US FDA approves Basilea Pharmaceutica's antibiotic

The Switzerland-based company was seeking approval of its antibiotic ceftobiprole for the treatment of three conditions - Staphylococcus aureus bacteremia (SAB), acute bacterial skin and skin structure infections, and community-acquired bacterial pneumonia.

By Sriparna Roy and Unnamalai L

London: The U.S. health regulator approved Basilea Pharmaceutica's antibiotic for bacterial infections including multidrug-resistant strains, the FDA said on Wednesday.

The Switzerland-based company was seeking approval of its antibiotic ceftobiprole for the treatment of three conditions - Staphylococcus aureus bacteremia (SAB), acute bacterial skin and skin structure infections, and community-acquired bacterial pneumonia.

The approval expands options for patients who may have developed a resistance to currently available antibiotics. More than 2.8 million antimicrobial-resistant infections occur each year in the U.S., according to government data.

The U.S. market for the intravenous antibiotic, which will be sold under the brand name Zevtera, is projected to be $5.50 billion and is probably going to be the "lion's share of the market for this drug", said Soo Romanoff, analyst at Edison Group.

She added that the drug is differentiated from the current drugs available in the market which have not been updated for decades.

The indications for the drug include SAB, which is a serious cause of bloodstream infection associated with high death rates, and acute bacterial skin and skin structure infections, which cause swelling of the skin.

The approval was based on data from three separate late-stage studies for each indication in which Zevtera met the main goals and showed improvement in symptoms.

The antibiotic is approved and marketed as Zevtera and Mabelio in several countries outside U.S.

(Reporting by Sriparna Roy, Unnamalai L and Christy Santhosh in Bengaluru; Editing by Vijay Kishore)

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