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Ziihera (*zanidatamab*)

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

What is Ziihera and what is it used for?

Ziihera is a medicine used in adults to treat biliary tract cancer (cancer of the structures that store and transport bile) when the cancer has high levels of a protein called HER2, measured with a test called immunohistochemistry. High levels of HER2 help the tumour cells grow more quickly. Ziihera is used when the cancer is unresectable (cannot be removed by surgery) and is locally advanced (has spread to nearby tissues) or metastatic (has spread to other parts of the body) and has previously been treated with at least one other systemic cancer medicine. Systemic means that the medicine works throughout the whole body.

Ziihera contains the active substance zanidatamab.

How is Ziihera used?

Ziihera can only be obtained with a prescription, and treatment must be started by a doctor experienced in the diagnosis and treatment of patients with biliary tract cancer. It should be given by a qualified healthcare professional in a setting where resuscitation equipment is available in case patients develop severe allergic reactions.

It is given by infusion (drip) into a vein every 2 weeks. Patients will be given other medicines before treatment with Ziihera to reduce the risk of allergic reactions, pain and fever. Treatment should continue until the disease gets worse or side effects are no longer tolerated by the patient.

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

How does Ziihera work?

The active substance in Ziihera, zanidatamab, is an antibody (a type of protein) that recognises and attaches to two different parts of the HER2 protein. By attaching to HER2, zanidatamab activates cells of the immune system (the body's natural defences), which remove and kill the cancer cells. This reduces the levels of HER2 and stops the cancer from growing.

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What benefits of Ziihera have been shown in studies?

A main study looked at the effect of Ziihera in 80 patients with unresectable locally advanced or metastatic biliary tract cancer who had received at least one chemotherapy treatment containing gemcitabine (another cancer medicine) and whose cancer had worsened or stopped responding to the most recent treatment. In the 62 patients whose cancer produced high levels of HER2, the cancer shrank or was no longer detectable in around 52% (32 out of 62) after an average follow up period of 34 months. In addition, patients lived for an average of 15 months without their disease getting worse. The study did not compare Ziihera with either placebo (a dummy treatment) or another cancer medicine.

What are the risks associated with Ziihera?

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

The most common side effects with Ziihera (which may affect more than 1 in 10 people) include diarrhoea, reactions related to the infusion (including feeling sick, fever and chills), tiredness, anaemia (low levels of red blood cells) and rash.

Some side effects can be serious. The most frequent serious side effects with Ziihera (which may affect up to 1 in 10 people) include diarrhoea and tiredness.

Why is Ziihera authorised in the EU?

Ziihera has been shown to have a beneficial and durable effect in patients with advanced or metastatic HER2-positive biliary tract cancer who had previously received at least one chemotherapy treatment. Although the number of people involved in the main study was small and the medicine was not compared with other treatments, the benefits are considered relevant for these patients who had limited treatment options at the time of authorisation. The side effects of the medicine are in line with those seen with other HER2 antibodies and are considered acceptable in this disease setting.

Ziihera has been given conditional authorisation for use in the EU. This means that it has been authorised on the basis of less comprehensive data than are normally required because it fulfils an unmet medical need. The European Medicines Agency considers that the benefit of having the medicine available earlier outweighs any risks associated with using it while awaiting further evidence.

The company must provide further data on Ziihera. To confirm the safety and effectiveness of the medicine in its approved use, the company must submit results from an ongoing study comparing the effect of Ziihera given together with standard-of-care treatment with standard-of-care alone in adults with advanced HER2-positive biliary tract cancer. Every year, the Agency will review any new information that becomes available.

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

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

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

Other information about Ziihera

Ziihera received a conditional marketing authorisation valid throughout the EU on 27 June 2025.

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

This overview was last updated in 06-2025.