

MONJUVI- tafasitamab-cxix injection, powder, lyophilized, for solution Incyte Corporation

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use MONJUVI safely and effectively. See full prescribing information for MONJUVI.

MONJUVI® (tafasitamab-cxix) for injection, for intravenous use
Initial U.S. Approval: 2020

RECENT MAJOR CHANGES

Indications and Usage, Relapsed or Refractory Follicular Lymphoma (1.2)	6/2025
Dosage and Administration, Recommended Dosage for Relapsed or Refractory Follicular Lymphoma (2.3)	6/2025
Dosage and Administration, Recommended Premedications and Prophylactic Medication (2.4)	6/2025
Warnings and Precautions, Infusion-Related Reactions (5.1)	6/2025
Warnings and Precautions, Myelosuppression (5.2)	6/2025
Warnings and Precautions, Infections (5.3)	6/2025

INDICATIONS AND USAGE

MONJUVI is a CD19-directed cytolytic antibody indicated:

- in combination with lenalidomide 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). (1.1)
- in combination with lenalidomide and rituximab for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL). (1.2)

Limitations of Use:

MONJUVI is not indicated and is not recommended for the treatment of patients with relapsed or refractory marginal zone lymphoma outside of controlled clinical trials. (1.2, 14.3)

DOSAGE AND ADMINISTRATION

- Administer premedications prior to starting MONJUVI. (2.4)
- See Full Prescribing Information for instructions on preparation and administration. (2.6)

Diffuse Large B-cell Lymphoma

- The recommended dosage of MONJUVI is 12 mg/kg as an intravenous infusion according to the following dosing schedule: (2.2)
 - Cycle 1: Days 1, 4, 8, 15, and 22 of the 28-day cycle.
 - Cycles 2 and 3: Days 1, 8, 15, and 22 of each 28-day cycle.
 - Cycle 4 and beyond: Days 1 and 15 of each 28-day cycle.
- Administer MONJUVI in combination with lenalidomide for a maximum of 12 cycles and then continue MONJUVI as monotherapy until disease progression or unacceptable toxicity. (2.2)

Follicular Lymphoma

- The recommended dosage of MONJUVI is 12 mg/kg as an intravenous infusion according to the following dosing schedule: (2.3)
 - Cycles 1 to 3: Days 1, 8, 15, and 22 of each 28-day cycle.
 - Cycles 4 to 12: Days 1 and 15 of each 28-day cycle.
- Administer MONJUVI in combination with lenalidomide (Cycles 1 to 12) and rituximab (Cycles 1 to 5). (2.3)

DOSAGE FORMS AND STRENGTHS

For injection: 200 mg of tafasitamab-cxix as lyophilized powder in single-dose vial for reconstitution. (3)

CONTRAINDICATIONS

None. (4)

WARNINGS AND PRECAUTIONS

- **Infusion-Related Reactions:** Monitor patients frequently during infusion. Interrupt or discontinue infusion based on severity. (2.5, 5.1)
- **Myelosuppression:** Monitor complete blood counts. Manage using dose modifications and growth factor support. Interrupt or discontinue MONJUVI based on severity. (2.5, 5.2)
- **Infections:** Bacterial, fungal and viral infections can occur during and following MONJUVI. Monitor patients for infections. (2.5, 5.3)

- **Embryo-Fetal Toxicity:** May cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus and use of effective contraception. (5.4)

----- **ADVERSE REACTIONS** -----

The most common adverse reactions ($\geq 20\%$) in patients with relapsed or refractory DLBCL are neutropenia, respiratory tract infection, fatigue, anemia, diarrhea, thrombocytopenia, cough, pyrexia, peripheral edema, and decreased appetite. (6.1)

The most common adverse reactions ($\geq 20\%$), excluding laboratory abnormalities, in patients with relapsed or refractory FL are respiratory tract infections, diarrhea, rash, fatigue, constipation, musculoskeletal pain, and cough. The most common Grade 3 or 4 laboratory abnormalities ($\geq 20\%$) are decreased neutrophils and decreased lymphocytes.

To report SUSPECTED ADVERSE REACTIONS, contact Incyte Corporation at 1-855-463-3463 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

----- **USE IN SPECIFIC POPULATIONS** -----

Lactation: Advise not to breastfeed. (8.2)

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

Revised: 6/2025

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

1.1 Relapsed or Refractory Diffuse Large B-cell Lymphoma

MONJUVI, 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 [see *Clinical Studies (14.1)*]. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

1.2 Relapsed or Refractory Follicular Lymphoma

MONJUVI, in combination with lenalidomide and rituximab, is indicated for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL).

Limitations of Use: MONJUVI is not indicated and is not recommended for the treatment of patients with relapsed or refractory marginal zone lymphoma outside of controlled clinical trials [see *Clinical Studies (14.3)*].

2 DOSAGE AND ADMINISTRATION

2.1 Important Dosing Information

MONJUVI should be administered by a healthcare professional with immediate access to emergency equipment and appropriate medical support to manage infusion-related reactions [see *Warnings and Precautions (5.1)*].

2.2 Recommended Dosage for Relapsed or Refractory Diffuse Large B-cell Lymphoma

The recommended dose of MONJUVI is 12 mg/kg based on actual body weight administered as an intravenous infusion in combination with lenalidomide, according to the dosing schedule in Table 1.

Table 1: MONJUVI Dosing Schedule for Patients with Relapsed or Refractory DLBCL

Cycle*	Dosing Schedule
Cycle 1	Days 1, 4, 8, 15, and 22
Cycles 2 and 3	Days 1, 8, 15, and 22
Cycle 4 and beyond	Days 1 and 15

* Each treatment cycle is 28 days.

Administer MONJUVI in combination with lenalidomide 25 mg for a maximum of 12 cycles, then continue MONJUVI as monotherapy until disease progression or

unacceptable toxicity [see *Clinical Studies (14.1)*]. Refer to the lenalidomide prescribing information for lenalidomide dosage recommendations, including for patients with renal insufficiency.

2.3 Recommended Dosage for Relapsed or Refractory Follicular Lymphoma

The recommended dose of MONJUVI is 12 mg/kg based on actual body weight administered as an intravenous infusion in combination with lenalidomide and rituximab, according to the dosing schedule in Table 2.

