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Polivy (*polatuzumab vedotin*)

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

What is Polivy and what is it used for?

Polivy is a cancer medicine used to treat adults with diffuse large B-cell lymphoma (DLBCL, a blood cancer affecting white blood cells):

- in patients whose cancer has not been treated before. It is used in combination with rituximab, cyclophosphamide and doxorubicin (other cancer medicines) and prednisone (a corticosteroid);
- in patients whose cancer has returned or has stopped responding to other treatments and who cannot have a stem cell transplantation (a procedure where the patient's bone marrow is replaced by stem cells from a donor to form new bone marrow), Polivy is used in combination with two other cancer medicines, bendamustine and rituximab.

DLBCL is rare, and Polivy was designated an 'orphan medicine' (a medicine used in rare diseases) on 16 April 2018. Further information on the orphan designation can be found here: ema.europa.eu/medicines/human/orphan-designations/eu3182013.

Polivy contains the active substance polatuzumab vedotin.

How is Polivy used?

Polivy can only be obtained with a prescription, and treatment must be given under the supervision of a healthcare professional experienced in the diagnosis and treatment of cancer.

Polivy is given as an infusion (drip) into a vein. The first infusion of Polivy should last 90 minutes, but subsequent infusions may be given over 30 minutes if side effects with the earlier infusion were acceptable. Polivy is given in six 21-day cycles together with other cancer medicines, and the dose depends on the patient's weight.

Before receiving Polivy, patients are given preventive medicines to reduce the risk of reactions to the infusion. If the patient develops an infusion-related reaction, the infusion should be slowed down or interrupted. The doctor will check the patient for signs of peripheral neuropathy (nerve damage in the arms and legs) or side effects affecting blood cells and may reduce the dose or stop treatment with Polivy if these develop or get worse.

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

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How does Polivy work?

Patients with DLBCL have cancerous B cells, which are a type of white blood cell. The active substance in Polivy, polatuzumab vedotin, is made up of a monoclonal antibody (a type of protein) combined with a substance called monomethyl auristatin E (MMAE). The monoclonal antibody attaches to a protein called CD79b on B cells, including cancerous B cells, and in doing so causes MMAE to be released inside the cells. Once inside the B cell, MMAE stops them from dividing and causes them to die.

What benefits of Polivy have been shown in studies?

In a main study involving 879 patients with previously untreated DLBCL, Polivy given together with rituximab plus cyclophosphamide, doxorubicin and prednisone (R-CHP) was compared with the standard regimen of rituximab plus cyclophosphamide, doxorubicin, vincristine and prednisone (R-CHOP). After 28 months, 24% (107) of patients receiving Polivy plus R-CHP experienced worsening of their disease or had died compared with 31% (134) of patients receiving standard treatment.

Polivy was investigated in a second main study involving 80 patients with DLBCL whose cancer had returned or stopped responding to other treatments. Half of the patients received Polivy added to the standard regimen of bendamustine plus rituximab, whereas the other half received bendamustine plus rituximab alone. After 6 to 8 weeks of treatment, there were no signs of the cancer (complete response) in 40% of patients receiving Polivy plus rituximab and bendamustine compared with 18% of patients receiving rituximab and bendamustine alone.

What are the risks associated with Polivy?

Polivy can affect the production of blood cells. The most common side effects of Polivy in combination with rituximab, cyclophosphamide, doxorubicin and prednisone (which may affect more than 3 in 10 people) are peripheral neuropathy, nausea (feeling sick), neutropenia (low levels of white blood cells) and diarrhoea. Serious side effects (which may affect up to 2 in 10 people) include febrile neutropenia (low levels of white blood cells with fever) and pneumonia (infection of the lungs).

The most common side effects with Polivy in combination with bendamustine and rituximab (which may affect more than 3 in 10 people) are neutropenia, diarrhoea, nausea, thrombocytopenia (low levels of blood platelets), anaemia (low levels of red blood cells) and peripheral neuropathy. Serious side effects (which may affect up to 2 in 10 people) include febrile neutropenia, sepsis, pneumonia and fever.

The medicine must not be given to patients who have a severe infection. For the full list of side effects and restrictions of Polivy, see the package leaflet.

Why is Polivy authorised in the EU?

Polivy has been shown to be effective at treating patients with previously untreated DLBCL, as well as those whose disease was not responding to previous treatment or had returned and who could not have a stem cell transplant.

Serious side effects can occur; however, these are manageable if appropriate measures are in place. The Agency therefore decided that Polivy's benefits are greater than its risks and it can be authorised for use in the EU.

Polivy was originally given a 'conditional authorisation' because there was more evidence to come about the medicine. As the company has supplied the additional information necessary, the authorisation has been switched from conditional to full authorisation.

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

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

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

Other information about Polivy

Polivy received a conditional marketing authorisation valid throughout the EU on 16 January 2020. This was switched to a full marketing authorisation on <date of CD>.

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

This overview was last updated in 04-2022.