

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 LINE¹

MONJUVI[®]
tafasitamab-cxix | 200mg
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^{3,4†}:

▶ **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^{1,5}

▶ Enrolled patients at the time of the trial were not eligible for or refused ASCT¹

▶ 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! [†]Assessed by an Independent Review Committee! [‡]Kaplan-Meier estimate!^{1,4}

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 (tafasitamab-cxix) can cause infusion-related reactions (IRRs).

In L-MIND, infusion-related reactions occurred in 6% of the 81 patients with DLBCL

who received MONJUVI. 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 generally 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.

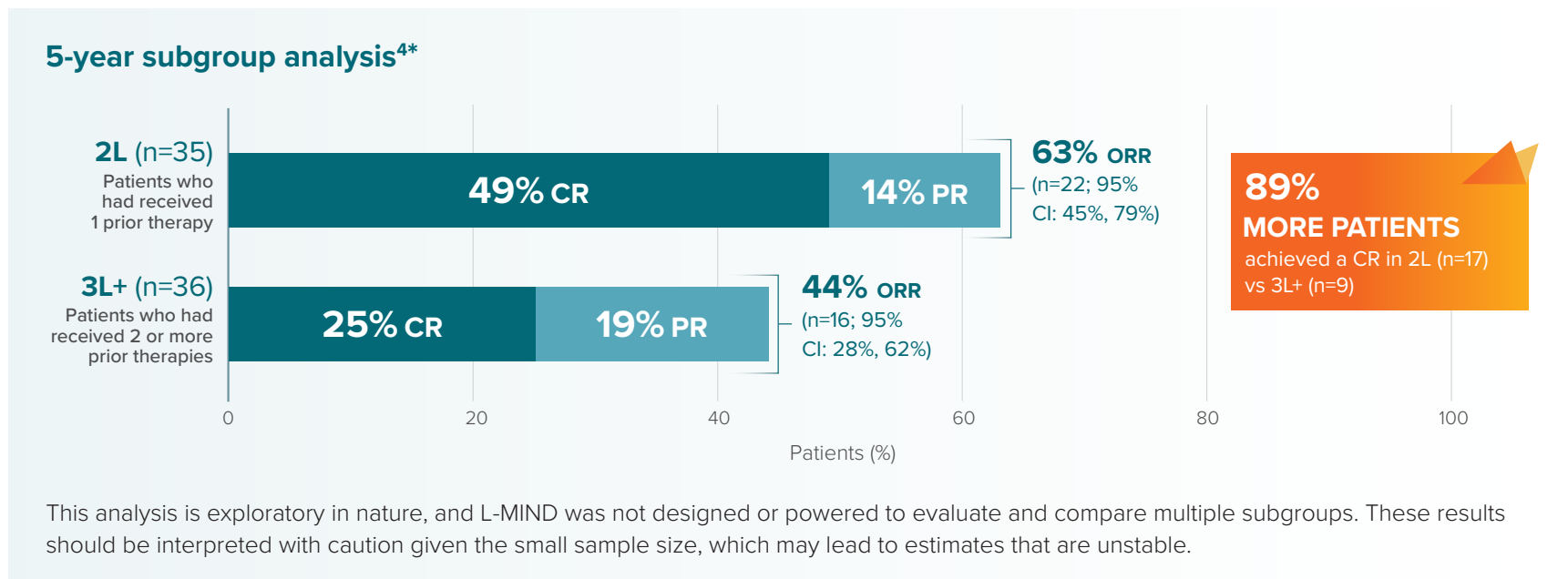
Please see additional Important Safety Information throughout and the full [Prescribing Information](#) for more information about MONJUVI.

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^{4*}: best ORR: 54% (n=38; 95% CI: 41%, 66%); CR: 37%; PR: 17%



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

¹Assessed by an Independent Review Committee.¹

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.^{2,3}

3L=third line.