Table 2: MONJUVI Dosing Schedule for Patients with Relapsed or Refractory FL

Cycle*	Dosing Schedule
Cycles 1 to 3	Days 1, 8, 15, and 22
Cycles 4 to 12	Days 1 and 15

* Each treatment cycle is 28 days.

Administer MONJUVI in combination with lenalidomide 20 mg (Days 1-21 in Cycles 1 to 12) and rituximab 375 mg/m² (Cycles 1 to 5) [see *Clinical Studies (14.2)*]. Refer to the rituximab prescribing information and the lenalidomide prescribing information for the respective dosage recommendations, including lenalidomide dosage recommendations for patients with renal insufficiency.

2.4 Recommended Premedications and Prophylactic Medication

Premedication

Administer premedications 30 minutes to 2 hours prior to starting MONJUVI infusion to minimize infusion-related reactions [see *Warnings and Precautions (5.1)*]. Premedications may include acetaminophen, histamine H₁ receptor antagonists, histamine H₂ receptor antagonists, and/or glucocorticosteroids.

For patients not experiencing infusion-related reactions during the first 3 infusions, premedication is optional for subsequent infusions.

If a patient experiences an infusion-related reaction, administer premedications before each subsequent infusion.

Thromboprophylaxis

Refer to the lenalidomide prescribing information for recommendations on prophylaxis for venous and arterial thrombotic events.

2.5 Dosage Modifications for Adverse Reactions

The recommended dosage modifications for adverse reactions are summarized in Table 3.

Table 3: Dosage Modifications for Adverse Reactions

Adverse Reaction	Severity	MONJUVI Dosage Modification
	Grade 2 (moderate)	<ul style="list-style-type: none"> 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.
Infusion-related reactions [see <i>Warnings and Precautions (5.1)</i>]*	Grade 3 (severe)	<ul style="list-style-type: none"> • 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 Grade 3 reaction returns, stop the infusion immediately and permanently discontinue MONJUVI.
	Grade 4 (life-threatening)	<ul style="list-style-type: none"> • Stop the infusion immediately and permanently discontinue MONJUVI.
	Platelet count of 50,000/mcL or less	<ul style="list-style-type: none"> • Withhold MONJUVI and lenalidomide and monitor complete blood count (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.
Myelosuppression [see <i>Warnings and Precautions (5.2)</i>]	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	<ul style="list-style-type: none"> • 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 lenalidomide prescribing information for dosage modifications.

* Ensure premedications administered before subsequent infusions [see *Dosage and Administration (2.4)*].

2.6 Preparation and Administration

Reconstitute and dilute MONJUVI prior to infusion.

Reconstitution

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. 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.

Administration

- Administer MONJUVI as an intravenous infusion.
 - 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.
 - Administer all subsequent infusions within 1.5 to 2 hours.
- Infuse the entire contents of the bag containing MONJUVI.
- Do not co-administer other drugs through the same infusion line.
- No incompatibilities have been observed between MONJUVI with infusion containers made of polypropylene (PP), polyvinylchloride (PVC), polyethylene (PE), polyethylene terephthalate (PET), or glass and infusion sets made of polyurethane (PUR) or PVC.

3 DOSAGE FORMS AND STRENGTHS

For injection: 200 mg of tafasitamab-cxix as white to slightly yellowish lyophilized powder in single-dose vial for reconstitution and further dilution.

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Infusion-Related Reactions

MONJUVI can cause infusion-related reactions [see *Adverse Reactions* (6.1)].

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. In inMIND, infusion-related reactions occurred in 16% of the 274 patients with FL who received MONJUVI in combination with lenalidomide and rituximab. 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 [see *Dosage and Administration* (2.4)]. Monitor patients frequently during infusion. Based on the severity of the infusion-related reaction, interrupt or discontinue MONJUVI [see *Dosage and Administration* (2.5)]. Institute appropriate medical management.

5.2 Myelosuppression

MONJUVI can cause serious or severe myelosuppression, including neutropenia, lymphopenia, thrombocytopenia, and anemia [see *Adverse Reactions* (6.1)].

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 with DLBCL. Febrile neutropenia occurred in 12%.

In inMIND, among 274 patients with FL who received MONJUVI in combination with lenalidomide and rituximab, new or worsening Grade 3 or 4 cytopenias included decreased neutrophils in 48% (Grade 4, 19%), decreased lymphocytes in 22% (Grade 4, 1.8%), decreased hemoglobin in 9%, and decreased platelets in 8% (Grade 4, 4%). Febrile neutropenia occurred in 4.4%.

Monitor CBCs before each treatment cycle and throughout treatment. Monitor patients with neutropenia for signs of infection. Consider granulocyte colony-stimulating factor administration. Withhold MONJUVI based on the severity of the adverse reaction [see *Dosage and Administration* (2.5)]. Refer to the lenalidomide prescribing information for dosage modifications.

5.3 Infections

Fatal and serious infections, including opportunistic infections, occurred in patients during treatment with MONJUVI and following the last dose [see *Adverse Reactions* (6.1)].

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%).

Among 274 patients with FL who received MONJUVI in combination with lenalidomide and rituximab in inMIND, Grade 3 or higher infections occurred in 24%, including fatal infections in 1.1% of patients. The most frequent Grade \geq 3 infections were respiratory tract infections (19%), including Grade 3 or higher pneumonia (14%) and COVID-19 infection (11%). Opportunistic infections of any grade occurred in 6% of patients, including herpes simplex or zoster infection (5%), fungal pneumonia (1.1%, including *Pneumocystis jirovecii* pneumonia in 0.4%), and cytomegalovirus (CMV) reactivation (0.4%).

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.

5.4 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 females of reproductive potential to use effective contraception during treatment with MONJUVI and for 3 months after the last dose [see *Use in Specific Populations (8.1, 8.3)*].

The combination of MONJUVI with lenalidomide and of MONJUVI with lenalidomide and rituximab 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.

6 ADVERSE REACTIONS

The following clinically significant adverse reactions are described elsewhere in the labeling:

- Infusion-related reactions [see *Warnings and Precautions (5.1)*]
- Myelosuppression [see *Warnings and Precautions (5.2)*]
- Infections [see *Warnings and Precautions (5.3)*]

6.1 Clinical Trials Experience

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.

