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US FDA grants accelerated approval for Iovance's skin cancer cell therapy

By **Pratik Jain**

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The corporate logo of the U.S. Food and Drug Administration (FDA) is shown in Silver Spring, Maryland, November 4, 2009. REUTERS/Jason Reed/File Photo *Purchase Licensing Rights*

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Feb 16 (Reuters) - Iovance Biotherapeutics (IOVA.O) said on Friday the U.S. health regulator has granted an accelerated approval for its cell therapy for adult patients with advanced melanoma, the first such treatment to be approved for the deadliest form of skin cancer.

The agency's greenlight for the first cell therapy targeting a solid tumor allows use in patients who have been previously treated with other therapies, but their cancer has spread to other parts of the body, and cannot be removed with surgery.

Lifileucel, branded as Amtagvi, is a tumor derived immunotherapy composed of a patient's own disease-fighting white blood cells known as T-cells, with a specific type called tumor-infiltrating lymphocytes (TIL).

Amtagvi will be sold in the U.S. at a list price of $515,000 per patient, interim CEO Frederick Vogt said on a conference call.

The accelerated approval of Amtagvi is based on safety and effectiveness data from a global study of 73 patients. The therapy will require confirmatory trials to receive the U.S. Food and Drug Administration's traditional approval.

"The potential market for TIL therapy is sizable, as 90% of all cancers are solid tumors compared to 10% as blood cancers," Dr. Jason Bock, co-founder and CEO of Cell Therapy Manufacturing Center, said.

The study data showed the objective response rate, a measure of treatment effectiveness, in patients treated with Amtagvi at the recommended dose, was 31.5%.

"With approval in hand, the company has a scarce wholly-owned asset and would make a nice tuck-in for big pharma who could leverage this even better," brokerage Jefferies analyst Michael Yee said in a note.

The therapy's label comes with a boxed warning for treatment-related mortality, prolonged severe cytopenia, severe infection, and cardiopulmonary and renal impairment.

Vogt said the company does not see the boxed warning having any impact on sales and expects to begin reporting significant revenue in the second quarter of this year.

"TIL therapy offers a promising option for patients with solid tumors," Bock said, adding "CAR-T or other cell therapies have so far not shown great success in treating these cancer types."

Iovance is also conducting a late-stage trial to confirm clinical benefits of the therapy.

Reporting by Pratik Jain in Bengaluru; Editing by Shinjini Ganguli, Anil D'Silva and Chris Reese

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