

US FDA approves GSK's oral antibiotic for drug-resistant UTIs

The approval of the oral antibiotic, branded as Utebzi, offers a more convenient way to treat complicated infections-including a type of kidney inflammation called pyelonephritis-at home instead of in a hospital.



London: The U.S. FDA has approved GSK's oral antibiotic to treat complicated urinary tract infections, the regulator said on Wednesday, giving patients a new treatment

option against drug-resistant infections.

The approval of the oral antibiotic, branded as Utebzi, offers a more convenient way to treat complicated infections-including a type of kidney inflammation called pyelonephritis-at home instead of in a hospital.

While simple UTIs respond well to outpatient antibiotics, complicated UTIs carry a higher risk of treatment failure and can sometimes be fatal. Complicated UTIs affect more than 2.8 million people in the United States each year.

GSK said the drug is expected to be available to U.S. patients by the end of 2026.

The approval makes GSK's drug the first oral carbapenem, a class of antibiotics which are widely used for the treatment of drug-resistant gram-negative bacterial infections.

Current carbapenems, which are considered the standard of care for many serious infections, are only been available in intravenous forms. This often requires patients to remain in a hospital, visit an infusion center or arrange for home IV therapy to complete their course of treatment.

"We don't see tebi as expanding that (patient) pool but serving the patients within the carbapenem footprint with an oral option," said Amanda Peppercorn, who leads the drug's development program at GSK.

She said physicians were likely to use the drug to help stable patients leave hospital sooner and simplify their treatment course.

In a late-stage trial with 1,690 adult patients who were hospitalized with complicated UTIs, the drug was as good as a broad spectrum antibiotic combination called imipenem-cilastatin, and was stopped early for efficacy in May last year.

The approval adds to GSK's trio of anti-infective drugs, including Blujepa and Brexafemme, which the company has projected could bring in more than £2 billion in peak annual sales collectively.

Last year, the FDA approved GSK's Blujepa for women aged 12 years and older to treat uncomplicated UTIs. (Reporting by Sriparna Roy in Bengaluru and Bhanvi Satija in London; Editing by Tasim Zahid and Devika Syamnath)

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