US FDA approves Precigen's immunotherapy for rare respiratory disease

The approval was based on an early-to-mid-stage study data that showed 51 per cent of patients required no surgeries in the 12 months after the treatment.

Bengaluru: The U.S. Food and Drug Administration has approved Precigen's immunotherapy to treat adults with a rare respiratory disease, making it the first treatment for the condition to receive the health regulator's nod.

Shares of the company surged more than 81% to $3.36 in premarket trading on Friday.

The therapy, Papzimeos, was approved to treat recurrent respiratory papillomatosis (RRP) - a condition that causes growth of wart-like tumors in the respiratory tract due to human papillomavirus (HPV) infection.

RRP can be fatal as there is no cure and the current standard-of-care is repeated surgeries. A distinguishing aspect of this disease is the tendency for the growth to return even after removing them through surgical procedures.

"Everybody is anxiously awaiting a new treatment for this disease. The patients are and the surgeons are. There's nothing more frustrating than doing a surgery and then having the patient come back six months later," said Simon Best, associate professor of Otolaryngology at Johns Hopkins Hospital.

Precigen estimates about 27,000 adult RRP patients in the U.S. It did not immediately respond to a Reuters request for comment on the treatment's pricing.

"There is so much hope in the community right now, the common theme is we may finally be able to say no more surgery," said Kim McClellan, president of the Recurrent Respiratory Papillomatosis Foundation. McClellan herself was diagnosed with RRP at the age of five and has since then had more than 250 surgeries.

The approval was based on an early-to-mid-stage study data that showed 51% of patients required no surgeries in the 12 months after the treatment.

"Randomized trials are not always needed to approve medical products and this approval is proof of that philosophy," said Vinay Prasad, who recently returned to the FDA to oversee vaccine, gene therapy and blood product regulation.

Papzimeos is designed to stimulate an immune response against cells infected with HPV types 6 and 11 - the strains that cause the disease.

J.P.Morgan analysts estimate peak sales for the drug in the U.S. to be about $250 million. (Reporting by Kamal Choudhury and Sneha S K in Bengaluru; Editing by Shilpi Majumdar)

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