US FDA approves Insmed's drug as first treatment for a chronic lung disease

The FDA and the company agreed to make both doses available, leaving the choice to the prescribing physician, CEO William Lewis told Reuters.

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Bengaluru: The U.S. Food and Drug Administration has approved <u>Insmed</u>'s oral drug for a type of lung disease, the company said on Tuesday, making it the first treatment for the chronic condition.

Shares of the New Jersey-based drugmaker rose 6% in afternoon trade.

Insmed's drug, branded as <u>Brinsupri</u>, targets <u>non-cystic fibrosis</u> <u>bronchiectasis</u>, a chronic lung condition characterized by permanently damaged airways, leading to persistent cough and excessive mucus production.

The condition affects 350,000 to 500,000 adults in the U.S., according to the American Lung Association.

Brinsupri works by blocking certain inflammatory enzymes in white blood cells, preventing them from becoming overactive and damaging the lungs. Earlier treatments for the condition focused on controlling symptoms by using antibiotics, surgery or devices such as flutter valves to clear the airways.

Insmed's application was based on a late-stage trial involving 1,680 adult and 41 adolescent patients, with the drug significantly reducing the frequency of respiratory symptoms such as chronic cough.

The drug was found to be safe and well-tolerated at the two tested doses of 10 milligrams and 25 milligrams.

The FDA and the company agreed to make both doses available, leaving the choice to the prescribing physician, CEO William Lewis told Reuters.

Both doses will be priced at \$88,000 per year, he added.

TD Cowen analyst Ritu Baral expects the drug to reach peak sales of \$3.7 billion in the United States by 2031. Brinsupri has the potential to drive future profitability for the company, she said.

Rival treatments in development for the chronic lung condition include AstraZeneca's benralizumab and Zambon's inhaled antibiotic therapy CMS I-neb.

This marks the second <u>FDA approval</u> for Insmed following <u>Arikayce</u>, which the agency cleared in 2018 to treat a chronic lung infection caused by bacteria commonly found in soil and water. (Reporting by Christy Santhosh and Unnamalai L in Bengaluru; Editing by Sriraj Kalluvila and Tasim Zahid)

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