Relapsed or Refractory Diffuse Large B-cell Lymphoma

The safety of MONJUVI in patients with relapsed or refractory DLBCL was evaluated in L-MIND [see *Clinical Studies (14.1)*]. Patients (N = 81) received MONJUVI 12 mg/kg intravenously in combination with lenalidomide for a maximum of 12 cycles, followed by MONJUVI as monotherapy until disease progression or unacceptable toxicity as follows:

- Cycle 1: Days 1, 4, 8, 15, and 22 of the 28-day cycle;
- Cycles 2 and 3: Days 1, 8, 15, and 22 of each 28-day cycle;
- Cycles 4 and beyond: Days 1 and 15 of each 28-day cycle.

Among patients who received MONJUVI, 57% were exposed for 6 months or longer, 42% were exposed for greater than one year, and 24% were exposed for greater than two years.

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%).

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 interruptions 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, respiratory tract infection, fatigue, anemia, diarrhea, thrombocytopenia, cough, pyrexia, peripheral

edema, and decreased appetite.

Table 4 summarizes the adverse reactions in L-MIND.

Table 4: Adverse Reactions (≥ 10%) in Patients with Relapsed or Refractory Diffuse Large B-cell Lymphoma Who Received MONJUVI in L-MIND

Adverse Reaction	MONJUVI in Combination with Lenalidomide (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
Infections		
Respiratory tract infection*	51	12
Urinary tract infection†	17	4.9
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
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

* Respiratory tract infection includes lower respiratory tract infection, upper respiratory tract infection, respiratory tract infection, bronchitis, pneumonia, nasopharyngitis, and related terms.

† Urinary tract infection includes urinary tract infection, urinary tract infection bacterial, and related terms.

‡ Fatigue includes asthenia and fatigue.

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

¶ Rash includes rash, rash maculopapular, rash pruritic, rash erythematous, and rash pustular.

Clinically relevant adverse reactions in < 10% of patients with relapsed or refractory DLBCL who received MONJUVI in L-MIND were:

- *Blood and lymphatic system disorders*: lymphopenia (6%)
- *General disorders and administration site conditions*: infusion-related reaction (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*: 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%)

Table 5 summarizes the laboratory abnormalities in L-MIND.

Table 5: Select Laboratory Abnormalities ($\geq 20\%$) Worsening from Baseline in Patients with Relapsed or Refractory Diffuse Large B-cell Lymphoma Who Received MONJUVI in L-MIND

Laboratory Abnormality	MONJUVI in Combination with Lenalidomide*	
	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.

Relapsed or Refractory Follicular Lymphoma

The safety of MONJUVI in patients with relapsed or refractory FL was evaluated in the inMIND trial [see *Clinical Studies (14.2)*]. Patients received MONJUVI 12 mg/kg (N = 274) or placebo (N = 272) intravenously for a maximum of 12 cycles in combination with lenalidomide 20 mg (Days 1-21 of Cycles 1 to 12) and rituximab 375 mg/m² (Cycles 1 to 5). MONJUVI was administered as follows:

- Cycle 1 to 3: Days 1, 8, 15, and 22 of each 28-day cycle;
- Cycles 4 to 12: Days 1 and 15 of each 28-day cycle.

In the MONJUVI arm, 54% of patients completed all 12 cycles. The median age in that arm was 64 years (range: 36-88 years); 20% were age 75 years or older; 55% were male; 80% were White, 15% Asian, and 0.4% Black.

In the MONJUVI arm, serious adverse reactions occurred in 33% of patients, including serious infections in 24% of patients (including pneumonia and COVID-19 infection). Other serious adverse reactions in $\geq 2\%$ of patients included renal insufficiency (3.3%), second primary malignancies (2.9%), and febrile neutropenia (2.6%). Fatal adverse reactions occurred in 1.5% of patients, including from COVID-19, sepsis, and adenocarcinoma.

Adverse reactions led to permanent discontinuation of MONJUVI in 11% of patients and

dosage interruptions in 74%. The most frequent adverse reactions leading to dosage interruptions of MONJUVI were neutropenia (37% of all patients), COVID-19 (22%), pneumonia (11%), and infusion-related reaction (8%).

The most common adverse reactions ($\geq 20\%$) in recipients of MONJUVI, excluding laboratory abnormalities, were respiratory tract infections (including COVID-19 infection and pneumonia), diarrhea, rash, fatigue, constipation, musculoskeletal pain, and cough. The most common Grade 3 or 4 laboratory abnormalities ($\geq 20\%$) were decreased neutrophils and decreased lymphocytes.

Table 6 summarizes the adverse reactions in inMIND. Adverse reactions occurring at least 5% more frequently in the MONJUVI arm included COVID-19 infection, pneumonia, diarrhea, pruritus, fatigue, musculoskeletal pain, and mucositis.

Table 6: Adverse Reactions ($\geq 10\%$) in Patients with Relapsed or Refractory Follicular Lymphoma Who Received MONJUVI in inMIND

Adverse Reaction	MONJUVI in Combination with Lenalidomide and Rituximab (N = 274)		Placebo in Combination with Lenalidomide and Rituximab (N = 272)	
	All Grades (%)	Grade 3 or 4 (%)	All Grades (%)	Grade 3 or 4 (%)
Infections				
Respiratory tract infection	56	18	56	9
COVID-19 infection*	34 [†]	10	24 [†]	2.9
Pneumonia [‡]	18	14	11 [§]	7
Upper respiratory tract infection [¶]	17	1.1	22	0.4
Gastrointestinal disorders				
Diarrhea	38	0.7	28	1.8
Constipation	29	0.7	25	0
Nausea	18	0.4	14	0.4
Abdominal pain	13	0	18	2.2
Skin and subcutaneous tissue disorders				
Rash [#]	37	3.6	33	1.5
Pruritus	16	0.4	10	0
General disorders				
Fatigue ^p	34	2.9	25	0.7
Pyrexia	19	1.8	16	2.2
Mucositis ^β	17	0.4	11	0
Edema ^α	11	0.7	17	1.1
Musculoskeletal and connective tissue disorders				
Musculoskeletal pain ^ε	24	0.4	16	0.4
Muscle contracture ^δ	18	0	19	0
Respiratory, thoracic and mediastinal disorders				
Cough	21	0	19	0
Procedural complications				
Infusion-related reaction ^θ	16	0.7	16	0.4
Nervous system disorders				
Peripheral neuropathy ^γ	12	0	11	0.4
Headache	10	0.4	7	0
Metabolism and nutrition disorders				

Decreased appetite	10	0	9	0.7
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The table includes a combination of grouped and ungrouped terms. Adverse reactions were graded using NCI CTCAE version 5.0

* Includes COVID-19, COVID-19 pneumonia, and coronavirus test positive.

