MHRA approves zanidatamab (Ziihera) for the treatment of biliary tract cancer

24.2.2026 - | Her Majesty's Revenue and Customs

Zanidatamab is used when the cancer cannot be removed by surgery and has spread to nearby tissues or other parts of the body.

The Medicines and Healthcare products Regulatory Agency (MHRA) has today, 19 February 2026, approved zanidatamab (Ziihera) for use in adults to treat biliary tract cancer (cancer of the structures that store and transport bile) whose cancer has high levels of a protein called HER2 and has progressed after previous treatment.

Zanidatamab is used when the cancer cannot be removed by surgery and has spread to nearby tissues or other parts of the body.

Zanidatamab is administered by an infusion drip into a vein every two weeks.

A study in 80 patients with locally advanced or metastatic biliary tract cancer that could not be removed by surgery found that, among the 62 patients with high levels of HER2, the cancer shrank or was no longer detectable in around 52% of patients after an average follow-up of 34 months. The study did not compare Ziihera with placebo or another cancer medicine.

Julian Beach, Interim Executive Director of Healthcare Quality and Access at the MHRA, said:

“Zanidatamab provides a new treatment option for adults with advanced biliary tract cancer whose disease has high levels of HER2 and has progressed following previous treatment.

“This approval reflects the MHRA’s commitment to ensuring patients can access safe and effective medicines where there is an unmet clinical need.

“As with all approved medicines, we will continue to monitor the safety and effectiveness of zanidatamab as it is used more widely.”

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

Notes to editors

- The approval was granted on 19/02/2026 to Jazz Pharmaceuticals Research UK Limited.
- This product was submitted and approved via the International Recognition Procedure.
- More information can be found in the Summary of Product Characteristics and Patient Information Leaflets which will be published on the MHRA Products website within 7 days of approval.
- The Medicines and Healthcare products Regulatory Agency (MHRA) is responsible for

regulating all medicines and medical devices in the UK by ensuring they work and are acceptably safe. All our work is underpinned by robust and fact-based judgements to ensure that the benefits justify any risks.

- The MHRA is an executive agency of the Department of Health and Social Care.

- For media enquiries, please contact newscentre@mhra.gov.uk or call 020 3080 7651.

https://www.gov.uk/government/news/mhra-approves-zanidatamab-ziihera-for-the-treatment-of-biliary-tract-cancer