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Zynyz (*retifanlimab*)

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

What is Zynyz and what is it used for?

Zynyz is a medicine used in adults to treat Merkel cell carcinoma (MCC; a type of skin cancer) that cannot be cured by surgery or radiation therapy. It is used when the cancer is metastatic (has spread to other parts of the body) or has come back and is locally advanced (has spread nearby).

Merkel cell carcinoma is rare, and Zynyz was designated an 'orphan medicine' (a medicine used in rare diseases) on 13 January 2023. Further information on the orphan designation can be found on the EMA website.

Zynyz contains the active substance retifanlimab.

How is Zynyz used?

The medicine can only be obtained with a prescription and treatment should be started and monitored by a doctor experienced in the treatment of cancer.

Zynyz is given once every 4 weeks by infusion (drip) into a vein, which lasts around 30 minutes. Treatment should continue for a maximum of 2 years or until the cancer gets worse. The doctor may interrupt treatment if certain side effects occur or stop it altogether if the side effects are severe.

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

How does Zynyz work?

The active substance in Zynyz, retifanlimab, is a monoclonal antibody, a protein that has been designed to block a receptor (target) called PD-1 on certain cells of the immune system (the body's natural defences). Some cancers can make proteins (PD-L1 and PD-L2) that combine with PD-1 to switch off the activity of the immune cells, preventing them from attacking the cancer. By blocking PD-1, retifanlimab stops the cancer switching off these immune cells, thereby increasing the immune system's ability to kill the cancer cells.

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What benefits of Zynyz have been shown in studies?

Zynyz was shown to be effective at clearing the cancer in an ongoing study involving 101 patients with metastatic or locally advanced MCC that came back and could not be cured by surgery or radiation. The study did not compare Zynyz with other medicines or placebo (a dummy treatment).

In the study, around 54% of patients responded to treatment, including around 17% who had a complete response (no signs of cancer) and around 37% who had a partial response (decrease in the extent of cancer). Within the study the patients' response to treatment lasted on average for 25 months before the disease worsened.

What are the risks associated with Zynyz?

For the full list of side effects and restrictions with Zynyz, see the package leaflet.

The most common side effects with Zynyz (which may affect more than 1 in 10 people) include tiredness, rash, diarrhoea, anaemia (low levels of red blood cells), itching, joint pain, constipation, nausea (feeling sick), fever and reduced appetite.

Most of the serious side effects are related to the medicine's effect on the immune system, such as inflammation in various body organs and tissues, and rash.

Why is Zynyz authorised in the EU?

At the time of approval there were limited treatment options for patients with metastatic or advanced MCC who cannot have treatment to cure their cancer. In particular, there were no approved therapies for locally advanced MCC that came back. Despite some uncertainties associated with the design of the main study, such as the lack of a comparator medicine, Zynyz was shown to be effective in the treatment of metastatic or locally advanced MCC that has come back and cannot be cured by surgery or radiation therapy.

The side effects seen with Zynyz are mainly related to its effects on the immune system. Overall, the medicine's safety profile, which is comparable to that of other cancer medicines from the same class, is considered acceptable.

The European Medicines Agency therefore decided that Zynyz's benefits are greater than its risks and it can be authorised for use in the EU.

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

The company that markets Zynyz will provide a patient card about side effects affecting the immune system and when and where to seek help if these occur. This card will also inform healthcare professionals that the patient is being treated with Zynyz.

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

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

Other information about Zynyz

Zynyz received a marketing authorisation valid throughout the EU on 19 April 2024.

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

This overview was last updated in 04-2024.