Iovance Biotherapeutics Reports Potential Best-in-Class Clinical Data for Lifileucel TIL Cell Therapy in Advanced Non-Small Cell Lung Cancer (NSCLC)

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26% Objective Response Rate

Median Duration of Response Not Reached after 25 Months Follow Up

Lifileucel Launch in Previously Treated Advanced NSCLC Expected in Second Half of 2027

SAN CARLOS, Calif., Nov. 03, 2025 (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 interim data from its registrational Phase 2 IOV-LUN-202 trial of lifileucel monotherapy in patients with previously treated advanced nonsquamous NSCLC without actionable genetic mutations.

The objective response rate (ORR) was 25.6% by RECIST v1.1 following one-time treatment with lifileucel monotherapy in patients with advanced nonsquamous NSCLC. An objective response was observed in 10 out of 39 patients, including 2 complete responses, 7 partial responses (PRs), and 1 unconfirmed PR (pending confirmatory assessment), with a disease control rate of 71.8%.[1] The median duration of response (mDOR) was not reached after a median follow up of 25.4 months.

Iovance will present additional data from the IOV-LUN-202 trial at an upcoming medical meeting in 2026. The U.S. Food and Drug Administration (FDA) previously provided positive regulatory feedback on the IOV-LUN-202 trial design and the proposed potency assay matrix to support registration. This trial design aligns with FDA guidance for single-arm trials to support accelerated approvals in conditions with unmet medical need. The IOV-LUN-202 trial is expected to progress in 2026 towards a supplemental Biologics License Application for lifileucel in nonsquamous NSCLC and a potential launch in the second half of 2027.

“It is exciting to see such an impressive response rate and durability observed in previously treated patients with NSCLC, because today there are only very limited treatment options, none of which demonstrate this quality of response and durability,” said Martin Wermke, M.D., Professor for Experimental Cancer Therapy and Director at the National Center for Tumor Diseases Dresden. “One-time treatment with lifileucel monotherapy has the potential to benefit many patients with advanced NSCLC following initial treatment with an immune checkpoint inhibitor.”

Following initial treatment with immune checkpoint inhibitor and chemotherapy, patients with advanced NSCLC have limited treatment options and often receive chemotherapy, which has limited durability. Standard-of-care docetaxel monotherapy in patients with nonsquamous NSCLC previously treated with immune checkpoint inhibitors and chemotherapy has recently shown an ORR of 12.8% with an mDOR of 5.6 months and overall survival of 12.3 months, without any complete responses.[2]

The safety profile for the lifileucel treatment regimen was consistent with the underlying disease, non-myeloablative lymphodepletion (NMA-LD), and interleukin-2 (IL-2). Improvements in the overall safety profile have been observed, without affecting efficacy, following the introduction of an updated regimen of reduced NMA-LD for IOV-LUN-202. Patients treated with the updated regimen showed a reduction of median post-IL-2 hospitalization days by more than half and lower incidence and shorter time to resolution of cytopenias compared with the initial regimen.

“Lifileucel has demonstrated a potentially best-in-class clinical profile in previously treated advanced nonsquamous NSCLC. The duration of response is unprecedented and is combined with an impressive response rate in a one-time monotherapy for a difficult-to-treat patient population,” stated Friedrich Graf Finckenstein, M.D., Chief Medical Officer of Iovance. “We will pursue regulatory approvals for lifileucel monotherapy to effectively address the tens of thousands of patients with previously treated nonsquamous advanced NSCLC.”

Additional details on the interim data for IOV-LUN-202 are available here: https://ir.iovance.com/news-events/events-presentations.

About Non-Small Cell Lung Cancer

Lung cancer is the most commonly diagnosed cancer and the leading cause of cancer death worldwide, with an estimated 2.5 million new cases and 1.8 million deaths globally each year, and an estimated 226,000 new cases and 125,000 deaths in the U.S. each year.[3,4] Approximately 85% of lung cancer cases are NSCLC, with non-squamous NSCLC representing an estimated 75% of NSCLC cases.[4]

About IOV-LUN-202

IOV-LUN-202 is a registrational, global phase 2 study investigating lifileucel monotherapy in patients with advanced (metastatic or unresectable) NSCLC without EGFR, ROS1 or ALK actionable genetic mutations and previously treated with an immune checkpoint inhibitor and chemotherapy. Enrollment is expected to be completed during the second half of 2026.

