US FDA approves Verona Pharma's inhaled COPD therapy

The therapy is a type of single-drug medication designed to relax the muscles around the airways, making it easier to breathe, while reducing inflammation in the lungs without using steroids.

By Pratik Jain and Sruthi Narasimha Chari

London: The U.S. Food and Drug Administration has granted approval to a treatment from Verona Pharma for a chronic lung disease that commonly affects smokers, the U.K.-based company said on Wednesday.

U.S.-listed shares of the company surged 11 per cent in extended trading. The U.S. FDA's assent for the therapy, to be sold under the brand Ohtuvayre, is the company's first and provides a new inhaled non-steroidal treatment for chronic obstructive pulmonary disease.

COPD, a chronic condition which causes restricted airflow and breathing problems, commonly affects cigarette smokers and is also known as "smoker's lungs". Other contributing factors for COPD include fumes, chemicals and dust in many working environments.

It affects around 16 million Americans and is the sixth leading cause of death in the country, according to government data.

Verona's application was backed by efficacy and safety data from two late-stage trials in which Ohtuvayre demonstrated improvements in lung function and symptoms, substantially reducing the risk of exacerbation in mild-to-severe COPD patients.

The therapy is a type of single-drug medication designed to relax the muscles around the airways, making it easier to breathe, while reducing inflammation in the lungs without using steroids.

"Physicians are wildly excited about this drug because it is very safe and it helps patients breathe to a measurable extent," BTIG analyst Thomas Shrader told Reuters ahead of the regulator's decision.

Shrader estimated the drug could generate $3.6 billion in peak sales.

The company expects to have around 100 sales representatives to reach about 15,000 physicians and is "in a very good position to execute on that" if it gets approval, Chief Commercial Officer Christopher Martin told Reuters ahead of the FDA decision.

The company said it planned to provide details on pricing during an investor conference call on Thursday.

The add-on COPD drug market is seeing interest from larger drugmakers as well, especially Regeneron and Sanofi's blockbuster anti-inflammatory drug Dupixent, although the FDA extended its review deadline to Sept. 27 in late May

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