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) whose cancer has returned or has stopped responding to other treatments and who cannot have a bone-marrow transplantation.

It is used in combination with two other 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 for infusion (drip) into a vein over 90 minutes. It is given in 21-day cycles with rituximab and bendamustine. The dose of Polivy depends on the patient’s bodyweight and is given for 6 cycles.

Patients are given paracetamol and an antihistamine medicine before receiving Polivy 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 may reduce or stop the dose of Polivy if the patient develops side effects affecting blood cells.

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

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 them. MMAE then stops the B cells from dividing and causes them to die.
What benefits of Polivy have been shown in studies?

Polivy was investigated in a study involving 80 patients with DLBCL. 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 with Polivy in combination with bendamustin and rituximab (which may affect more than 3 in 10 people) were anaemia (low red blood cell count), thrombocytopenia (low blood platelet count), neutropenia (low white blood cell count), tiredness, diarrhoea, nausea (feeling sick) and fever. Serious side effects (which may affect up to 1 in 10 people) include febrile neutropenia (low white blood cell count with fever), fever, and pneumonia (infection of the lungs).

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?

The main study showed that Polivy is effective at treating patients whose disease was not responding to previous treatment or had returned and who could not have a transplant. Although the study included a limited number of patients and more data are needed to confirm the results, the European Medicines Agency considered that Polivy meets an unmet medical need.

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 has been given a ‘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 Polivy?

Since Polivy has been given conditional authorisation, the company that markets Polivy will provide further data on its effects to confirm Polivy’s safety and effectiveness when used in combination with other cancer medicines in patients with DLBCL.

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.

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

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