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

# NOW APPROVED

## A NEW OPTION FOR ADULT PATIENTS WITH RELAPSED OR REFRACTORY DIFFUSE LARGE B-CELL LYMPHOMA

### INDICATION

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).

### 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.

*(continued on page 4)*

**Please see additional Important Safety Information on page 4 and full Prescribing Information.**

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| | |
|---|---|
| **Manufactured by** | *MorphoSys US Inc.*<br>844-MOR-1992 |
| **Marketed by** | *MorphoSys US Inc.*<br>www.MorphoSys-US.com<br>*Incyte Corporation*<br>www.Incyte.com |
| **Product Name** | MONJUVI |
| **Established Name** | tafasitamab-cxix |
| **Product Website** | www.MONJUVIHCP.com |


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| PRODUCT INFORMATION | |
|---|---|
| **Description** | 200 mg single-dose vial as lyophilized powder for reconstitution |
| **Sales Unit** | One single-dose vial |
| **Units Per Case** | One vial per carton |
| **NDC** | *10-Digit* - 73535-208-01<br>*11-Digit* - 73535-**0**208-01 |
| **Global Trade Identification Numbers** | 00373535208013<br>30373535208014 (case) |

| HCPCS CODING | PRICING |
|---|---|
| J9999 (not otherwise classified, antineoplastic drugs)<br>J3490 (unclassified drugs)<br>J3590 (unclassified biologics)<br>C9399 (unclassified drugs or biologicals) - Hospital Outpatient Setting<br>MONJUVI specific HCPCS code expected in 2021 | Wholesale Acquisition Cost (WAC)<br>$1,200 / Vial<br>(as of August 2020) |

**Please see Important Safety Information on pages 1 and 4 and full Prescribing Information.**

## DOSAGE AND ADMINISTRATION HIGHLIGHTS

- 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)

**See full Prescribing Information for additional details on dosing and administration including preparing the infusion, prophylaxis for infusion related reactions, and dose modifications for adverse reactions.**

## STORAGE INFORMATION

- MONJUVI 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
- 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
- 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. Do not freeze or shake
- 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 freeze or shake

## IMPORTANT SAFETY INFORMATION *(continued)*

### Warnings and Precautions *(continued):*

- **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.**

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