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Summary report on authorisation dated 10 October 2025

Blenrep® (active substance: belantamab mafodotin)

Authorisation in Switzerland: 19 June 2025

Powder for solution for infusion for the treatment of adults with relapsed or refractory multiple myeloma after at least one prior therapy.

About the medicinal product

The medicinal product Blenrep contains the active substance belantamab mafodotin and is a powder for solution for infusion.

Blenrep is used in combination with the medicinal products pomalidomide and dexamethasone for the treatment of relapsed or refractory[1] multiple myeloma in adults who have received at least one prior therapy including lenalidomide, and who experienced disease progression during the last treatment.

Multiple myeloma (MM) is a rare form of cancer that accounts for around 1-2% of all cancers. The frequency of new cases of MM in Switzerland is 9.6 per 100,000 inhabitants. The disease is characterised by excessive replication of plasma cells, which are a type of white blood cell. The plasma cells multiply in an uncontrolled way in the bone marrow, which often leads to bone damage.

The previous temporary authorisation granted on 20 June 2022 for Blenrep as monotherapy was withdrawn.

Mode of action

The active substance belantamab mafodotin fights cancer cells in the body by binding to a specific marker, known as the BCMA marker, on the surface of these cells. When belantamab mafodotin binds to this marker, the active substance penetrates the cancer cell and releases a substance that inhibits cell growth and ultimately destroys the cell. This can help slow the progression of the disease or keep it under control.

1 In relation to cancer, refractory means that the cancer is resistant to treatment and does not recede or may even progress, despite treatment.

Administration

Blenrep is a prescription-only medicine used in combination with the medicinal products pomalidomide and dexamethasone. The treatment may be administered only by doctors with experience in treating multiple myeloma. Blenrep is supplied as a powder and is dissolved in liquid to produce a solution for infusion. This is administered as an intravenous infusion over approximately 30 minutes. A dose of 2.5 mg per kg body weight is administered at the start of treatment (in the first cycle). From the second cycle, the patient receives 1.9 mg/kg every four weeks. In view of the risk of eye problems, an examination by an ophthalmologist is required before each cycle.

Efficacy

In the pivotal trial (DREAMM-8), the new combination therapy of Blenrep together with pomalidomide and dexamethasone (BPd) was compared with a standard treatment (pomalidomide, bortezomib and dexamethasone; PVd). 302 patients who had received at least one prior therapy with lenalidomide took part in the trial. The BPd combination significantly prolonged the period without disease progression (progression-free survival) compared to the PVd group. The risk reduction was 48%.

Precautions, undesirable effects, & risks

The most common undesirable effects, occurring in more than 20 % of patients, included reduced visual acuity and corneal examination findings. Since these can be serious, an ophthalmological examination is required before each treatment cycle. The Information for healthcare professionals includes a specific boxed warning to this effect.

Another frequent undesirable effect is a low platelet count (thrombocytopenia), which can lead to serious bleeding events. In addition, hypersensitivity reactions can occur during the infusion, possibly requiring treatment discontinuation in rare cases.

All precautions, risks and other possible undesirable effects are listed in the Information for healthcare professionals.

Why the medicinal product has been authorised

New treatment options are urgently needed for patients with multiple myeloma. This particularly applies to patients whose disease continues to progress despite treatment with lenalidomide and an anti-CD38 antibody. In the DREAMM-8 trial, the combination of belantamab mafodotin plus pomalidomide and dexamethasone prolonged disease progression compared to a conventional treatment. As regards the side effects, eye problems pose a serious risk, hence the need for regular monitoring by an ophthalmologist and, if necessary, dose adjustment.

Taking all the risks and precautions into account, and based on the available data, the benefits of Blenrep outweigh the risks. Swissmedic has therefore authorised Blenrep in Switzerland for the treatment of relapsed or refractory multiple myeloma.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Blenrep®

Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Summary report on authorisation.

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