About TIL Cell Therapy

Tumor infiltrating lymphocytes (TIL) are naturally occurring immune cells that are on constant surveillance to recognize, attack and kill cancer cells. TIL cells recognize cancer through tumor markers on the surface of cancer cells that are unique to each person. The majority of solid tumor immune targets are patient-specific, with fewer than 1% shared among patients. When cancer invades and prevails, the TIL cells are unable to perform their

intended function. Cancer can then evade the immune system, exhausting the TIL cells and rendering them ineffective.

TIL cell therapy is intended to reinvigorate and expand a patient's TIL cells so they can be deployed to fight cancer. A patient's naturally occurring TIL cells are collected from a portion of their own tumor and grown outside the body using Iovance's proprietary manufacturing process. Individualized TIL therapy is a one-time treatment to deliver these cells back to the patient. Once inside the body, TIL cell therapy deploys billions of personalized, patient-specific TIL cells to recognize, target, and destroy diverse cancer cells.

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.

References

1. Interim data cut as of October 10, 2025 of nonsquamous NSCLC patients with minimum cell dose based on FDA feedback.
2. Ahn MJ et al. J Clin Onc 2024;43:260-272.
3. World Health Organization International Agency for Research on Cancer (IARC). GLOBOCAN 2022.
4. National Cancer Institute Surveillance, Epidemiology and End Results (SEER) Program. 2025 Estimates, Lung and Bronchus.

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, including Amtagvi, for which we have obtained U.S. Food and Drug Administration ("FDA") approval, and Proleukin, for which we have obtained FDA and European Medicines Agency ("EMA") approval; the risk that the EMA or other ex- U.S. regulatory authorities may not approve or may delay approval for our marketing authorization application submission for lifileucel in metastatic melanoma; the acceptance by the market of our products, including Amtagvi and Proleukin, and their potential pricing and/or reimbursement by payors, if approved (in the case of our product candidates), in the U.S. and other international markets and whether such acceptance is sufficient to support continued commercialization or development of our products, including Amtagvi and Proleukin, or product candidates, respectively; future competitive or other market factors may adversely affect the commercial potential for Amtagvi or Proleukin; the risk regarding our ability or inability to manufacture our therapies using third party manufacturers or at our own facility, including our ability to increase manufacturing capacity at such third party manufacturers and our own facility, may adversely affect our commercial launch; the results of clinical trials with collaborators using different manufacturing processes may not be reflected in our sponsored trials; the risk that the successful development or commercialization of our products, including Amtagvi and Proleukin, 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 FDA, EMA, or other regulatory authority approval of, or other action with respect to, our product candidates; whether clinical trial results from our pivotal studies and cohorts, and meetings with the FDA, EMA, or other regulatory authorities may support registrational studies and subsequent approvals by the FDA, EMA, or other regulatory authorities, including the risk that the single arm Phase 2 IOV-LUN-202 trial may not support registration; preliminary and interim clinical results, which may include efficacy and safety results from ongoing clinical trials or cohorts, including interim results for the IOV-LUN-202 trial, 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 enrollment may need to be adjusted for our trials and cohorts within those trials based on FDA and other regulatory agency input; the risk that the changing landscape of care for cervical cancer patients may impact our clinical trials in this indication; the risk that we may be required to conduct additional clinical trials or modify ongoing or future clinical trials based on feedback from the FDA, EMA, or other regulatory authorities; the risk that our interpretation of the results of our clinical trials or communications with the FDA, EMA, or other regulatory authorities may differ from the interpretation of such results or communications by such regulatory authorities (including from our prior meetings with the FDA regarding our non-small cell lung cancer clinical trials) and our expected approval and commercial launch timelines may be delayed; 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 our restructuring plan and workforce reduction will not result in the intended benefits or savings; the risk that we may not be able to recognize revenue for our products; the risk that Proleukin revenues may not continue to 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 pandemic; the effects of global and domestic geopolitical factors; 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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