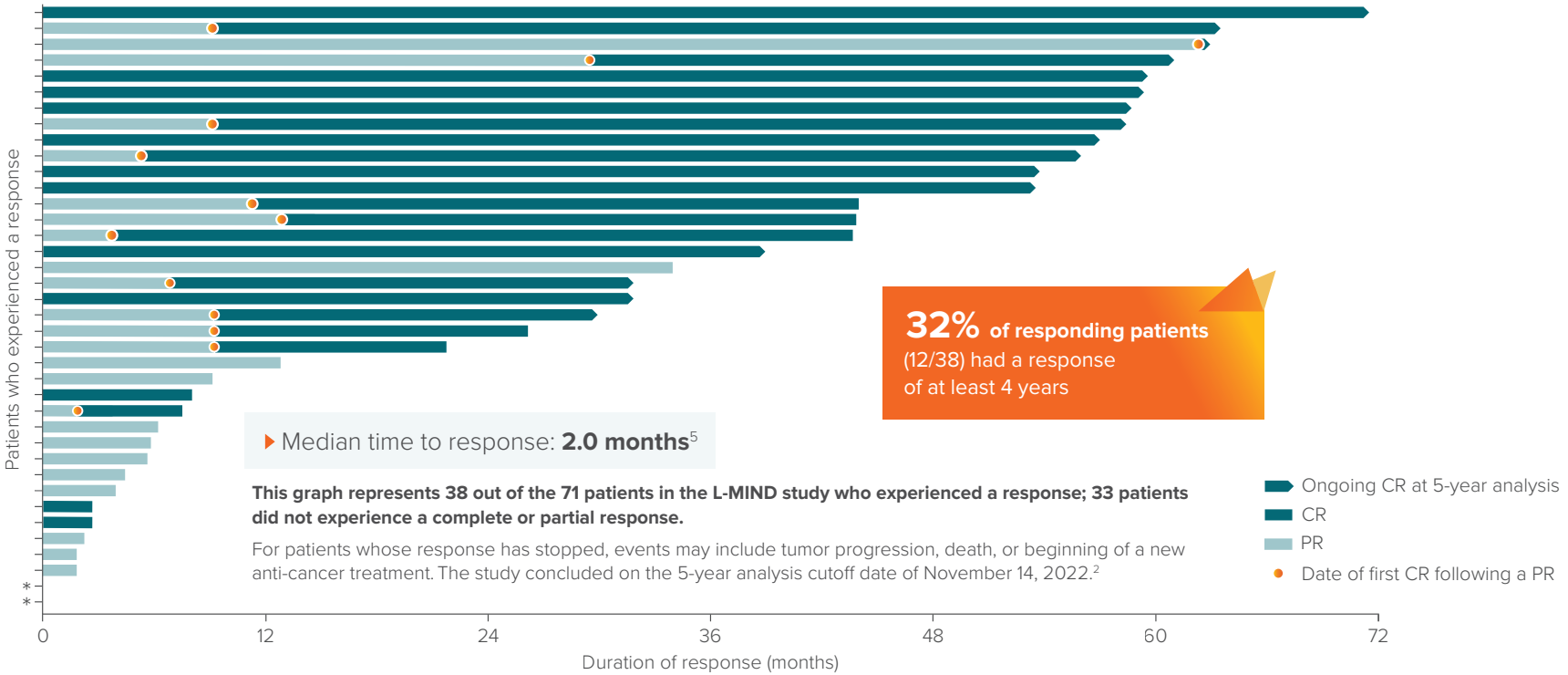

This analysis is exploratory in nature. These results should be interpreted with caution due to single-arm studies not adequately characterizing time-to-event endpoints, and the small sample size, which may lead to estimates that are unstable.

*Two patients started a new anti-cancer treatment immediately after a response was recorded at the end of the treatment assessment.[2]

The initial assessment of efficacy/disease response was performed and recorded at Cycle 3, Day 1.[4]

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.[2,4]

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and Precautions (cont'd)

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.

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REACH FOR TARGETED IMMUNOTHERAPY WITH MONJUVI[1]*

Responses at 5-year follow-up analysis[2]

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68%

of responders (26/38) achieved a best response of CR[2]

55%

of responding patients (21/38) had a response of at least 2 years[2]

1 out of 3

responders (13/38) converted from a PR to a CR[2]

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 (NCCN Category 2A).[6†]

To download resources, visit MonjuviHCP.com/educational-materials

*MONJUVI is a CD19-directed cytolytic monoclonal antibody.[1]

†It is unclear if tafasitamab or loncastuximab tesirine or if any other CD19-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 (cont'd)

Warnings and Precautions (cont'd)

Infections (cont'd)

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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REACH FOR MONJUVI for a chance to achieve sustained remission

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MONJUVI is the only outpatient targeted immunotherapy for adult NTE patients with R/R DLBCL in 2L with 5-year data[1,2]*

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*MONJUVI is a CD19-directed cytolytic monoclonal antibody.[1] †Assessed by an Independent Review Committee.[1] ‡Kaplan-Meier estimates.[1]

An estimated

>4000

patients have received MONJUVI in the US[7§]

§Since FDA approval in 2020.

- To learn more, visit MonjuviHCP.com
- For information about patient assistance, visit HCP.IncyteCARES/MONJUVI

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).

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IMPORTANT SAFETY INFORMATION (cont'd)

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%).

Please see the Full Prescribing Information.

REFERENCES: 1. MONJUVI Prescribing Information. Wilmington, DE: Incyte Corporation. **2.** Data on file. 5-year follow-up analysis. Incyte Corporation. **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 April 4, 2024. **4.** Data on file. CSR. Incyte Corporation. **5.** Data on file. Time to response tables. Incyte Corporation. **6.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for B-Cell Lymphomas V2.2024. © National Comprehensive Cancer Network, Inc. 2024. All rights reserved. Accessed June 1, 2024. To view the most recent and complete version of the guidelines, go online to NCCN.org. **7.** Data on file. Number of patients treated. Incyte Corporation.