MONJUVI® (tafasitamab-cxix) for injection, for intravenous use – FDA Approval Notification

We are sending this communication on behalf of MorphoSys US Inc. and Incyte Corporation, to announce the approval of MONJUVI® (tafasitamab-cxix) for injection, for intravenous use by the U.S. Food and Drug Administration (FDA) on 07/31/2020.

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).

Please see Important Safety Information below and the full Prescribing Information for MONJUVI.[1]

Product Name	Packaging	National Drug Code (NDC)	Wholesale Acquisition Cost (WAC)
MONJUVI (tafasitamab-cxix) for injection, for intravenous use	One 200 mg single-dose vial of MONJUVI	73535-**0**208-01*	$1,200 / vial (as of August 2020)

*The NDC has been "zero-filled" to ensure creation of an 11-digit code that meets Health Insurance Portability and Accountability Act (HIPAA) standards for billing. The zero-fill location is indicated in bold.

DOSAGE AND ADMINISTRATION

The recommended dose of MONJUVI is 12 mg/kg based on actual body weight administered as an intravenous infusion according to the dosing schedule shown below.

Administer MONJUVI in combination with lenalidomide 25 mg orally on Days 1 to 21 of each 28-day cycle for a maximum of 12 cycles, then continue MONJUVI as monotherapy until disease progression or unacceptable toxicity. Refer to the lenalidomide prescribing information for lenalidomide dosage recommendations.

MONJUVI 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

MONJUVI should be administered by a healthcare professional with immediate access to emergency equipment and appropriate medical support to manage infusion-related reactions (IRRs).

Administer premedication, including acetaminophen, histamine H_1 and H_2 receptor blockers, and/or glucocorticosteroids, 30 to 120 minutes prior to MONJUVI infusions to minimize infusion-related reactions.

See full Prescribing Information for additional details on dosing and administration including, infusion preparation, premedication for prophylaxis of infusion related reactions, and dose modifications for adverse reactions.

IMPORTANT SAFETY INFORMATION

Contraindications: None.

Warnings and Precautions:

- **Infusion-Related Reactions (IRRs).** MONJUVI can cause IRRs, including chills, flushing, dyspnea, and hypertension. Premedicate patients

and monitor frequently during infusion. Based on the severity of the IRR, interrupt or discontinue MONJUVI and institute appropriate medical management.

- **Myelosuppression.** MONJUVI can cause serious or severe myelosuppression, including neutropenia, thrombocytopenia, and anemia. 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 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. 73% of the 81 patients developed an infection. The most frequent infections were respiratory tract infection, urinary tract infection, bronchitis, nasopharyngitis and pneumonia. Grade 3 or higher infection occurred (30% of 81 patients). The most frequent grade 3 or higher infection was pneumonia. Infection-related deaths were reported (2.5% of 81 patients). Monitor patients for signs and symptoms of infection and manage infections as appropriate.
- **Embryo-Fetal Toxicity.** Based on its mechanism of action, MONJUVI may cause fetal B-cell depletion when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus and women of reproductive potential to use effective contraception during treatment with MONJUVI and for at least 3 months after the last dose. The combination of MONJUVI with lenalidomide is contraindicated in pregnant women. Refer to the lenalidomide prescribing information on use during pregnancy.

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

You may report side effects to the FDA at (800) FDA-1088 or www.fda.gov/medwatch. You may also report side effects to MORPHOSYS US INC. at (844) 667-1992.

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

For questions regarding MONJUVI, please contact MorphoSys at 844-MOR-1992 or Info.US@MorphoSys.com.

For more information, please visit http://www.MONJUVIHCP.com.

Sincerely,

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References:

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

For price transparency information, please click here.

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