Iovance's Amtagvi® (lifileucel) Granted Approval for the Treatment of Advanced Melanoma in Australia

June 3, 2026

First T cell therapy for a solid tumor cancer and first treatment option approved in Australia for advanced melanoma after anti-PD-1 and targeted therapy

SAN CARLOS, Calif., June 03, 2026 (GLOBE NEWSWIRE) -- Iovance Biotherapeutics, Inc. (NASDAQ: IOVA), a commercial biotechnology company focused on innovating, developing, and delivering novel polyclonal tumor infiltrating lymphocyte (TIL) therapies for patients with cancer, today announced that the Therapeutic Goods Administration (TGA) of Australia granted approval with conditions of Amtagvi® (lifileucel), a tumor-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.

"This approval in Australia is our third marketing authorization 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 authorizing our first Australian treatment center as we advance our expansion strategy for Amtagvi in additional markets with a high prevalence of advanced melanoma."

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.[1,2] Similar to the U.S. and other global markets, there is a significant need for new therapies for patients with advanced melanoma.

TGA granted approval based on safety and efficacy results from the global, multicenter C-144-01 trial investigating Amtagvi in patients with advanced melanoma previously treated with anti-PD-1 therapy and targeted therapy, if applicable.

About the C-144-01 Clinical Trial
C-144-01 is a global, multicenter Phase 2 study in which patients received lifileucel monotherapy. The study enrolled patients with metastatic melanoma who were previously treated with at least one systemic therapy, including a PD-1 blocking antibody, and, if BRAF V600 mutation positive, a BRAF inhibitor or a BRAF inhibitor with a MEK inhibitor. Efficacy was established on the basis of objective response rate (ORR) and duration of response (DOR) by Independent Review Committee (IRC) per Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1. The detailed results of C-144-01 were published in the Journal for ImmunoTherapy of Cancer in 2022. A five-year analysis of C-144-01 was published in the Journal of Clinical Oncology in 2025.

Iovance is investigating Amtagvi in frontline advanced melanoma in the Phase 3 trial, TILVANCE-301 (NCT05727904), as well as in additional solid tumor types.

About Iovance Biotherapeutics, Inc.

Iovance Biotherapeutics, Inc. aims to be the global leader in innovating, developing, and delivering tumor infiltrating lymphocyte (TIL) therapies for patients with cancer. We are pioneering a transformational approach to cure cancer by harnessing the human immune system's ability to recognize and destroy diverse cancer cells in each patient. The Iovance TIL platform has demonstrated promising clinical data across multiple solid tumors. Iovance's Amtagvi ® is the first FDA-approved T cell therapy for a solid tumor indication. We are committed to continuous innovation in cell therapy, including gene-edited cell therapy, that may extend and improve life for patients with cancer. For more information, please visit www.iovance.com.

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1. Cancer Australia, Melanoma of the Skin Statistics, https://www.canceraustralia.gov.au/cancer-types/melanoma-skin/melanoma-skin-statistics (Accessed March 2026)
2. Melanoma Institute Australia, Melanoma Facts, https://melanoma.org.au/about-melanoma/melanoma-facts/ (Accessed March 2026)

Forward-Looking Statements

Certain matters discussed in this press release are "forward-looking statements" of Iovance Biotherapeutics, Inc. (hereinafter referred to as the "Company," "we," "us," or "our") within the meaning of the Private Securities Litigation Reform Act of 1995 (the "PSLRA"). Without limiting the foregoing, we may, in some cases, use terms such as "predicts," "believes," "potential," "achievable," "continue," "estimates," "anticipates," "expects," "plans," "intends," "forecast," "guidance," "outlook," "may," "can," "could," "might," "will," "should," or other words that convey uncertainty of future events or outcomes and are intended to identify forward-looking statements. Forward-looking statements are based on assumptions and assessments made in light of management's experience and perception of historical trends, current conditions, expected future developments, and other factors believed to be appropriate. Forward-looking statements in this press release are made as of the date of this press release, and we undertake no duty to update or revise any such statements, whether as a result of new information, future events or otherwise. Forward-looking statements are not guarantees of future performance and are subject to risks, uncertainties, and other factors, many of which are outside of our control, that may cause actual results, levels of activity, performance, achievements, and developments to be materially different from those expressed in or implied by these forward-looking statements. Important factors that could cause actual results, developments, and business decisions to differ materially from forward-

looking statements are described in the sections titled "Risk Factors" in our filings with the U.S. Securities and Exchange Commission, including our most recent Annual Report on Form 10-K and Quarterly Reports on Form 10-Q, and include, but are not limited to, the following substantial known and unknown risks and uncertainties inherent in our business: the risks related to our ability to successfully commercialize our products; the acceptance by the market of our products and product candidates, if approved, and their potential pricing and/or reimbursement by payors, and whether such acceptance is sufficient to support continued commercialization or development of our products or product candidates; the risk regarding our ability to manufacture our therapies at our Iovance Cell Therapy Center facility, including the risk that our ability to increase manufacturing capacity at our facility may adversely affect our commercial launch; the risk that the successful development or commercialization of our products may not generate sufficient revenue from product sales, and we may not become profitable in the near term, or at all; the risks related to the timing of and our ability to successfully develop, submit, obtain, or maintain regulatory authority approval of our product candidates; whether clinical trial results from our pivotal studies and cohorts, and meetings with regulatory authorities may support registrational studies and subsequent approvals by regulatory authorities, including the risk that the planned registrational trial in advanced sarcomas may not support approval; preliminary and interim clinical results, which may include efficacy and safety results, from ongoing clinical trials or cohorts may not be reflected in the final analyses of our ongoing clinical trials or subgroups within these trials or in other prior trials or cohorts; the risk that we may be required to conduct additional clinical trials or modify ongoing or future clinical trials based on feedback from regulatory authorities; the risk that our interpretation of the results of our clinical trials or communications with regulatory authorities may differ from the interpretation of such results or communications by such regulatory authorities; the risk that clinical data from ongoing clinical trials of Amtagvi will not continue or be repeated in ongoing or planned clinical trials or may not support regulatory approval or renewal of authorization; the risk that unanticipated expenses may decrease our estimated cash balances and forecasts and increase our estimated capital requirements; the risk that we may not be able to recognize revenue for our products; the risk that Proleukin revenues, and other factors such as the number of authorized treatment centers, may not serve as a leading indicator for Amtagvi revenues; the risks regarding our anticipated operating and financial performance, including our financial guidance and projections; the effects of global and domestic geopolitical factors or public health events; and other factors, including general economic conditions and regulatory developments, not within our control. Any financial guidance provided in this press release assumes the following: no material change in our ability to manufacture our products; no material change in payor coverage; no material change in revenue recognition policies; no new business development transactions not completed as of the period covered by this press release; and no material fluctuation in exchange rates.

CONTACTS

Investors
IR@iovance.com
650-260-7120 ext. 150

Media
PR@iovance.com
650-260-7120 ext. 150

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