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Blenrep (*belantamab mafodotin*)

An overview of Blenrep and why it is authorised in the EU

What is Blenrep and what is it used for?

Blenrep is a cancer medicine used to treat multiple myeloma (a cancer of the bone marrow). It is given to adults who have received at least four previous treatments and whose disease does not respond to treatment with at least one proteasome inhibitor, one immunomodulatory agent, and an anti-CD38 monoclonal antibody (types of cancer medicines), and whose cancer has worsened since receiving the last treatment.

Multiple myeloma is rare, and Blenrep was designated an 'orphan medicine' (a medicine used in rare diseases) on 16 October 2017. Further information on the orphan designation can be found here: ema.europa.eu/medicines/human/orphan-designations/eu3171925.

Blenrep contains the active substance belantamab mafodotin.

How is Blenrep used?

Blenrep can only be obtained with a prescription and treatment should be started and supervised by a doctor experienced in the treatment of multiple myeloma. It is given by infusion (drip) into a vein once every three weeks, and the dose depends on body weight. Treatment should continue until the patient no longer benefits from it, or the side effects become unacceptable.

Because Blenrep could damage the cornea (the transparent layer in front of the eye that covers the pupil and iris), patients should have their eyes checked before and during treatment. Patients should use preservative-free artificial tears at least 4 times a day beginning on the first day of treatment with Blenrep, as this may reduce corneal side effects.

For more information about using Blenrep, see the package leaflet or contact your doctor or pharmacist.

How does Blenrep work?

The active substance in Blenrep, belantamab mafodotin, consists of a monoclonal antibody (a type of protein) attached to a cytotoxic (cell-killing) molecule. The antibody has been designed to attach to a protein called B-cell maturation antigen (BCMA), which is present on the surface of abnormal immature plasma cells (myeloma cells). When Blenrep is given to the patient, the medicine's antibody portion

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

attaches to BCMA on the myeloma cells and delivers the cytotoxic molecule into the cells. Once inside, the cytotoxic molecule kills the cells by interfering with their ability to divide and grow. Blenrep also stimulates the immune system (the body's natural defences) to attack the myeloma cells, and these actions combined are expected to slow down progression of the disease.

What benefits of Blenrep have been shown in studies?

An ongoing main study involving 196 patients showed that Blenrep was effective at clearing cancer cells in patients with multiple myeloma that had returned and did not respond to other treatments. Almost a third of patients (32%) given the recommended dose responded to treatment with Blenrep. The response lasted on average for 11 months.

What are the risks associated with Blenrep?

The most common side effects with Blenrep are keratopathy (damage to the cornea, which may affect more than 7 in 10 people) and thrombocytopenia (low blood platelet counts, which may affect more than 3 in 10 people).

The most common serious side effects (which may affect up to 1 in 10 people) are pneumonia (lung infection), fever, and reactions related to the infusion. For the full list of side effects and restrictions of Blenrep, see the package leaflet.

Why is Blenrep authorised in the EU?

Blenrep was effective at clearing myeloma cells, with almost a third of patients in the main study responding to treatment. The duration of the response was also clinically meaningful. The side effects of Blenrep are mostly reversible and manageable with dose modifications and close monitoring. The European Medicines Agency therefore decided that Blenrep's benefits are greater than its risks and it can be authorised for use in the EU.

Blenrep has been given 'conditional authorisation'. This means that there is more evidence to come about the medicine, which the company is required to provide. Every year, the Agency will review any new information that becomes available and this overview will be updated as necessary.

What information is still awaited for Blenrep?

Since Blenrep has been given conditional authorisation, the company that markets the medicine will provide the final results of the main study mentioned above and the results of another study comparing Blenrep with pomalidomide plus low-dose dexamethasone, which is an approved treatment option for patients with multiple myeloma that has come back.

What measures are being taken to ensure the safe and effective use of Blenrep?

The company that markets Blenrep will provide educational material to healthcare professionals, including eye specialists, to inform them that Blenrep can affect the eyes and vision. Patients who are prescribed Blenrep will also be provided with educational materials including a patient alert card with this information.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Blenrep have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Blenrep are continuously monitored. Side effects reported with Blenrep are carefully evaluated and any necessary action taken to protect patients.

Other information about Blenrep

Blenrep received a conditional marketing authorisation valid throughout the EU on 25 August 2020.

Further information on Blenrep can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/blenrep.

This overview was last updated in 08-2020.