Iovance Announces Positive Results from the First Clinical Trial for TIL Cell Therapy in Soft Tissue Sarcomas

February 24, 2026

50% Objective Response Rate (ORR) in Advanced Sarcomas

Significant Market Opportunity with More than 8,000 Patients Diagnosed Annually in the U.S. and Europe

SAN CARLOS, Calif., Feb. 24, 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 positive early data from a pilot clinical trial led by Memorial Sloan Kettering Cancer Center (MSKCC) and supported by Iovance of lifileucel in patients with advanced (metastatic or unresectable) undifferentiated pleomorphic sarcoma (UPS) or dedifferentiated liposarcoma (DDLPS) who were refractory to at least one prior line of systemic therapy.

Among the first six evaluable patients treated with lifileucel monotherapy, physician-assessed confirmed ORR by RECIST v1.1 was 50%. All evaluable patients had advanced disease, were refractory to prior therapy, and had significant disease burden, with a mean sum of diameters of 117 millimeters at baseline and a mean of more than two prior lines of therapy. Patients experienced deep responses that improved over time, consistent with lifileucel in melanoma, non-small-cell lung cancer, and other solid tumors. The safety profile was favorable and consistent with lifileucel therapy in other indications. Based on these results, Iovance plans to commence a single arm registrational trial in second-line advanced UPS and DDLPS in the second quarter of 2026 and will engage with the U.S. Food and Drug Administration (FDA) on an accelerated path to expedite approval. Iovance also plans to explore lifileucel in other high grade soft tissue sarcoma subtypes with high unmet need as part of its clinical development program.

UPS and DDLPS are high grade, aggressive soft tissue sarcomas associated with poor prognosis that impact more than 3,000 patients in the U.S. and more than 5,000 patients in Europe annually, including more than 3,500 patients with advanced disease.[1-3] There is a high unmet medical need for new treatment options for second-line patients with recent clinical studies reporting ORRs of less than 5%, median progression-free survival (mPFS) of ~2-3 months, and median overall survival (mOS) of ~9-10 months.[4-6]

Lauren Baker Banks, MD, PhD, Sarcoma Medical Oncologist, MSKCC, stated, “In the first clinical trial of a TIL cell therapy in UPS and DDLPS, one-time treatment with lifileucel demonstrated compelling and unprecedented response rates with the potential to address a significant unmet need in patients who are refractory to frontline standard of care. Patients with UPS and DDLPS suffer from high disease burden, poor quality of life, and a lack of effective treatments, including no approved immunotherapy options. In the second-line setting, mPFS for many patients is only a few months with mOS less than a year. We look forward to presenting these results at a medical conference in 2026.”

Dr. Brian Gastman, EVP Translational Medicine and Research at Iovance, stated, “The exciting clinical results show that lifileucel could offer a new, highly efficacious, and durable immunotherapy option in two aggressive forms of advanced sarcoma and further illustrate the promise of our TIL cell therapy platform to offer meaningful clinical benefit in multiple solid tumor cancers. Chemotherapy with extremely poor efficacy remains the second-line standard of care for these patients after progression on front-line chemotherapy. We look forward to bringing lifileucel to UPS and DDPLS patients as quickly as possible.”

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 http://www.iovance.com/.

References
1. CancerMPact Patient Metrics for US Soft Tissue Sarcoma (accessed 02/13/2026) with custom analysis to size the UPS & DDLPS populations.
2. Incidence of UPS & DDLPS extrapolation from US to all of Europe based on Global burden of soft tissue sarcomas in 204 countries and territories from 1990 to 2021: data from the global burden of disease study 2021.
3. CancerMPact Treatment Architecture for Sarcoma for the US & EU5 (May 2025) to inform treatment rates in the US and EU5.
4. Parikh RC, et al. Treatment patterns and survival among older adults in the United States with advanced soft-tissue sarcomas. Cancer. 2018.
5. Italiano A, et al. Advanced well-differentiated/dedifferentiated liposarcomas: role of chemotherapy and survival. Ann Oncol. 2012.
6. Jones RL et al. Efficacy and safety findings from MANTRA: A global, randomized, multicenter, phase III study of the MDM2 inhibitor milademetan vs trabectedin in patients with dedifferentiated liposarcomas, Ann Oncol. 2023.

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,” “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 *i*CTC 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 ATCs, 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.

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Source: Iovance Biotherapeutics, Inc.