IMPORTANT SAFETY INFORMATION

Warnings and Precautions (cont'd)

Myelosuppression

MONJUVI can cause serious or severe myelosuppression, including neutropenia, lymphopenia, thrombocytopenia, and anemia.

In L-MIND, among 81 patients with DLBCL who received MONJUVI, Grade 3 neutropenia was reported in 25%, Grade 3 thrombocytopenia in 12%, and Grade 3 anemia in 7%. Grade 4 neutropenia was reported in 25% and Grade 4 thrombocytopenia in 6%. Neutropenia led to treatment discontinuation in 3.7% of the patients. Febrile neutropenia occurred in 12%.

Please see additional Important Safety Information throughout and the full [Prescribing Information](#) for more information about MONJUVI.

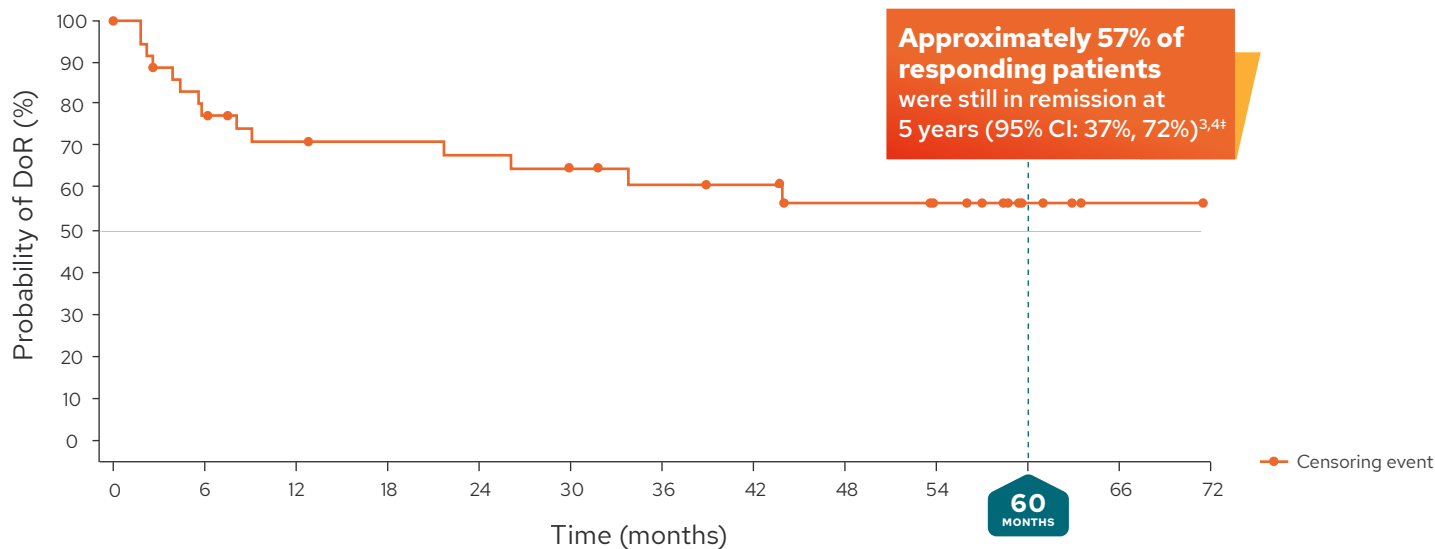
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SUSTAINED REMISSION IN PATIENTS WITH R/R DLBCL^{1,3,4}

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])^{3,4**}



Number of patients at risk

38 27 23 22 21 19 16 15 12 10 4 1 0

*Assessed by an Independent Review Committee.¹

[†]Kaplan-Meier estimate.^{1,4}

[‡]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.^{2,3}

IMPORTANT SAFETY INFORMATION

Warnings and Precautions (cont'd)

Myelosuppression (cont'd)

Monitor complete blood counts (CBCs) before 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.

