FDA Approves New Targeted Treatment for Biliary Tract Cancer

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The FDA has approved a new drug, zanidatamab, for adults with advanced biliary tract cancer, or BTC. Marketed under the brand name Ziihera, it is a first-of-a-kind treatment for patients with HER2-positive cancer that has spread or can't be removed by surgery after prior treatment.

BTC begins in either the gallbladder or bile duct (branched tubes connecting the liver and gall bladder to the small intestine), with less than 5% of patients surviving five years when it spreads. Advanced HER2-positive cases (where tumors produce high levels of the HER2 protein that promotes cancer growth) are usually more aggressive and have limited treatment options.

The drug is a targeted antibody against HER2 and is the first to attack the protein at two sites, stopping tumor growth. It also helps the body's immune system identify and attack cancer cells. This multifaceted action makes the drug better at reducing disease progression.

The FDA also approved the Ventana Pathway anti-HER-2/neu (4B5) Rabbit Monoclonal Primary Antibody, a test to detect HER2-positive tumors and confirm that people are eligible for the new treatment.

Ziihera was approved after a trial with 62 advanced cancer patients who had tried gemcitabine-based chemotherapy. Tumors shrank in 52% of patients, with effects lasting about 15 months, on average.

In its approval statement, the FDA included a warning that Ziihera may harm an unborn baby. Jazz Pharmaceuticals, the maker of Ziihera, has advised patients of reproductive age to use effective contraception during treatment. Other common side effects may include diarrhea, infusion-related reactions, stomachache, and tiredness.

The company, in a news release, announced the drug with standard therapy is being tested against standard therapy alone for first-line treatment of HER2-positive BTC. The drug's continued approval depends on confirming benefits in this trial.

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