FDA Approves Blenrep for Multiple Myeloma [UPDATE]

The antibody-drug-conjugate produced an overall response rate of 31%.

November 28, 2022 By Food and Drug Administration (FDA)

[UPDATE 11/28/22: In November 2022, GSK withdrew Blenrep from the U.S. market at the request of the Food and Drug Administration after a confirmatory trial did not meet the requirements for FDA accelerated approval.]

This announcement was originally published on August 8, 2022.

FDA granted accelerated approval to belantamab mafodotin-blmf for multiple myeloma

On August 5, 2020, the Food and Drug Administration granted accelerated approval to belantamab mafodotin-blmf (Blenrep, GlaxoSmithKline) for adult patients with relapsed or refractory multiple myeloma who have received at least 4 prior therapies, including an anti-CD38 monoclonal antibody, a proteasome inhibitor, and an immunomodulatory agent.

Belantamab mafodotin-blmf was evaluated in DREAMM-2 (NCT 03525678), an open-label, multicenter trial. Patients received either belantamab mafodotin-blmf, 2.5 mg/kg or 3.4 mg/kg intravenously, once every 3 weeks until disease progression or unacceptable toxicity.

Efficacy was based on overall response rate (ORR) and response duration, as evaluated by an independent review committee using the International Myeloma Working Group uniform response criteria. The ORR was 31% (97.5% CI: 21%, 43%). Seventy-three percent of responders had response durations ≥6 months. These results were observed in patients receiving the recommended dose of 2.5 mg/kg.

The prescribing information includes a Boxed Warning stating belantamab mafodotin-blmf causes changes in the corneal epithelium resulting in alterations in vision, including severe vision loss and corneal ulcer, and symptoms, such as blurred vision and dry eyes. Ophthalmic exams at baseline, prior to each dose, and promptly for worsening symptoms should be conducted.

Because of the risks of ocular toxicity, belantamab mafodotin-blmf is only available through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS), called the BLENREP REMS.

Adverse reactions in ≥20% patients who received belantamab mafodotin-blmf were keratopathy, decreased visual acuity, nausea, blurred vision, pyrexia, infusion-related reactions, and fatigue.

The recommended belantamab mafodotin-blmf dose is 2.5 mg/kg as an intravenous infusion over approximately 30 minutes once every 3 weeks.

View full prescribing information for BLENREP.

This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

This review used the Real-Time Oncology Review (RTOR), which streamlined data submission prior to the filing of the entire clinical application, and the Assessment Aid, a voluntary submission from the applicant to facilitate the FDA's assessment.

FDA granted orphan drug designation, breakthrough therapy designation, and priority review to belantamab mafodotin-blmf for this indication. 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 August 5, 2020.

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http://beta.docker.cancerhealth.com/blog/fda-approves-blenrep-multiple-myeloma