

Orchid Pharma gets new drug approval from USFDA

Orchid Pharma on Friday said it has received approval from the US health regulator to market a medication used to treat patients with complicated urinary tract infection. The drug firm has received new drug approval from the US Food and Drug Administration (USFDA) for Enmetazobactam, Orchid Pharma said in a statement.



New Delhi: Orchid Pharma on Friday said it has received approval from the US health regulator to market a medication used to treat patients with complicated urinary tract infection. The drug firm has received new drug approval from the US Food and Drug

Administration (USFDA) for Enmetazobactam, Orchid Pharma said in a statement.

The approval paves the way for the introduction of Enmetazobactam in the US, the largest pharmaceutical market in the world, it added.

The product is expected to be launched within the next couple of quarters in the US market, the Chennai-based firm said.

The approval 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.

"..the USFDA approval reinforces Orchid's position on the safety of the drug and its innate need in the times of increasing antimicrobial resistance," Orchid Pharma MD Manish Dhanuka said.

First discovered in 2008, it has taken 16 years of painstaking work to get the product to market, he added.

Orchid claimed it is the first Indian firm to have invented a product which has received a new drug approval from the USFDA.

It is a significant development in addressing the global need for affordable and efficacious drugs to combat Anti-microbial Resistance (AMR), it added.

Shares of Orchid Pharma on Friday ended 6.72 per cent up at Rs 1,228.25 apiece on the BSE.

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