US FDA approves Merck's blood pressure therapy

Merck received the rights to Winrevair as part of its $11.5 billion acquisition of Acceleron Pharma in 2021. It has been beefing up its portfolio of cardiovascular drugs as part of its strategy to counter a possible hit to sales to its cancer treatment Keytruda, the world's top selling medicine, from biosimilars later in the decade.

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By Leroy Leo and Michael Erman

London: The U.S. Food and Drug Administration on Tuesday approved Merck's treatment for adults with high blood pressure due to constriction of lung arteries, adding another potential blockbuster drug to the pharmaceutical giant's portfolio.

Shares of Merck were up more than 5 per cent in extended trading.

> The therapy, branded Winrevair, is approved for treating pulmonary arterial hypertension (PAH), which affects about 40,000 people in the United States.
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> "We look forward to making a significant difference for these patients that are left with a disease where the five year mortality is 43 per cent," Jannie Oosthuizen, president of Merck's U.S. Human Health business, told Reuters.

Winrevair will carry a list price of $14,000 per vial, Oosthuizen said. According to data from the company's trial, most patients will use a single vial every three weeks, which would translate to $238,000 per year.

The drug maker expects to be able to bring the drug to the market by the end of April.

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Winrevair becomes the first treatment to secure FDA approval from its class of drugs, which target a type of protein called activin that lead to higher levels of a follicle-stimulating hormone associated with the disease.

It is the second drug to be approved for PAH in less than a week, after Johnson & Johnson's Opsynvi - a combination of J&J's older PAH drug Opsumit and generic drug tadalafil - received the FDA's nod late Friday.

PAH is caused by a constriction of arteries in the lungs, leading to high blood pressure and symptoms such as shortness of breath, chest pain and dizziness.

The hypertension also makes the heart work harder to pump blood, eventually causing heart failure.

In October, J.P. Morgan analyst Chris Schott had estimated the therapy would reach peak sales of $3 billion to $4 billion.

Approval for Merck's drug was based on a 24-week long late-stage trial of 323 patients with PAH.

In the trial, patients treated with the drug showed a significant improvement in exercise capacity, increasing their 6 minutes walking distance by 40.8 meters, compared to the placebo.

(Reporting by Leroy Leo, Christy Santhosh and Mariam Sunny in Bengaluru and Michael Erman in New Jersey; Editing by Shinjini Ganguli and Krishna Chandra Eluri)

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