



Iovance Presents New Data at ESMO 2026 Demonstrating Deep, Durable Responses with Lifileucel TIL Cell Therapy Plus Pembrolizumab in Frontline Advanced Melanoma

October 23, 2026

62.5% Confirmed Objective Response Rate (ORR) and 29.2% Complete Response (CR) Rate in Final Phase 2 Analysis

Median Overall Survival (OS) Not Reached at More than 4 Years of Median Follow-up

Oral Presentation at the European Society for Medical Oncology (ESMO) Congress 2026 Reinforces Ongoing TILVANCE-301 Phase 3 Trial

PHILADELPHIA and MADRID, Oct. 23, 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 one-time lifileucel combined with pembrolizumab demonstrated a 62.5% ORR and a 29.2% CR rate, with median OS not reached at 50.9 months of median study follow-up in the final Phase 2 analysis in frontline advanced melanoma. The Phase 2 results were presented on October 23, 2026 in a Proffered Paper oral session at the ESMO Congress 2026 in Madrid, Spain.

In frontline advanced melanoma, approximately half of patients treated with combination immune checkpoint inhibitor (ICI) therapy do not achieve long-term benefit, a widely recognized unmet need.¹ Following successful adoption of lifileucel in the post-anti-PD-1 therapy setting, this Phase 2 data supports the earlier use and potential approval of lifileucel plus pembrolizumab in frontline advanced melanoma. Iovance estimates that 70,000 patients with frontline advanced melanoma are addressable each year in global markets with high prevalence.²

ESMO Presentation Highlights: Cohort 1A of the IOV-COM-202 Trial (NCT03645928)

IOV-COM-202 is a multicohort, multicenter Phase 2 trial of lifileucel plus pembrolizumab in patients with solid tumors. The final analysis in frontline advanced melanoma (Cohort 1A) included 24 patients treated with one-time lifileucel that met pre-determined manufacturing specifications and pembrolizumab monotherapy for up to 24 months.

The physician-assessed confirmed ORR by RECIST v1.1 was 62.5% (15/24; 95% CI: 40.6, 81.2), including a 29.2% CR rate. The disease control rate was 83.3% (20/24; 95% CI: 62.6, 95.3). Median duration of response (DOR) was not reached (range: 4.3 to 57.7+ months) at a median follow-up of 26.9 months for DOR.

Median progression-free survival (PFS) was 19.8 months (95% CI: 3.6 months to not reached). Median PFS after second line of therapy was 34.3 months (95% CI: 6.8 months to not reached), indicating that subsequent systemic therapy remains feasible after frontline lifileucel and pembrolizumab, including additional ICI therapy. Median OS was not reached (95% CI: 19.2 months to not reached) at a median study follow-up of 50.9 months.

Safety was consistent with the underlying disease and known safety profiles of one-time lifileucel and pembrolizumab. Late adverse events were consistent with continuous use of pembrolizumab monotherapy, further differentiating lifileucel plus pembrolizumab from ICI combinations used in the frontline setting.

"About half of patients do not experience lasting benefit with frontline combination immunotherapy for advanced melanoma," stated Dr. Andrew J.S. Furness, Consultant Medical Oncologist and Solid Tumour Cellular Therapy Lead at The Royal Marsden National Health Service Foundation Trust, Leader of the Cellular Therapy and Translational Immunology Group at The Institute of Cancer Research, London, and Principal Investigator in IOV-COM-202 and TILVANCE-301 trials. "A single administration of lifileucel plus pembrolizumab demonstrated compelling response rates and durability that compare favorably to other ICI combination approaches in frontline advanced melanoma, with median overall survival not reached at more than four years of follow-up. These remarkable Phase 2 results provide a strong scientific rationale to investigate earlier treatment with lifileucel in the TILVANCE-301 trial."

Translational analyses support the positive clinical results in Cohort 1A. T-cell receptor (TCR) sequencing detected clones from the infused lifileucel product in the peripheral blood for as long as 12 months after infusion (n=13), consistent with the strong DOR benefit of lifileucel.

