US FDA approves AbbVie-Pfizer's treatment for intra-abdominal infections

AbbVie and co-developer Pfizer's drug, Emblaveo, is approved in combination with an antibiotic medication for patients 18 years and older with such infections.



Bengaluru: AbbVie said on Friday that the U.S. Food and Drug Administration approved its drug for complicated intra-abdominal infections, including those caused by drug-resistant bacteria.

AbbVie and co-developer Pfizer's drug, Emblaveo, is approved in combination with an antibiotic medication for patients 18 years and older with such infections.

Deaths from antibiotic-resistant bacteria, also known as superbugs, have been on the rise globally, and health regulators have called for the development of newer treatments as resistance to older antibiotics grows.

Intra-abdominal infections (IAIs) are a group of infections that occur in the abdominal cavity. They can range from uncomplicated appendicitis to more serious conditions where the infection spreads from the pancreas. IAIs, which affect about 3.5 million people in the U.S. annually, lead to symptoms such as abdominal pain, fever, nausea and vomiting.

AbbVie said Emblaveo can be used to treat IAIs, including those caused by Gram-negative bacteria that have developed a high resistance to antimicrobial medicines.

The approval was based on a late-stage study with 422 patients, where the drug met the main goal of complete resolution of clinical symptoms of an infection.

Emblaveo was approved in Europe in April last year and will be available in the U.S. in the third quarter of 2025.

AbbVie holds the rights to commercialize the therapy in the U.S. and Canada, with Pfizer responsible for its commercialization in all other areas.

News Source:

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