† Includes 2 cases in each arm with fatal outcome.

‡ Includes pneumonia, COVID-19 pneumonia, pneumonia fungal, *Pneumocystis jirovecii* pneumonia, and other types of pneumonia.

§ Includes 3 cases with fatal outcome, including 2 reported under COVID-19 infection.

¶ Includes upper respiratory tract infection, nasopharyngitis, sinusitis, laryngitis, and related terms.

Includes rash, urticaria, dermatitis, drug eruption, and related terms.

⌘ Includes fatigue and asthenia.

β Includes oropharyngeal pain, stomatitis, mucosal inflammation, mouth ulceration, odynophagia, aphthous ulcer, esophageal pain, and related terms.

à Includes edema, peripheral edema, pulmonary edema, generalized edema, and related terms.

è Includes back pain, pain in extremity, myalgia, bone pain, neck pain, spinal pain, limb discomfort, musculoskeletal chest pain, musculoskeletal discomfort, and sacral pain.

ð Includes muscle spasms and muscle contractions involuntary.

ø Includes infusion-related reaction and cytokine release syndrome.

ý Includes peripheral neuropathy, paresthesia, peripheral sensory neuropathy, neuralgia, dysesthesia, hyperesthesia, and peripheral motor neuropathy.

In the MONJUVI arm, clinically relevant adverse reactions in < 10% of patients with relapsed or refractory FL included thrombosis, febrile neutropenia, second primary malignancy, sepsis, interstitial lung disease, and tumor lysis syndrome.

Table 7 summarizes the laboratory abnormalities in inMIND. Grade 4 laboratory abnormalities in > 1% of patients included neutrophils decreased (19%), platelets decreased (4%) and lymphocytes decreased (1.8%).

Table 7: Select Laboratory Abnormalities (> 20%) Worsening from Baseline in Patients with Relapsed or Refractory Follicular Lymphoma Who Received MONJUVI in inMIND

Laboratory Abnormality	MONJUVI in Combination with Lenalidomide and Rituximab*		Placebo in Combination with Lenalidomide and Rituximab*	
	All Grades (%)	Grade 3 or 4 (%)	All Grades (%)	Grade 3 or 4 (%)
Hematology				
Neutrophils decreased	75	48	71	44
Hemoglobin decreased	60	9	54	7
Lymphocytes decreased	57	22	51	19
Platelets decreased	40	8	43	9
Chemistry				
Alanine aminotransferase increased	47	1.5	42	1.5
Alkaline phosphatase increased	33	0	27	0
Creatinine increased	29	1.5	30	0.7
Aspartate aminotransferase increased	29	0	31	0.4

Glucose increased	28	0.4	28	1.1
Potassium decreased	24	3.3	24	3
Sodium decreased	24	1.5	22	0.4

* The denominator used to calculate the rate varied from 268 - 274 based on the number of patients with a baseline value and at least 1 post-treatment value.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Based on its mechanism of action, MONJUVI may cause fetal B-cell depletion when administered to a pregnant woman [see *Clinical Pharmacology (12.1)*]. There are no available data on MONJUVI use in pregnant women to evaluate for a drug-associated risk. Animal reproductive toxicity studies have not been conducted with tafasitamab-cxix.

In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

MONJUVI is administered in combination with lenalidomide, as well as in combination with lenalidomide and rituximab for up to 12 cycles. Lenalidomide can cause embryo-fetal harm and is contraindicated for use in pregnancy. Refer to the lenalidomide prescribing information for additional information. Lenalidomide is only available through a REMS program.

Clinical Considerations

Fetal/Neonatal Adverse Reactions

Immunoglobulin G (IgG) monoclonal antibodies are transferred across the placenta. Based on its mechanism of action, MONJUVI may cause depletion of fetal CD19 positive immune cells. Defer administering live vaccines to neonates and infants exposed to tafasitamab-cxix in utero until a hematology evaluation is completed.

Data

Animal Data

Animal reproductive studies have not been conducted with tafasitamab-cxix. Tafasitamab-cxix is an IgG antibody and thus has the potential to cross the placental barrier permitting direct fetal exposure and depleting fetal B lymphocytes.

8.2 Lactation

Risk Summary

There are no data on the presence of tafasitamab-cxix in human milk or the effects on the breastfed child or milk production. Maternal immunoglobulin G is known to be present in human milk. The effects of local gastrointestinal exposure and limited systemic exposure in the breastfed infant to MONJUVI are unknown. Because of the potential for serious adverse reactions in the breastfed child, advise women not to breastfeed during treatment with MONJUVI and for 3 months after the last dose. Refer to lenalidomide prescribing information for additional information.

8.3 Females and Males of Reproductive Potential

MONJUVI can cause fetal B-cell depletion when administered to a pregnant woman [see *Use in Specific Populations (8.1)*].

Pregnancy Testing

Refer to the prescribing information for lenalidomide for pregnancy testing requirements prior to initiating the combination of MONJUVI with lenalidomide or the combination of MONJUVI with lenalidomide and rituximab .

Contraception

Females

Advise females of reproductive potential to use effective contraception during treatment with MONJUVI and for 3 months after the last dose. Additionally, refer to the lenalidomide prescribing information for additional recommendations for contraception.

Males

Refer to the lenalidomide prescribing information for recommendations.

8.4 Pediatric Use

The safety and effectiveness of MONJUVI in pediatric patients have not been established.

