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Orchid Pharma's Exblifep receives US FDA approval

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European Medicines Agency granted Exblifep approval in January 2024

Orchid Pharma, based in Chennai, has received approval by the United States Food and Drug Administration (USFDA) for its novel invention, 'Enmetazobactam'. This development comes in close succession to the recent recommendation for approval by the European Medicines Agency (EMA). Enmetazobactam is the first completely invented-in-India Beta Lactamase Inhibitor.

This USFDA approval paves the way for the introduction of Enmetazobactam in the United States, the largest pharmaceutical market in the world. The product is expected to be launched within the next couple of quarters in the US market.

This New Drug Approval (NDA) allows the use of Exblifep (Cefepime and Enmetazobactam) as an injection for the treatment of patients 18 years and older with complicated urinary tract infections (cUTI) including pyelonephritis caused by the following susceptible microorganisms: Escherichia coli, Klebsiella pneumoniae, Pseudomonas aeruginosa, Proteus mirabilis, and Enterobacter cloacae complex.

Orchid is the first company from India, ever to have invented a product which has received a New Drug Approval (NDA) from USFDA. It is a significant development in addressing the global need for affordable and efficacious drugs to combat Anti-Microbial Resistance (AMR).

Enmetazobactam was invented in India by Orchid and then out licensed to Allecra Therapeutics for further development.