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2 minute read · April 17, 2023 12:42 PM PDT · Last Updated 2 days ago

US allows use of Gamida's therapy in blood cancer treatment

Reuters

Signage is seen outside of the Food and Drug Administration (FDA) headquarters in White Oak, Maryland, U.S., August 29, 2020. REUTERS/Andrew Kelly

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April 17 (Reuters) - The U.S. Food and Drug Administration said on Monday it had approved the use of Gamida Cell Ltd's (GMDA.O) cell therapy for cutting the risk of infection in patients undergoing treatment for blood cancer, sending the company's shares up 46%.

The approval allows the company to launch its first-ever commercial therapy under the brand name Omisirge for patients who are 12 years or older and are undergoing stem cell transplantation.

Prior to the process of the transplantation, patients often undergo radiation or chemotherapy, which can weaken their immune system and expose them to the risk of severe and sometimes deadly infections.

The therapy is given as a single intravenous dose and is made using donor stem cells obtained from umbilical cord blood. Omisirge helps fasten the recovery of a type of white blood cell called neutrophils.

Gamida has previously said it was targeting to treat about 2,500 patients per year by 2027.

"I think the main market opportunity or the segment that this product could help are patients who have no immediately available donor," Oppenheimer analyst Mark Briedenbach said ahead of the approval.

Briedenbach estimates that at its peak, the therapy could target between 600 and 700 patients per year with revenue of about $130 million from peak U.S. sales.

Gamida declined to comment on the therapy's pricing and availability.

The approval is based on a late-stage study that showed a quicker recovery of neutrophils in patients taking Omisirge, compared with those who received umbilical cord blood transplantation.

The health regulator's decision comes weeks after Gamida said it would scrap plans for its pre-clinical candidates to save costs and gear up for the launch of Omisirge.

Reporting by Pratik Jain in Bengaluru

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