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Elahere (mirvetuximab soravtansine)

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

What is Elahere and what is it used for?

Elahere is a cancer medicine used for the treatment of adult patients with advanced cancers of the ovaries fallopian tubes (the tubes connecting ovaries to the uterus) and the peritoneum (the membrane lining the abdomen).

Elahere can only be used when the cancer cells have receptors (targets) for proteins called folate-alpha on their surface (folate receptor-alpha (FRα) positive). It is only used when the cancer has become resistant to platinum-based cancer treatment.

Ovarian cancer is rare, and Elahere was designated an 'orphan medicine' (a medicine used in rare diseases) on 19 March 2015. Further information on the orphan designation can be found on the EMA website.

Elahere contains the active substance mirvetuximab soravtansine.

How is Elahere used?

Elahere can only be obtained with a prescription and treatment should be started and supervised by a doctor who has experience in the treatment of cancer. The doctor will check the levels of FRα before starting treatment.

Elahere is given as an infusion (drip) into a vein. Infusions should be given once every three weeks for as long as the patient benefits from the medicine and tolerates it. The doctor will closely monitor patients for side effects and may interrupt or stop treatment if the patient develops certain serious side effects.

Before giving Elahere the patient should receive medicines to prevent certain side effects such as those related to the infusion, nausea (feeling sick), and vomiting.

Elahere can cause severe eye problems; patients should see an eye specialist before starting treatment and if they develop any new or worsening eye symptoms before each dose. Patients should use eye drops to moisturise the eyes during treatment. In case they develop certain side effects affecting the eyes, the doctor may recommend they use eye drops containing corticosteroids as well.

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

How does Elahere work?

The active substance in Elahere, mirvetuximab soravtansine, is a monoclonal antibody (a type of protein) that has been designed to recognise and attach to folate receptors on the surface of cancer cells. When mirvetuximab soravtansine binds to the FRα receptor, it is taken up by the cell where it releases a chemotherapy medicine called DM4. Once inside, DM4 kills the cancer cells by interfering with their ability to divide and grow.

What benefits of Elahere have been shown in studies?

The benefits of Elahere were evaluated in a study involving 453 adults with advanced platinum-resistant cancers of the ovary, fallopian tubes and the peritoneum that were FRα positive.

In this study, Elahere was compared with standard chemotherapy treatment. Patients who received Elahere lived on average for around 5.6 months without their disease getting worse while those who received standard treatment lived for around 4.0 months without their disease getting worse. In addition, patients who received Elahere lived longer (around 16.5 months) compared to those given standard treatment (around 12.8 months).

What are the risks associated with Elahere?

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

The most common side effects with Elahere (which may affect more than 1 in 10 people) were blurred vision, nausea (feeling sick), diarrhoea, tiredness, abdominal pain (belly pain), keratopathy (damage to the cornea, the transparent layer in front of the eye that covers the pupil and iris), dry eye, constipation, vomiting, decreased appetite, peripheral neuropathy (nerve damage in arms and legs), headache, weakness, increased liver enzyme levels <in the blood> and joint pain.

Some side effects can be serious. Those most frequently reported serious side effects include pneumonitis (inflammation in the lungs), obstruction of the small intestine, obstruction of the intestine pleural effusion (fluid around the lungs), abdominal pain, dehydration, constipation, nausea, ascites (a build-up of fluid in the abdomen) and thrombocytopenia (low levels of blood platelets, components that help the blood to clot).

Why is Elahere authorised in the EU?

Elahere is effective in the treatment of cancer in patients who have ovarian, fallopian tube, or peritoneal cancer that is resistant to platinum-based treatments. Although there were some study limitations and treatment with Elahere showed limited improvements in delaying the progression of the cancer, the benefit on overall survival rate was significant. These findings are important considering the limited treatment options for these patients.

In terms of safety, Elahere has some important side effects which can be managed by careful monitoring and adjusting the dose of treatment, if needed. Considering how severe the disease is, the side effects of Elahere are considered acceptable.

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

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

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

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

Other information about Elahere

Elahere received a marketing authorisation valid throughout the EU on 14 November 2024.

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

This overview was last updated in 11-2024.