25 April 2025
EMA/124079/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Ziihera

zanidatamab

On 25 April 2025, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a conditional[2] marketing authorisation for the medicinal product Ziihera[3], intended for the treatment of adults with unresectable locally advanced or metastatic HER2-positive biliary tract cancer. The applicant for this medicinal product is Jazz Pharmaceuticals Ireland Limited.

Ziihera will be available as a 300 mg powder for concentrate for solution for infusion. The active substance of Ziihera is zanidatamab, a HER2 inhibitor (ATC code: L01FD07). Zanidatamab is a dual HER2-targeted bispecific antibody that simultaneously binds extracellular domains 2 and 4 on separate HER2 monomers. Binding of zanidatamab with HER2 results in internalisation, leading to a reduction of HER2 on the cell surface. Zanidatamab induces complement-dependent cytotoxicity, antibody-dependent cellular cytotoxicity and antibody-dependent cellular phagocytosis, resulting in tumour growth inhibition and tumour cell death.

The benefits of Ziihera are its confirmed objective response rate and duration of response in patients with HER2-positive unresectable locally advanced or metastatic biliary tract cancer who had previously received chemotherapy, as shown in a single-arm open-label study.

The most common side effects with Ziihera include diarrhoea, infusion-related reactions, fatigue, anaemia and rash.

The full indication is:

> Ziihera as monotherapy is indicated for the treatment of adults with unresectable locally advanced or metastatic HER2-positive (IHC3+) biliary tract cancer (BTC) previously treated with

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion
[2] A conditional marketing authorisation is granted to a medicinal product that fulfils an unmet medical need when the benefit to public health of immediate availability outweighs the risk inherent in the fact that additional data are still required. The marketing authorisation holder is expected to provide comprehensive clinical data at a later stage.
[3] This product was designated as an orphan medicine during its development. EMA will now review the information available to date to determine if the orphan designation can be maintained

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

at least one prior line of systemic therapy (for biomarker-based patient selection, see section 4.2).

Treatment with Ziihera should be initiated and supervised by physicians experienced in the diagnosis and treatment of biliary tract cancer.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union languages after the marketing authorisation has been granted by the European Commission.