8.5 Geriatric Use

Relapsed or Refractory Diffuse Large B-Cell Lymphoma

Among the 81 patients who received MONJUVI and lenalidomide in L-MIND, 72% were 65 years and older, while 38% were 75 years and older. Clinical studies of MONJUVI did not include sufficient numbers of patients aged 65 and older to determine whether effectiveness differs compared to that of younger subjects. Patients 65 years and older had more serious adverse reactions (57%) than younger patients (39%).

Relapsed or Refractory Follicular Lymphoma

Among the 274 patients with FL who received MONJUVI in combination with lenalidomide and rituximab in inMIND, 137 (50%) were 65 years and older and 54 (20%) were 75 years and older. No clinically meaningful differences in safety or effectiveness were observed between these patients and younger patients.

11 DESCRIPTION

Tafasitamab-cxix is a humanized CD19-directed cytolytic monoclonal antibody that contains an IgG1/2 hybrid Fc-domain with 2 amino acid substitutions to modify the Fc-mediated functions of the antibody. It is produced by recombinant DNA technology in mammalian cells (Chinese hamster ovary). Tafasitamab-cxix has a molecular weight of approximately 150 kDa.

MONJUVI (tafasitamab-cxix) for injection is supplied as a sterile, preservative-free, white to slightly yellowish lyophilized powder in a single-dose vial for intravenous use after reconstitution and further dilution. After reconstitution with 5 mL of Sterile Water for Injection, USP, the resulting concentration is 40 mg/mL with a pH of 6.0. Each single-dose vial contains 200 mg tafasitamab-cxix, citric acid monohydrate (3.7 mg), polysorbate 20 (1 mg), sodium citrate dihydrate (31.6 mg) and trehalose dihydrate (378.3 mg).

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Tafasitamab-cxix is an Fc-modified monoclonal antibody that binds to CD19 antigen expressed on the surface of pre-B and mature B lymphocytes and on several B-cell malignancies, including diffuse large B-cell lymphoma (DLBCL) and follicular lymphoma (FL).

Upon binding to CD19, tafasitamab-cxix mediates B-cell lysis through apoptosis and immune effector mechanisms, including antibody-dependent cellular cytotoxicity (ADCC) and antibody-dependent cellular phagocytosis (ADCP).

In studies conducted in vitro in DLBCL tumor cells, tafasitamab-cxix in combination with lenalidomide resulted in increased ADCC activity compared to tafasitamab-cxix or lenalidomide alone.

12.2 Pharmacodynamics

Tafasitamab-cxix reduced peripheral blood B cell counts by 97% after 8 days of treatment in patients with relapsed or refractory DLBCL. Nadir, with a reduction to undetectable levels (< 1 cell/microliter), was reached within 16 weeks of treatment.

Circulating B-cells decreased to undetectable levels (< 1 cell/microliter) by Cycle 1 Day 15 after administration of the recommended dosage of MONJUVI in patients with FL who had detectable B-cells at treatment initiation and the depletion was sustained while patients remained on treatment.

12.3 Pharmacokinetics

Pharmacokinetic (PK) parameters are presented as geometric mean (CV%) unless otherwise specified.

Tafasitamab-cxix maximum concentration is achieved at the end of weekly dosing (i.e., end of Cycle 3). PK exposures are summarized for the recommended dosage of MONJUVI in Table 8.

Table 8: Exposure Parameters of Tafasitamab-cxix in Patients with Relapsed or Refractory DLBCL and Relapsed or Refractory FL Following Recommended Dosage

	C_{avg} (mcg/mL)*	C_{max} (mcg/mL)*	C_{trough} (mcg/mL)*
End of weekly dosing (end of Cycle 3) (N = 367)	315 (30.3%)	489 (22.8%)	226 (38.5%)
Steady state [†] with every 2-week dosing (N = 285)	185 (32.5%)	375 (20.8%)	112 (44.8%)

* Values are geometric mean with geometric CV%.

† Steady state values are approximated at Cycle 6

Distribution

Tafasitamab-cxix steady state total volume of distribution was 7.11 L (29.7%).

Elimination

Tafasitamab-cxix estimated elimination half-life was 13.4 days (31.7%) with an apparent clearance of 0.44 L/day (29.2%).

Specific Populations

Body weight (37.6 to 163 kg) has a significant effect on the PK of tafasitamab-cxix, with

higher clearance and volume of distribution expected with higher body weight. No clinically meaningful differences in the PK of tafasitamab-cxix were observed based on age (16 to 90 years), sex, race (Asian versus non-Asian), mild to severe renal impairment (creatinine clearance [CLcr] 15 to < 90 mL/min as estimated by Cockcroft-Gault formula), and mild to moderate hepatic impairment (total bilirubin \leq ULN and AST > ULN, or total bilirubin 1 to 3.0 times ULN and any AST).

The effect of end-stage renal disease (CLcr < 15 mL/min) and severe hepatic impairment (total bilirubin > 3.0 times ULN and any AST) on the PK of tafasitamab-cxix are unknown.

Drug Interaction Studies

No clinical studies evaluating the drug interaction potential of tafasitamab-cxix have been conducted. In population PK analyses, no clinically meaningful differences in tafasitamab-cxix PK were observed when used concomitantly with lenalidomide and with the combination of lenalidomide and rituximab.

12.6 Immunogenicity

The observed incidence of anti-drug antibodies (ADA) is highly dependent on the sensitivity and specificity of the assay. Differences in assay methods preclude clinically meaningful comparisons of the incidence of ADA in the studies described below with the incidence of ADA in other studies, including those of MONJUVI or other tafasitamab products.

Following MONJUVI treatment, anti-tafasitamab-cxix antibodies developed in 2.5% (2/81) of patients with DLBCL in Study L-MIND (up to 23 cycles) and 0.9% (3/327) of patients with FL in Study inMIND (up to 12 cycles) [see *Clinical Studies (14.1, 14.2)*]. Because of the low occurrence of ADA, the effect of these antibodies on the pharmacokinetics, pharmacodynamics, safety, and effectiveness of tafasitamab products is unknown.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenicity and genotoxicity studies have not been conducted with tafasitamab-cxix.

Fertility studies have not been conducted with tafasitamab-cxix.

In the 13-week repeat-dose general toxicity study in cynomolgus monkeys, no adverse effects on male and female reproductive organs were observed up to the highest dose tested, 100 mg/kg/week (approximately 9 times the human exposure based on AUC at the clinical dose of 12 mg/kg/week).

