

Iovance's Amtagvi® (lifileucel) receives approval for treatment of Advanced Melanoma in Australia

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First treatment option approved in Australia for advanced melanoma after anti-PD-1 and targeted therapy



Iovance Biotherapeutics, Inc., a US-based biotechnology company focused on innovating, developing, and delivering novel polyclonal tumor infiltrating lymphocyte (TIL) therapies for patients with cancer, has announced that the Therapeutic Goods Administration (TGA) of Australia has granted approval with conditions of Amtagvi® (lifileucel), a tumour-derived autologous T cell immunotherapy, for previously treated advanced (metastatic or unresectable) melanoma.

Amtagvi is indicated for the treatment of adult patients with unresectable or metastatic melanoma previously treated with a PD-1 blocking antibody, and if BRAF V600 mutation positive, a BRAF inhibitor with or without a MEK inhibitor.

Australia has the highest rate of melanoma globally, with an estimated 17,000 new cases diagnosed each year and more than 1,500 deaths annually. Similar to the US and other global markets, there is a significant need for new therapies for patients with advanced melanoma.

"This approval in Australia is our third marketing authorisation for Amtagvi and marks a significant step forward for Iovance in the country with the highest rate of melanoma globally," said Frederick Vogt, Ph.D., J.D., Interim Chief Executive Officer and President of Iovance. "We are in the process of authorising our first Australian treatment centre as we advance our expansion strategy for Amtagvi in additional markets with a high prevalence of advanced melanoma."