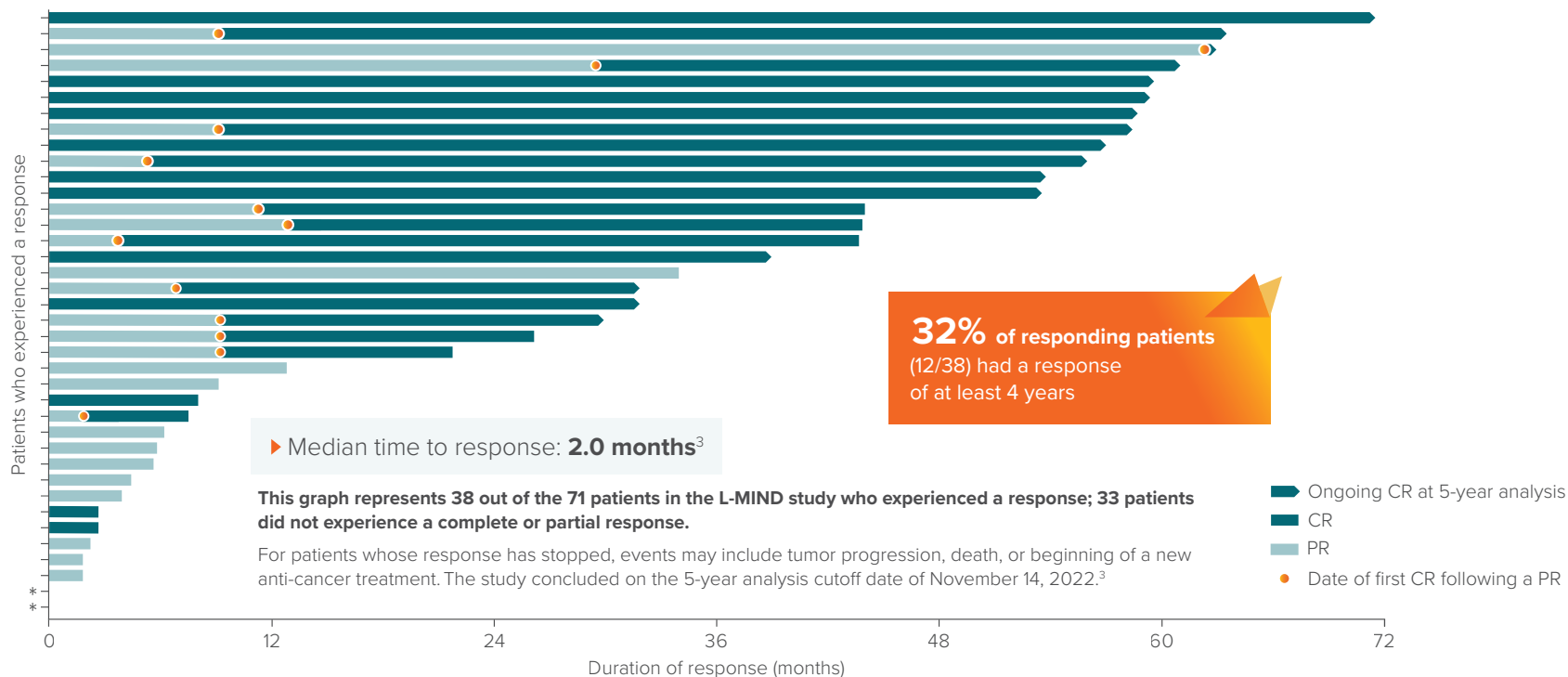
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DURATION OF RESPONSE BY PATIENT³

DoR by patient from time of initial response³

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.



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.³

The initial assessment of efficacy/disease response was performed and recorded at Cycle 3, Day 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 5-year follow-up analysis was November 14, 2022, and occurred after the last patient enrolled had completed 5 years of follow-up.^{2,3}

IMPORTANT SAFETY INFORMATION

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 with DLBCL who received MONJUVI developed an infection. Grade 3 or higher infection occurred in 30%. Infection-related deaths occurred in 2.5% of patients, including a case of progressive multifocal leukoencephalopathy (PML). The most frequent Grade 3 or higher infection was pneumonia (7%). The most frequent infections of any grade were respiratory tract infections (51%, including pneumonias) and urinary tract infection (17%).

