

Subject: Now Approved – MONJUVI® (tafasitamab-cxix)
To: Pat Troy
From: Katrina Gekas/ agekas@incyte.com

Dear Pat,

On behalf of MorphoSys US Inc. and Incyte Corporation, I am pleased to inform you that on July 31, 2020, the US Food and Drug Administration (FDA) granted approval for MONJUVI® (tafasitamab-cxix), a new treatment:

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).

MorphoSys AG and Incyte Corporation have entered into a collaboration agreement to commercialize MorphoSys' proprietary anti-CD19 antibody tafasitamab-cxix, MONJUVI, in the United States.

Below are some statements about MONJUVI that you may wish to consider including in your communication, if you choose to share news of this approval:

- 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).
- The MONJUVI Biologics License Application (BLA) was approved under Priority Review¹
- MONJUVI's Patient Support Program, My MISSION Support, offers resources for eligible patients and caregivers. More information can be found at www.MyMISSIONSupport.com or by calling 855-421-6172

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.

Thank you and please let me know if you require any additional information.

Kind regards,
Katrina Gekas

Oncology Therapeutic Specialist

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Reference: 1. Data on File. FDA BLA Acceptance Letter. March 2020.

For price transparency information, please [click here](#).
To review our privacy policy, [click here](#).



MONJUVI is a registered trademark of MorphoSys AG.

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