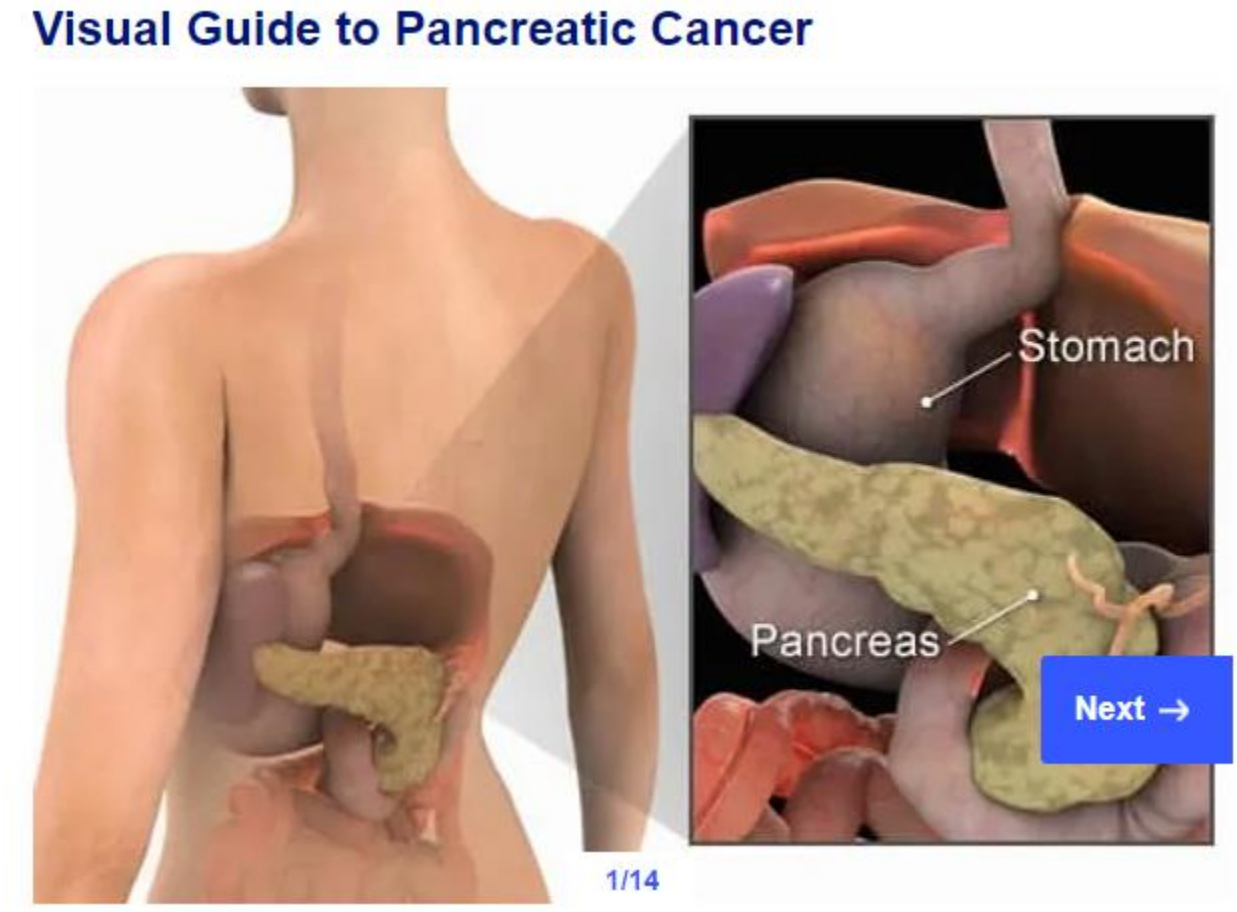
FDA Approves New Drug for Lung and Pancreatic Cancers

The FDA has granted accelerated approval to zenocutuzumab, a new drug for adults with advanced non-small-cell lung cancer (NSCLC) or pancreatic cancer. The drug is the first comprehensive treatment approved for cancers with NRG1 fusion that have spread or that can't be surgically removed and have worsened after previous treatments.

NRG1 fusions are rare genetic changes that play an important role in certain types of pancreatic cancers and NSCLC. They produce unique “fusion proteins” that attach to specific targets (HER2 and HER3) on cancer cells, triggering cell signals that promote tumor growth and spread. This makes NRG1-positive cancers fast-growing, aggressive, and difficult to treat with standard treatments, highlighting the need for new therapies to target fusion proteins.



What It Is

Pancreatic cancer happens when malignant (cancerous) cells grow, divide, and spread in the pancreas. The pancreas is a 6-inch-long, spongy, tube-shaped organ located in the back of the abdomen, behind the stomach. It has two major jobs in the body: to make digestive juices (called enzymes) that help break down food, and to make hormones -- including insulin -- that control the body's use of sugars and starches.

Zenocutuzumab, marketed under the brand name Bizengri, is a targeted antibody, a type of drug that uses your body's immune system to fight cancer. It blocks HER2 and HER3 proteins on cancer cells and prevents NRG1 fusion proteins from binding with them. Additionally, Bizengri may also help the body's immune system kill cancer cells directly. This dual action slows down the growth and spread of cancer cells more effectively.

Bizengri will be given once in two weeks and it is expected to be available in the coming weeks, according to a press release by Merus N.V., the drug's maker.

The effectiveness of Bizengri was tested in a study that included 64 adults with advanced NSCLC and 30 with advanced pancreatic cancer, all with NRG1 fusions, who had tried other treatments without success. The study used next-generation sequencing to identify NRG1 gene fusions. Tumors shrank in 33% of patients with NSCLC, with effects lasting for 7.4 months on average; while for pancreatic cancer, tumors shrank in 40% of patients and the effects lasted 3.7 to 16.6 months. Merus N.V. reported that continued approval depends on the clinical benefits being confirmed in further trials.

Bizengri may cause muscle pain, tiredness, rashes, infusion reactions, breathing trouble, nausea, diarrhea, constipation, vomiting, stomach pain, and swelling. It can also lead to changes in liver enzymes, hemoglobin, blood electrolytes, low red blood cell and platelet counts, and low sodium levels. The FDA warns it may harm unborn babies, so patients should confirm they're not pregnant and use contraception during treatment and for two months afterward. Since Bizengri can affect the heart and lungs, patients with heart or lung conditions should inform their doctor before starting Bizengri.

News Source:

https://www.webmd.com/cancer/news/20241205/fda-approves-new-drug-lung-pancreatic-cancer