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REACH FOR TARGETED IMMUNOTHERAPY WITH MONJUVI^{1*}

Responses at 5-year follow-up analysis³

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.

68%

of responders (26/38)
achieved a best
response of CR³

55%

of responding patients
(21/38) had a response
of at least 2 years³

1 out of 3

responders (13/38)
converted from a
PR to a CR³



National Comprehensive Cancer Network® (NCCN®) recommends as an NCCN Category 2A, Preferred Treatment Option

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) recommend tafasitamab-cxix (MONJUVI) + lenalidomide as an NCCN Category 2A preferred second-line or subsequent treatment option (if not previously used) for certain[†] patients living with DLBCL.^{6†}

To download resources, visit [MONJUVIhcp.com/educational-materials](https://www.monjuvihcp.com/educational-materials)

¹MONJUVI is a CD19-directed cytolytic monoclonal antibody.

³Category 2A treatment option for patients who relapsed in less than 12 months and are non-candidates for CAR T-cell therapy (excluding primary refractory disease); Category 2A treatment option for patients who relapsed after more than 12 months with no intention to proceed with transplant.⁶

[†]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

Warnings and Precautions (cont'd)

Infections (cont'd)

Monitor patients for signs and symptoms of infection and manage infections as appropriate. Consider infection prophylaxis per institutional guidelines. Consider treatment with subcutaneous or intravenous immunoglobulin (IVIg) 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 3 months after the last dose.

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 REMISSION¹

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3 key reasons to consider MONJUVI as a 2L treatment for adults with R/R DLBCL who are transplant ineligible:

1 Long-term efficacy data²



2 Well-established safety profile^{1,2}



3 Patients can receive treatment close to home—No hospitalization required for administration^{1*}



*MONJUVI should be administered by a healthcare professional with immediate access to emergency equipment and appropriate medical support to manage infusion-related reactions. Monitor patients frequently during infusion. Hospitalization may be required to manage adverse reactions.¹

An estimated

>4300

patients have received MONJUVI in the US³

Since FDA approval in 2020.

▶ To learn more, visit MONJUVIhcp.com

▶ For information about patient assistance, visit HCP.IncyteCARES/MONJUVI

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IMPORTANT SAFETY INFORMATION

Adverse Reactions

Serious adverse reactions occurred in 52% of patients who received MONJUVI. Serious adverse reactions in $\geq 6\%$ 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 additional Important Safety Information throughout and the full [Prescribing Information](#) for more information about MONJUVI.

REFERENCES: 1. MONJUVI Prescribing Information. Wilmington, DE: Incyte Corporation. 2. Duell J, Abrisqueta P, Andre M, et al. Tafasitamab for patients with relapsed or refractory diffuse large B-cell lymphoma: final 5-year efficacy and safety findings in the phase II L-MIND study. *Haematologica*. 2024;109(2):553-566. doi:10.3324/haematol.2023.283480 3. Data on File. Incyte Corporation. 4. Duell J, Abrisqueta P, Andre M, et al. Tafasitamab for patients with relapsed or refractory diffuse large B-cell lymphoma: final 5-year efficacy and safety findings in the phase II L-MIND study. *Haematologica*. 2024;109(2)(Suppl):553-566. doi:10.3324/haematol.2023.283480 5. 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 February 25, 2025. 6. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines[®]) for B-Cell Lymphomas V.3.2025. © National Comprehensive Cancer Network, Inc. 2025. All rights reserved. Accessed August 18, 2025. To view the most recent and complete version of the guideline, go online to NCCN.org.



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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%), and 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 ($\geq 20\%$) were neutropenia (51%), respiratory tract infection (51%), fatigue (38%), anemia (36%), diarrhea (36%), thrombocytopenia (31%), cough (26%), pyrexia (24%), peripheral edema (24%), and decreased appetite (22%).