14 CLINICAL STUDIES

14.1 Relapsed or Refractory Diffuse Large B-cell Lymphoma

The efficacy of MONJUVI in combination with lenalidomide followed by MONJUVI as monotherapy was evaluated in L-MIND, an open-label, multicenter, single arm trial (NCT02399085). Eligible patients had relapsed or refractory DLBCL after 1 to 3 prior systemic therapies, including a CD20-directed cytolytic antibody, and were not candidates for high dose chemotherapy (HDC) followed by autologous stem cell transplantation (ASCT). 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 as follows:

- Cycle 1: Days 1, 4, 8, 15 and 22 of the 28-day cycle;
- Cycles 2 and 3: Days 1, 8, 15 and 22 of each 28-day cycle;
- Cycles 4 and beyond: Days 1 and 15 of each 28-day cycle.

Of the 71 patients with DLBCL confirmed by central laboratory who received the combination therapy, the median age was 71 years (range: 41 to 86 years); 55% were males, and 100% had received a prior CD20-containing therapy. Race was collected in 92% of patients; of these, 95% were White, and 3% were Asian. The median number of prior therapies was 2; 49% had 1 prior line of treatment, and 51% had 2 to 4 prior lines. Thirty-two patients (45%) were refractory to their last prior therapy and 30 (42%) were refractory to rituximab. Nine patients (13%) had received prior ASCT. The primary reasons patients were not candidates for ASCT included age (47%), refractoriness to salvage chemotherapy (27%), comorbidities (13%) and refusal of high dose chemotherapy/ASCT (13%).

Efficacy was established based on best overall response rate, defined as the proportion of complete and partial responders, and duration of response, as assessed by an Independent Review Committee using the International Working Group Response Criteria (Cheson, 2007). Results are summarized in Table 9.

Table 9: Efficacy Results in Patients with Relapsed or Refractory Diffuse Large B-cell Lymphoma in L-MIND

	MONJUVI in Combination with Lenalidomide (N = 71)
Best overall response rate, n (%)	39 (55%)
(95% CI)	(43%, 67%)
Complete response rate	37%
Partial response rate	18%
Duration of response	
Median (range) in months*	21.7 (0, 24)

* Kaplan Meier estimate

14.2 Relapsed or Refractory Follicular Lymphoma

The efficacy of MONJUVI in combination with lenalidomide and rituximab in patients with relapsed or refractory FL was evaluated in inMIND, a randomized, double-blind, placebo-controlled trial (NCT04680052). The study enrolled a total of 548 patients with relapsed or refractory FL Grade 1, 2, or 3a after at least 1 systemic therapy, including an anti-CD20 antibody.

Patients were randomized in a 1:1 ratio to receive MONJUVI or placebo in combination with lenalidomide and rituximab. Randomization was stratified by progression of disease within 24 months after initial diagnosis (POD24) (yes versus no), refractoriness to prior CD20-directed antibody therapy (yes versus no), and the number of prior lines of systemic therapy (< 2 versus ≥ 2). Treatment was administered in 28-day cycles as follows:

- MONJUVI 12 mg/kg intravenously (Days 1, 8, 15, and 22 of Cycles 1 to 3 and on Days 1 and 15 of Cycles 4 to 12) in combination with lenalidomide 20 mg orally once daily (Days 1 to 21 of Cycles 1 to 12) and rituximab 375 mg/m² intravenously (Days 1, 8, 15, and 22 of Cycle 1 and on Day 1 of Cycles 2 to 5).

Patients on the control arm received the same regimen, but with placebo in lieu of MONJUVI.

Of all patients with FL randomized, the median age was 64 years (range: 31-88 years),

with 20% being age 75 or older; 55% were male; 80% were White, 15% Asian, and 0.2% were Black. The median number of prior lines of systemic therapy was 1 (range 1-10) with 55% receiving 1 prior line, 25% receiving 2 prior lines, and 20% receiving 3 or more prior lines. In total, 32% had POD24 and 43% had refractory disease to prior CD20-directed therapy.

The major efficacy outcome measure was investigator-assessed progression-free survival (PFS) using the Lugano criteria. Efficacy results are summarized in Table 10 and Figure 1. The median duration of PFS follow-up was 14.1 months.

Table 10: Efficacy Results in Patients with Relapsed or Refractory FL in inMIND

Outcome per Investigator	MONJUVI in Combination with Lenalidomide and Rituximab (N = 273)	Placebo in Combination with Lenalidomide and Rituximab (N = 275)
Progression-free survival		
Patients with event, n (%)	75 (27.5)	131 (47.6)
Disease progression	67 (24.5)	124 (45.1)
Death	8 (2.9)	7 (2.5)
Median PFS (95% CI), months*	22.4 (19.2, NE)	13.9 (11.5, 16.4)
Hazard ratio† (95% CI)	0.43 (0.32, 0.58)	
p-value	< 0.0001	
Overall response rate‡, n (%) (95% CI)	228 (84) (79, 88)	199 (72) (67, 78)

