US FDA approves Omeros' drug to treat dangerous transplant complication

The drug, branded Yartemlea, is used to treat a condition known as transplant-associated thrombotic microangiopathy, or TA-TMA, a serious complication that can develop after stem cell transplants, particularly those that use healthy cells from a donor.

Bengaluru: The U.S. Food and Drug Administration has approved Omeros' drug for a dangerous transplant complication in adults and children two years and older, marking the first treatment to be greenlit for the condition, the company said on Wednesday.

Omeros shares rose nearly 70% in morning trading.

The drug, branded Yartemlea, is used to treat a condition known as transplant-associated thrombotic microangiopathy, or TA-TMA, a serious complication that can develop after stem cell transplants, particularly those that use healthy cells from a donor.

TA-TMA occurs due to damaged blood vessels during or after a stem cell transplant as a result of an overactive immune system, causing inflammation. This leads to tiny blood clots that can harm organs such as the kidneys, sometimes causing life-threatening problems.

The FDA had initially declined to approve the drug in 2021, saying it could not determine a clear treatment effect and requested additional data to support approval.

A 28-patient trial showed the drug, chemically known as narsoplimab-wuug, improved survival in 61% of patients with high-risk TA-TMA who had it as a first-line treatment.

After a long delay following the initial complete response letter, H.C. Wainwright analyst Brandon Folkes noted Omeros had become a "show-me" story, but the FDA decision lifts that overhang and lets investors refocus on the value potential from both Yartemlea's approval and the broader pipeline.

Yartemlea, a monoclonal antibody drug, works by blocking the MASP-2 protein that plays a key role in the immune system.

AstraZeneca's Soliris, which is approved for atypical hemolytic uremic syndrome, another type of thrombotic microangiopathy, is used off-label to treat TA-TMA.

Omeros expects the treatment to be available on the market by January 2026. It did not immediately respond to a Reuters request for a comment on Yartemlea's pricing.

The company expects a decision from the European medicines regulator in mid-2026.

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