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Agius Pharma shares jump as US FDA expands approval for blood disorder drug

By Siddhi Mahatole

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Signage is seen outside of the Food and Drug Administration (FDA) headquarters in White Oak, Maryland, U.S., August 29, 2020.
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Dec 24 (Reuters) - Shares of Agios Pharmaceuticals ([AGIO.O](#)) [↗](#) jumped nearly 16% on Wednesday after the U.S. Food and Drug Administration approved the expanded use of its drug for the treatment of a type of blood disorder.

The drug, with chemical name mitapivat and branded Aqvesme, was approved as the first oral treatment for patients with anemia in both non-transfusion-dependent and transfusion-dependent alpha- or beta-thalassemia, the company said late on Tuesday.

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Thalassemia is an inherited blood disorder affecting the body's ability to produce hemoglobin and healthy red blood cells.

Aqvesme is expected to be available late next month, following the implementation of a required safety program.

It will carry a boxed warning for injury to liver cells, or hepatocellular injury, and requires liver function tests every four weeks during the first 24 weeks of treatment. The label will also advise against use in patients with cirrhosis.

At least two analysts said the label and requirements were in line with expectations.

The yearly price of the drug is about \$425,000 per patient, said Chief Financial Officer Cecilia Jones in an analyst call on Wednesday.

"This is a modest premium to Pyrukynd's wholesale acquisition cost price of \$335,000. We had expected parity pricing," said Cantor analyst Eric Schmidt.

The drug, under the brand name Pyrukynd, was already approved by the FDA in 2022 to treat low red blood cell counts in adults with pyruvate kinase deficiency.

"The approval unlocks an additional \$320 million in peak revenue opportunity layered atop the existing mitapivat franchise," Truist analyst Gregory Renza said.

The company targets a population of about 6,000 adult thalassemia patients in the U.S., of which about 4,000 will be addressable at launch.

The latest approval is based on a late-stage study in which patients receiving the drug showed a statistically significant increase in hemoglobin response compared with placebo.

Reporting by Siddhi Mahatole in Bengaluru; Editing by Vijay Kishore and Sahal Muhammed

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