FDA Approves Monjuvi for Diffuse Large B-cell Lymphoma

More than a third of people treated with Monjuvi plus Revlimid experienced complete remission.

August 4, 2020 By Food and Drug Administration (FDA)

FDA grants accelerated approval to tafasitamab-cxix for diffuse large B-cell lymphoma

On July 31, 2020, the Food and Drug Administration granted accelerated approval to tafasitamab-cxix (MONJUVI, MorphoSys US Inc.), a CD19-directed cytolytic antibody, indicated in combination with lenalidomide [Revlimid] for 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.

The efficacy of tafasitamab-cxix with lenalidomide was evaluated in L-MIND (NCT02399085), an open label, multicenter single-arm trial in 81 patients. Patients received tafasitamab-cxix 12 mg/kg intravenously with lenalidomide (25 mg orally on days 1 to 21 of each 28-day cycle) for maximum of 12 cycles, followed by tafasitamab-cxix as monotherapy.

Efficacy was based on best overall response rate (ORR), defined as complete and partial responders and response duration, as assessed by an independent review committee. The best ORR in 71 patients with a diagnosis of DLBCL confirmed by central pathology was 55% (95% CI: 43%, 67%), with complete responses in 37% and partial responses in 18% of patients. Median response duration was 21.7 months (range: 0, 24).

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

The recommended tafasitamab-cxix dose is 12 mg/kg as an intravenous infusion.

View full prescribing information for MONJUVI.

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).

This review used the Assessment Aid, a voluntary submission from the applicant to facilitate the

FDA’s assessment. The FDA approved this application one month ahead of the FDA goal date.

This application was granted priority review, fast track, breakthrough, and orphan product designation. A description of FDA expedited programs is in the Guidance for Industry: Expedited Programs for Serious Conditions-Drugs and Biologics.

Healthcare professionals should report all serious adverse events suspected to be associated with the use of any medicine and device to FDA’s MedWatch Reporting System or by calling 1-800-FDA-1088.

This announcement was originally published on the Food and Drug Administration website on July 31, 2020.