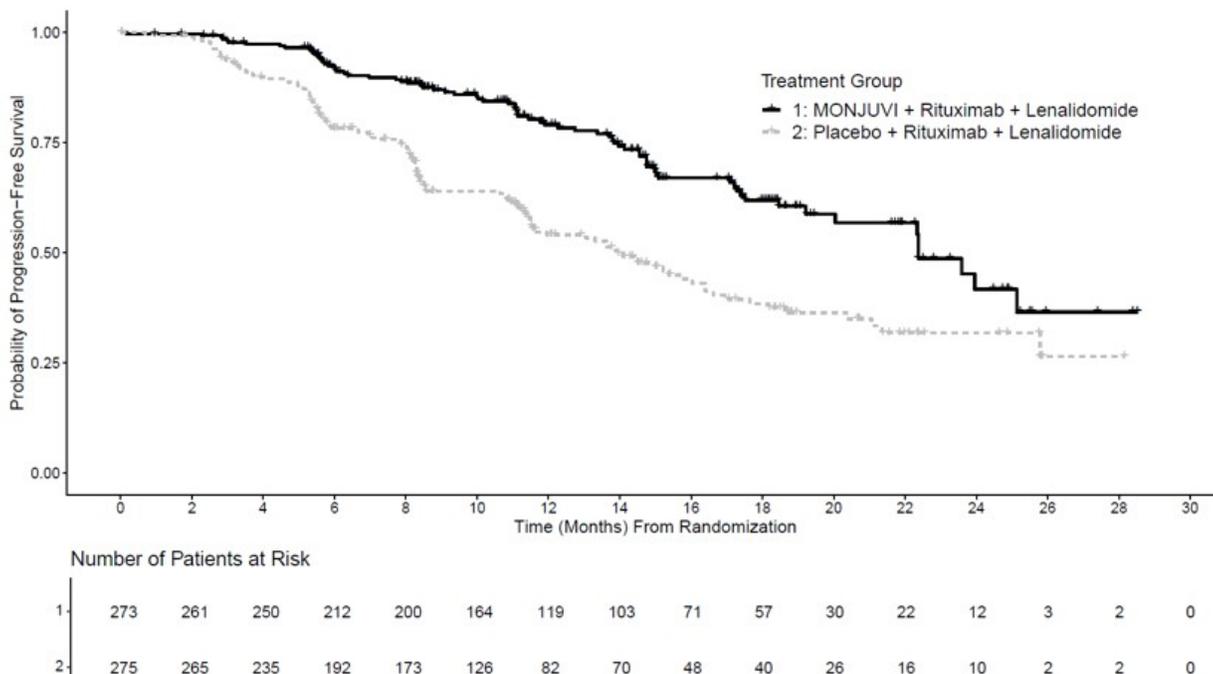
CI = confidence interval; NE = not evaluable

* Kaplan-Meier estimate.

† Hazard ratio based on a stratified Cox proportional hazard model.

‡ Complete response plus partial response.

Figure 1: Kaplan-Meier Curve for PFS by Investigator Assessment in inMIND



At the time of the PFS analysis, the median overall survival had not been reached in either arm with a total of 38 deaths: 15 deaths (5.5%) in the MONJUVI arm and 23 deaths (8.4%) in the placebo arm.

14.3 Lack of Efficacy in Relapsed or Refractory Marginal Zone Lymphoma

Lack of efficacy in patients with relapsed or refractory marginal zone lymphoma (MZL) was observed in the inMIND trial (NCT04680052), a prospective, randomized clinical trial in which a cohort of 106 patients with relapsed or refractory MZL were randomized 1:1 to receive MONJUVI or placebo in combination with lenalidomide and rituximab. There was no evidence of improvement in investigator-assessed PFS in the MONJUVI arm.

At the time of the PFS analysis, the median overall survival had not been reached in either arm with a total of 8 deaths: 7 deaths (13.2%) in the MONJUVI arm and 1 death (1.9%) in the placebo arm.

MONJUVI is not indicated and is not recommended for the treatment of patients with relapsed or refractory MZL outside of controlled clinical trials.

16 HOW SUPPLIED/STORAGE AND HANDLING

MONJUVI (tafasitamab-cxix) 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 50881-013-03).

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.

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Patient Information).

Infusion-Related Reactions

Advise patients to contact their healthcare provider if they experience signs and symptoms of infusion-related reactions [see *Warnings and Precautions (5.1)*].

Myelosuppression

Inform patients about the risk of myelosuppression. Advise patients to immediately contact their healthcare provider for a fever of 100.4°F (38°C) or greater or signs or symptoms of bruising or bleeding. Advise patients of the need for periodic monitoring of blood counts [see *Warnings and Precautions (5.2)*].

Infections

Inform patients about the risk of infections. Advise patients to immediately contact their healthcare provider for a fever of 100.4°F (38°C) or greater or signs or symptoms of infection [see *Warnings and Precautions (5.3)*].

Embryo-Fetal Toxicity

- Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to inform their healthcare provider of a known or suspected pregnancy [see *Warnings and Precautions (5.4)*, *Use in Specific Population (8.1)*].
- Advise females of reproductive potential to use effective contraception during treatment with MONJUVI and for 3 months after the last dose [see *Use in Specific Populations (8.3)*].
- 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 [see Use in Specific Populations (8.1, 8.3)].

Lactation

Advise women not to breastfeed during treatment with MONJUVI and for 3 months after the last dose [see Use in Specific Populations (8.2)].

Manufactured by:

Incyte Corporation

Wilmington, DE 19803

U.S. License No. 2228

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Patent Information: www.incyte.com/patents

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PATIENT INFORMATION

MONJUVI® (mon-JOO-vee)
(tafasitamab-cxix)
for injection

What is MONJUVI?

MONJUVI is a prescription medicine given:

- in combination with lenalidomide, to treat adults with certain types of diffuse large B-cell lymphoma (DLBCL) that has come back (relapsed) or that did not respond to previous treatment (refractory) and who cannot receive a stem cell transplant.
- in combination with a lenalidomide and rituximab, to treat adults with follicular lymphoma (FL) that has come back or that did not respond to previous treatment.

MONJUVI should not be used and is not recommended outside of clinical trials to treat people with a certain type of lymphoma, called marginal zone lymphoma, that has come back or that did not respond to previous treatment.

It is not known if MONJUVI is safe and effective in children.

Before you receive MONJUVI, tell your healthcare provider about all of your medical conditions, including if you:

- have an active infection or have had one recently.
- are pregnant or plan to become pregnant. MONJUVI may harm your unborn baby. You should not become pregnant during treatment with MONJUVI. Do not receive treatment with MONJUVI in combination with lenalidomide if you are pregnant because lenalidomide can cause birth defects and death of your unborn baby.
 - You should use an effective method of birth control (contraception) during treatment and for 3 months after your last dose of MONJUVI.
 - Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with MONJUVI.
- are breastfeeding or plan to breastfeed. It is not known if MONJUVI passes into your breastmilk. Do not breastfeed during treatment and for at least 3 months after your last dose of MONJUVI.

You should also read the lenalidomide Medication Guide for important information about pregnancy, contraception, and blood and sperm donation.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How will I receive MONJUVI?

- MONJUVI will be given to you by your healthcare provider as an intravenous (IV) infusion into one of your veins.

