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Public Summary SwissPAR dated 15.10.2021

Polivy® (active substance: polatuzumab vedotin)

First authorisation in Switzerland: 15 June 2021

Medicinal product in combination with bendamustine and rituximab 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

Polivy is a cancer treatment containing the active substance polatuzumab vedotin. It is a concentrate for solution for infusion that is injected into the veins.

Polivy 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).
Polivy is used to treat recurrent or refractory[2] lymphomas in patients who are not suitable candidates for a stem cell transplant.

The treatment with Polivy is administered in combination with two cancer drugs containing the active substances bendamustine and rituximab.

Since this is a rare disease, the medicine has been authorised as an orphan drug. The term "orphan drug" refers to important medicines for rare diseases that meet specific requirements.

Mode of action

The active substance in Polivy, polatuzumab vedotin, belongs to the new class of antibody-drug conjugates (ADC). It consists of a monoclonal antibody (immunologically active proteins) linked to the substance monomethyl auristatin E (MMAE). MMAE is a cytotoxin (cell poison) with the ability to kill cancer cells. The monoclonal antibody binds to a specific receptor (target site) on the B cells, causing MMAE to be released into the cells. As a result, the B cells stop dividing and cancer growth is inhibited.

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

Use

Polivy is a prescription-only medicine supplied as a powder for preparing a concentrate for solution for infusion at a dosage of 30 mg or 140 mg of the active substance. It is administered as an intravenous infusion at the recommended dose of 1.8 mg/kg bodyweight.

It is given every 21 days in combination with bendamustine and rituximab for 6 cycles. The patients should be monitored for infusion-related reactions during and after the infusion.

To reduce the risk of reactions to the infusion, patients are given certain anti-allergy medicines before the infusion is administered.

During the treatment there is a risk of neutropenia (very low number of a particular group of white blood cells). Since severe neutropenia increases the risk of infection, the blood count must be monitored regularly during treatment.

Efficacy

The efficacy of Polivy was evaluated on the basis of study GO29365. The participants in this study were 80 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. Half of the patients were treated with Polivy in combination with bendamustine and rituximab, while the other half received only bendamustine and rituximab.

6-8 weeks after the last treatment cycle, 42.5% of the patients who received Polivy in combination with bendamustine and rituximab showed no signs of cancer (complete response), compared to 17.5% of the patients who had received rituximab and bendamustine on their own.

The median[3] progression-free survival (PFS[4]) and the median overall survival[5] were better in the patients who received Polivy in combination with bendamustine and rituximab than in those patients who received the bendamustine and rituximab without Polivy.

Precautions, undesirable effects & risks

Polivy may not be used in those who are hypersensitive to the active substance or any of the excipients.

Polivy may cause serious side effects. The most common (affecting more than one in 10 patients) undesirable effects are anaemia (low red blood cell count), thrombocytopenia (low platelet count), neutropenia (low white blood cell count), as well as diarrhoea, nausea, fatigue and peripheral neuropathy (disorders of the peripheral nerves).

Other relevant side effects have occurred during the administration of Polivy (e.g. pneumonia, fever).

All precautions, risks and other possible undesirable effects are listed in the Information for patients (package leaflet) and

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

[5] Overall survival: The overall survival refers to the period between the start of treatment and the death of the patient.

the Information for healthcare professionals.

Why the medicinal product has been authorised

In the clinical trial described above, significant benefit was demonstrated for Polivy compared to the treatment without Polivy in adult patients with DLBCL. The benefit-risk profile is positive for patients who are not eligible for a stem cell transplant and who have either not responded to previous treatment or who have suffered a relapse of their disease.

Although serious side effects can occur, most are treatable with appropriate measures. Based on all the available data, the benefits of Polivy outweigh the risks. Swissmedic has therefore authorised the medicinal product Polivy with the active substance polatuzumab vedotin for use in Switzerland for the above-mentioned indication.

Further information on the medicinal product

At the time of publication of the Public Summary SwissPAR for Polivy, the Information for healthcare professionals and the Patient information (package leaflet) were not yet available. As soon as the medicine becomes available in Switzerland, the Information for healthcare professionals and the Patient information will be made available on the following website: www.swissmedicinfo.ch

Healthcare professionals (doctors, pharmacists and others) can answer any questions about this medicine.

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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