Belantamab mafodotin receives positive opinion from the EMA for relapsed and refractory myeloma

July 27, 2020

The Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion recommending the approval of belantamab mafodotin as monotherapy for the treatment of myeloma in adult patients, who have received at least four prior therapies.

The Committee for Medicinal Products for Human Use (CHMP) of the **European Medicines Agency (EMA)** adopted a positive opinion recommending the approval of **belantamab mafodotin as monotherapy** for the treatment of myeloma in adult patients, who have received at least four prior therapies and whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and an anti-CD38 monoclonal antibody, and who have demonstrated disease progression on the last therapy.

Belantamab mafodotin was granted PRIME designation in 2017 and the Conditional Marketing Authorisation Application (CMAA) was reviewed under **EMA's accelerated assessment procedure,** which is given if the CHMP determines the treatment is of major interest from a public health perspective and represents a therapeutic innovation. The CHMP positive opinion is one of the final steps before marketing authorisation is granted by the European Commission, which has the authority to approve medicines for use throughout the European Union.

The CMAA is based on data from **the pivotal DREAMM-2** (DRiving Excellence in Approaches to Multiple Myeloma) study including 13-month follow-up data. These data demonstrated that treatment with single-agent belantamab mafodotin, administered as a 2.5 mg/kg dose every three weeks (Q3W), resulted in an overall response rate of 32%. Median duration of response was 11 months and median overall survival was 13.7 months.

The **safety and tolerability profile** were consistent with previously reported data on belantamab mafodotin. The most commonly reported grade 3 or higher adverse events (occurring in more than 10% of patients) in patients receiving the 2.5 mg/kg dose were keratopathy/microcyst-like epithelial changes (MECs) (46%), thrombocytopenia (22%), anaemia (21%), lymphocyte count decreased (13%) and neutropenia (11%).

Belantamab mafodotin at ASH 2019 and ASCO 2020

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.**

Belantamab mafodotin was also one of the highlights presented at ASCO 2020. Watch **here** the interview filmed with Dr Weisel on ASCO 2020 myeloma highlights. If you prefer to watch this interview in German click **here.**