US FDA approves Inovio's treatment for rare throat disease; shares surge

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Bengaluru: The US Food and Drug Administration has approved Inovio Pharmaceuticals' treatment for a rare respiratory condition, the regulator said on Friday, marking the company's first approved product.

Shares of Inovio were up 215% in extending trading.

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Recurrent respiratory papillomatosis is characterized by recurrent wart-like growths in the throat and airways.

The condition is usually caused by HPV types 6 and 11 and can affect a person's ability to speak and breathe. Although the growths are not cancerous, they often return after treatment.

Doctors currently treat it by surgically removing the growths, but many patients require multiple procedures each year because the condition often recurs.

The most commonly reported adverse reactions to Inovio's Voceryq were injection site reactions, headache, fatigue, hypertension, nausea, and dizziness, the FDA said.

Inovio's application was supported by an early- to mid-stage study in adults who had undergone at least two or more surgeries in the previous year.

Last year, Precigen's Papzimeos for adults with recurrent respiratory papillomatosis became the first medicine to get US approval for the disease.

Inovio CEO Jacqueline Shea told Reuters ahead of the FDA decision that, unlike Precigen's Papzimeos, which uses a modified virus to trigger an immune response, Voceryq is a DNA-based immunotherapy. She said both therapies are designed to generate immune responses against HPV types 6 and 11, but do so through different mechanisms.

Shea said physicians are primarily looking for therapies that reduce the need for surgery, noting that every operation carries a risk of permanent vocal cord damage.

Inovio plans to commercialize the therapy on its own in the United States and is working with Syneos Health to support the launch.

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