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Minjuvi® (active substance: tafasitamab)

Temporary authorisation in Switzerland: 22 March 2022

Medicinal product in combination with lenalidomide for the treatment of adults with recurrent or refractory diffuse large B-cell lymphoma who are not eligible for a stem cell transplant

About the medicinal product

Minjuvi is a cancer medicine containing the active substance tafasitamab and is administered as an infusion into a vein.

Minjuvi is used to treat adults with a type of cancer called "diffuse large B-cell lymphoma" (DLBCL). DLBCL is a malignant disorder of the lymphatic system[1] that originates from mature B lymphocytes (white blood cells).
Minjuvi is used to treat recurrent or refractory[2] DLBCL. The patients have already received at least one previous treatment and are not suitable candidates for a stem cell transplant.

The treatment with Minjuvi is administered in combination with another cancer medicine containing the active substance lenalidomide.
Since this is a rare and life-threatening disease, the medicine has been authorised as an orphan drug. The term "orphan drug" is used to refer to important medicines for rare diseases.

Minjuvi was authorised in connection with "Project Orbis". Project Orbis is a programme for promising cancer treatments coordinated by the FDA, the US regulatory authority. It provides a framework for the concurrent submission and review of cancer medicines by several international partner authorities in various countries. The ultimate aim is to give patients faster access to innovative cancer treatments. Currently, the authorisation authorities in Australia (TGA), Brazil (ANVISA), Canada (HC), Israel (MOH), Singapore (HSA), Switzerland (Swissmedic) and the United Kingdom (MHRA) are represented in Project Orbis.

[1]Lymphatic system: The lymphatic system includes all the lymph pathways in the body plus the lymphatic organs, including the lymph nodes, the spleen, the lymphatic tissues in the gastrointestinal tract and throat and the thymus gland.

[2] Refractory: In the context of cancer, refractory means that the cancer does not respond to the treatment and fails to regress, or even progresses, despite the treatment.

Mode of action

Tafasitamab, the active substance in Minjuvi, is a modified monoclonal antibody (immunologically active protein).

The monoclonal antibody binds to a specific receptor (target site), the CD19 antigen on the surface of the precursor cells of B cells, and the B cells themselves. After binding to CD19, tafasitamab causes the B cells to be destroyed by the body's own immune system, thereby inhibiting the growth of the cancer.

Use

Minjuvi is a prescription-only medicine and is authorised as a vial containing 200 mg of tafasitamab powder. The powder is dissolved in sterile water, diluted as required with saline solution and administered slowly via a vein.

The recommended dose is 12 mg/kg body weight administered as an intravenous infusion.

It is administered in 28-day cycles in combination with lenalidomide capsules taken orally for a maximum of 12 cycles. After 12 cycles of combination therapy, the lenalidomide is stopped, but Minjuvi can be continued on its own until the disease progresses or unacceptable side effects occur. The patients should be monitored for infusion-related reactions during and after the infusion.

During the treatment there is a risk of neutropenia (very low number of a particular group of white blood cells). Severe neutropenia increases the risk of infection. There is also the risk of thrombocytopenia (low platelet count), which increases the bleeding risk. The treatment also involves the risk of anaemia (low red blood cell count). The blood count therefore needs to be monitored regularly during the treatment.

Efficacy

The efficacy of Minjuvi was evaluated on the basis of study MOR208C203 (L-MIND). The participants in this study were 81 patients with DLBCL who were not eligible for a stem cell transplant and who had either not responded to a previous treatment or had suffered a relapse of their disease.
80 of the patients who took part in the study received the active substance lenalidomide in addition to Minjuvi. Since one study participant was diagnosed with a serious kidney disease after the first treatment with Minjuvi, the combined treatment with lenalidomide was never started.

The median[3] treatment period was 9.2 months. The efficacy was evaluated on the basis of the objective overall response rate (ORR)[4], which was assessed by an independent review committee. Progression-free survival (PFS[5]) and median overall survival (OS)[6] were also considered in the evaluation of efficacy.

[3] Median: The value that lies exactly in the middle of a distribution of data is called the median or central value. Half of the data values are always smaller than the median, the other half are always greater.

[4] Objective overall response rate (ORR): The objective overall response rate refers to the percentage of patients with an objective reduction in cancer cells.

[5] PFS: Progression-free survival: Period between the start of a treatment or a clinical trial and the onset of disease progression or the death of the patient.

[6] Overall survival (OS): The overall survival refers to the period between the start of treatment and the death of the patient.

Precautions, undesirable effects & risks

Minjuvi may not be used in those who are hypersensitive to the active substance, any of the excipients or the combination medicine.

Minjuvi may cause serious side effects. The most common (affecting more than one in ten patients) undesirable effects are anaemia (low red blood cell count), thrombocytopenia (low platelet count), neutropenia (low white blood cell count), as well as back pain, rash, diarrhoea, nausea, constipation, vomiting, tiredness, feeling unwell, peripheral oedema (severely swollen arms and legs), fever, infections, headache, loss of appetite and hypokalaemia (excessively low blood potassium level).

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

Why the medicinal product has been authorised

The efficacy of Minjuvi in combination with lenalidomide in adult patients with recurrent or refractory DLBCL is promising in terms of both the objective response rate and the duration of the response.

In view of the low number of study participants and the lack of a comparison between Minjuvi and another treatment, the data are not sufficient for a definitive benefit-risk assessment and cannot currently serve as the basis for an ordinary authorisation. However, given the great medical need, the manageable toxicity profile and the efficacy in relation to the response rate and durability of the response, a provisional authorisation is justified.

For these reasons, the medicinal product Minjuvi has been authorised temporarily in Switzerland (Art. 9a TPA). The temporary authorisation is contingent on the timely submission of the data requested by Swissmedic. Once these authorisation conditions have been met, the temporary authorisation can be converted into an ordinary authorisation in the event of a positive benefit-risk assessment of the results.

Further information on the medicinal product

At the time of publication of the Public Summary SwissPAR for Minjuvi, the Information for healthcare professionals was not yet available. As soon as the medicine becomes available in Switzerland, the Information for healthcare professionals will be made available on the following website: www.swissmedicinfo.ch

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 Public Summary SwissPAR.

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