The FDA approves belantamab mafodotin for relapsed or refractory myeloma

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The US **Food and Drug Administration (FDA) has approved belantamab mafodotin** (BLENREP) as a monotherapy treatment for adult patients with **relapsed or refractory myeloma** who have received at least four prior therapies including an anti-CD38 monoclonal antibody, a proteasome inhibitor and an immunomodulatory agent. 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 drug is **the first anti-BCMA (B-cell maturation antigen) therapy approved** anywhere in the world.

In Europe, the Committee for Medicinal Products for Human Use (CHMP) of **the European Medicines Agency (EMA) adopted a positive opinion** recommending the approval of this drug at the end of last month.

Dr. Sagar Lonial, MD, Chief Medical Officer, Winship Cancer Institute of Emory University in Atlanta, Georgia, Chair of Emory Department of Hematology and Medical Oncology and Principal Investigator for DREAMM-2, said: *"While treatable, refractory multiple myeloma is a significant clinical challenge with poor outcomes for patients whose disease has become resistant to the current standard of care. Due to the limited options currently available, these patients are often retreated with drugs from the same classes after they relapse, which is why the approval of belantamab mafodotin, the first anti-BCMA therapy, is significant for both patients and physicians alike."*

In the **DREAMM-2 study,** treatment with single-agent belantamab mafodotin administrated as 2.5 mg/kg dose every three weeks demonstrated a clinically meaningful overall response rate (ORR) of 31% in patients who had received a median of seven prior lines of treatment. The median duration of response (DoR) had not been reached at the six-month analysis, but 73% of responders had a DoR equal to or greater than six months. The most reported adverse events were keratopathy, decreased visual acuity, nausea, blurred vision, pyrexia, infusion-related reactions, and fatigue. Keratopathy is characterized as changes in the corneal epithelium as seen on eye examination, which can manifest with or without symptoms.

Ocular adverse reactions occurred in 77% of the 218 patients in the pooled safety population and included keratopathy (76%), changes in visual acuity (55%), blurred vision (27%), and dry eye (19%). Corneal adverse events were monitored with eye exams prior to each dose, allowing for dose reductions or interruptions as appropriate. Patients also used preservative-free eye drops. Keratopathy leading to treatment discontinuation affected 2.1% of patients in the 2.5 mg/kg cohort.

The opinion of experts on belantamab mafodotin

Belantamab mafodotin has shown very promising results that has been presented in two of the most important scientific congresses: **American Society of Hematology (ASH) Annual Meeting** that took place in Orlando, Florida, USA, in December 2019; and the The **American Society of Clinical Oncology (ASCO) Annual Meeting** that were held virtually from 29 to 31 May 2020.

Myeloma Patients Europe (MPE) interviewed **Dr Katja Weisel from the University Medical Centre Hamburg-Eppendorf, in Germany,** to analyse the data presented in these congresses on belantamab mafodotin.

Watch **here** the interview filmed at ASH 2019 on the Dreamm-3 clinical trial and the opinion of this expert about **the role of belantamab mafodotin in the myeloma armamentarium and the ocular side effects** that this drug might have. If you prefer to watch this interview in German, click **here.**