Noah Berkowitz, M.D., Ph.D., Chief Medical Officer of Iovance, stated, "The final Cohort 1A results demonstrate unprecedented efficacy and a potentially best-in-class clinical profile for lifileucel combined with pembrolizumab in frontline advanced melanoma. These data, together with supportive translational findings, reinforce the importance of our ongoing TILVANCE-301 Phase 3 randomized trial to support a new approval for lifileucel in frontline advanced melanoma."

The [presentation](#) is available at www.iovance.com. Iovance will also present the first clinical data for lifileucel in soft tissue sarcomas in a Rapid Oral presentation on Monday, October 26, 2026 ([Abstract #3725RQ](#)).

About TILVANCE

[TILVANCE-301](#) (NCT05727904) is a Phase 3, multicenter, open-label, randomized, parallel group, treatment study to assess the efficacy and safety of lifileucel in combination with pembrolizumab compared with pembrolizumab alone in participants with untreated, unresectable or metastatic melanoma. The trial is enrolling at more than 80 sites in the U.S., Canada, Europe, and Asia-Pacific. The dual primary endpoints are ORR and PFS assessed by independent review committee. TILVANCE-301 is designed to support approval for lifileucel in combination with pembrolizumab in frontline advanced melanoma and to serve as the confirmatory trial for full U.S. approval of Amtagvi® in previously treated advanced melanoma.

About Iovance Biotherapeutics, Inc.

Iovance Biotherapeutics, Inc. is the global leader in innovating, developing, and delivering tumor infiltrating lymphocyte (TIL) cell therapies for patients with solid tumors. Amtagvi® (lifileucel) is the first FDA-approved, one-time treatment for previously treated advanced melanoma, now approved in three global markets and available at nearly 100 authorized treatment centers (ATCs). The Iovance TIL platform spans registrational trials and next-generation programs in additional solid tumors, including gene-edited and IL-12 tethered TIL therapies, next-generation IL-2, and precision immuno-oncology approaches. As the first and only company to take TIL therapy from concept to a broadly accessible commercial treatment, Iovance operates as an end-to-end cell therapy company, anchored by fully owned, centralized U.S.-based manufacturing that is scaled to serve thousands of cancer patients worldwide each year. Headquartered in Pennsylvania with offices and laboratories in California and Florida, Iovance serves patients at ATCs and clinical sites across almost the entire U.S. and in many countries around the world. For more information, please visit www.iovance.com.

Amtagvi® and its accompanying design marks, Proleukin®, Iovance®, and IovanceCares™ are trademarks and registered trademarks of Iovance Biotherapeutics, Inc. or its subsidiaries. All other trademarks and registered trademarks are the property of their respective owners.

Information on Iovance's broad, industry-leading patent portfolio is available on the Intellectual Property page on www.iovance.com.

About the ESMO Congress

The ESMO Congress is organized by the European Society for Medical Oncology (ESMO) and is one of the world's most influential annual oncology meetings, bringing together more than 37,000 clinicians, researchers, patient advocates, and industry representatives from around the world. The ESMO Congress 2026 takes place October 23–27, 2026, at IFEMA Madrid, Spain, and features presentations of practice-changing clinical data, translational science, and educational programming across all major tumor types. For more information, visit www.esmo.org.

References

1. Larkin J, et al. *N Engl J Med*. 2019;381:1535-46.
2. SEER and GLOBOCAN epidemiology data and internal data on file.

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 size of the addressable patient populations for, and 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 iCTC facility, including the risk that our ability to increase manufacturing capacity at our facility may adversely affect our commercial supply or clinical supply; the risks related to our ability to obtain, maintain and enforce patent and other intellectual property protection for our products and product candidates; 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 clinical studies and cohorts, and meetings with regulatory authorities, may support registrational studies and subsequent approvals by regulatory authorities, including the risk that our registrational trials, including TILVANCE-301, may be delayed, may not meet their primary endpoints, or may not support approval; clinical results, whether preliminary, interim, or final, which may include efficacy and safety results, from 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 or future trials or cohorts, including the risk that the Cohort 1A results of IOV-COM-202 may not be predictive of results in the ongoing TILVANCE-301 trial; 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 or others; 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.

CONTACTS

Investors

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

Media

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