- Your healthcare provider will give you medicines before each infusion to decrease your chance of infusion reactions. If you do not have any reactions, your healthcare provider may decide that you do not need these medicines with later infusions.
- Each treatment cycle of MONJUVI lasts for 28 days.
- Your healthcare provider may need to delay or completely stop treatment with MONJUVI if you have severe side effects.
- Your healthcare provider will decide how many treatments you need.
- If you miss any appointments, call your healthcare provider as soon as possible to reschedule your appointment.

What are the possible side effects of MONJUVI?

MONJUVI may cause serious side effects, including:

- **Infusion reactions.** Your healthcare provider will monitor you for infusion reactions during your infusion of MONJUVI. Tell your healthcare provider right away if you get fever, chills, rash, flushing, headache, or shortness of breath during an infusion of MONJUVI.
- **Low blood cell counts** (platelets, red blood cells, and white blood cells). Low blood cell counts are common with MONJUVI, but can also be serious or severe. Your healthcare provider will monitor your blood counts during treatment with MONJUVI. Tell your healthcare provider right away if you get a fever of 100.4°F (38°C) or above, or any bruising or bleeding.
- **Infections.** Serious infections, including infections that can cause death, have happened in people during treatment with MONJUVI and after the last dose. Tell your healthcare provider right away if you get a fever of 100.4°F (38°C) or above, or develop any signs or symptoms of an infection.

The most common side effects of MONJUVI when given with lenalidomide in people with DLBCL include:

- | | |
|---|--|
| <ul style="list-style-type: none"> • respiratory tract infection • feeling tired or weak • diarrhea • cough | <ul style="list-style-type: none"> • fever • swelling of lower legs or hands • decreased appetite |
|---|--|

The most common side effects of MONJUVI when given with lenalidomide and rituximab in people with FL include:

- | | |
|---|---|
| <ul style="list-style-type: none"> • respiratory tract infections • diarrhea • rash • feeling tired or weak | <ul style="list-style-type: none"> • muscle and bone pain • constipation • cough |
|---|---|

These are not all the possible side effects of MONJUVI. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of MONJUVI.

Medicines are sometimes prescribed for purposes other than those listed in this Patient Information. If you would like more information about MONJUVI, talk with your healthcare provider. You can ask your healthcare provider for information about MONJUVI that is written for health professionals.

What are the ingredients in MONJUVI?

Active ingredient: tafasitamab-cxix.

Inactive ingredients: citric acid monohydrate, polysorbate 20, sodium citrate dihydrate, and trehalose dihydrate.

Manufactured by: Incyte Corporation, Wilmington, DE 19803

U.S. License No. 2228

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Patent Information: www.incyte.com/patents

For more information, call 1-855-463-3463 or go to www.MONJUVI.com.

This Patient Information has been approved by the U.S. Food and Drug Administration.

Revised: 6/2025

PRINCIPAL DISPLAY PANEL - 200 mg Vial Carton

NDC 50881-013-03

MONJUVI®
(tafasitamab-cxix)

For Injection

200 mg/vial

For Intravenous
Infusion Only.
Reconstitute and
dilute prior to
administration.

Single-dose vial
Discard unused portion

1 Vial
Rx only

Incyte

200 mg / vial		For Injection MONJUVI ® (tafasitamab-cxix) NDC 50881-013-03	
MONJUVI ® (tafasitamab-cxix) For Injection NDC 50881-013-03	MONJUVI ® (tafasitamab-cxix) For Injection NDC 50881-013-03	<p>Reconstitute with 5 ml of Sterile Water for Injection, USP, resulting in a concentration of 40 mg/mL. Do not shake</p> <p>Must be further diluted with 0.9% Sodium Chloride Injection, USP before use.</p> <p>Each single-dose vial contains 200 mg tafasitamab-cxix, citric acid monohydrate (3.7 mg), polysorbate 20 (1 mg), sodium citrate dihydrate (31.6 mg) and trehalose dihydrate (378.3 mg).</p> <p>Store refrigerated at 36°F to 46°F (2°C to 8°C) in the carton to protect from light. Do not shake. Do not freeze. Keep out of reach of children.</p> <p>Dosage and storage: see Prescribing Information. No preservative.</p> <p>No U.S. Standard of Potency</p> <p>Rx only</p>	<p>3 50881-01303 4</p>  <p>Manufactured by: Incyte Corporation Wilmington, DE 19803 U.S.</p> <p>U.S. License No. 2228</p> <p>Product of Germany</p> <p>Marketed by Incyte Corp.</p>
200 mg / vial		200 mg / vial	
<p>For Intravenous Infusion Only. Reconstitute and dilute prior to administration.</p> <p>Single-dose vial Discard unused portion</p> <p>1 Vial Rx only</p> 	<p>For Intravenous Infusion Only. Reconstitute and dilute prior to administration.</p> <p>Single-dose vial Discard unused portion</p> <p>1 Vial Rx only</p> 	<p>EXP: MMYY : LOT: NNNNNN : SN: XXXXXXXXXXXX : GTIN: XXXXXXXXXXXX</p> 	

MONJUVI

tafasitamab-cxix injection, powder, lyophilized, for solution

Product Information				
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:50881-013	
Route of Administration	INTRAVENOUS			
Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
Tafasitamab (UNII: QQA9MLH692) (Tafasitamab - UNII:QQA9MLH692)	Tafasitamab	200 mg in 5 mL		
Inactive Ingredients				
Ingredient Name	Strength			
trisodium citrate dihydrate (UNII: B22547B95K)	31.6 mg in 5 mL			
citric acid monohydrate (UNII: 2968PHW8QP)	3.7 mg in 5 mL			
trehalose dihydrate (UNII: 7YIN7J07X4)	378.3 mg in 5 mL			
polysorbate 20 (UNII: 7T1F30V5YH)	1 mg in 5 mL			
Product Characteristics				
Color	white (white to slightly yellowish lyophilized powder)	Score		
Shape		Size		
Flavor		Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50881-013-03	1 in 1 CARTON	08/05/2020	
1		5 mL in 1 VIAL; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
BLA	BLA761163	08/05/2020		

Labeler - Incyte Corporation (556967347)

Revised: 6/2025

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