# Iovance Biotherapeutics Announces Clearance of Investigational New Drug (IND) Application for IL-12 Tethered TIL Therapy IOV-5001

June 1, 2026

*Next-Generation Platform Expands into Solid Tumors*
*Representing 100,000+ U.S. Deaths Annually*

SAN CARLOS, Calif., June 01, 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 allowance to proceed from the U.S. Food and Drug Administration (FDA) for the investigational new drug (IND) application for a Phase 1/2 basket trial of IOV-5001, a next-generation interleukin-12 (IL-12) tethered TIL therapy.

The Phase 1/2 trial will begin enrolling in the second half of 2026 to investigate the safety and efficacy of a one-time IOV-5001 treatment regimen without the use of IL-2. Cohorts include advanced colorectal, triple-negative, and estrogen receptor-low breast cancers, as well as other highly prevalent solid tumors representing more than 100,000 U.S. deaths annually.[1]

IOV-5001 is engineered to express IL-12 only within the tumor to enhance efficacy, particularly in cancers caused by immunologically cold tumors, and to tether IL-12 to the cell surface to prevent release into the bloodstream to optimize safety. IOV-5001 is designed to safely deliver significantly higher cell doses and improve upon an earlier secreted IL-12 TIL therapy that showed a 63% confirmed objective response rate.[2]

“Proceeding into the clinical trial of IOV-5001 is a defining moment as we extend our TIL platform across additional prevalent solid tumors,” said Frederick Vogt, Ph.D., J.D., Interim Chief Executive Officer and President of Iovance. “By tethering IL-12 to the TIL cell surface and targeting its activity inside the tumor, IOV-5001 is designed to activate cold tumors and open an entirely new frontier of massive opportunities for TIL cell therapy. We look forward to beginning patient enrollment in the second half of 2026.”

1. Surveillance, Epidemiology, and End Results Program Cancer Stat Facts (accessed May 2026).

2. Zhang L, Rosenberg SA, et al, Clin Cancer Res 2015;21(10):2278–2288.

**About IOV-5001**
IOV-5001 is an investigational second-generation TIL therapy engineered to express IL-12 only inside the tumor, where it is anchored to the TIL cell surface rather than released into the bloodstream. This design is intended to deliver the antitumor benefit seen with earlier IL-12 TIL therapies while avoiding systemic toxicity. In preclinical studies, IOV-5001 showed stronger antitumor activity and a healthier, more durable T cell profile than unmodified TIL therapies.

**About Iovance Biotherapeutics, Inc.**
Iovance Biotherapeutics, Inc. aims to be the global leader in innovating, developing, and delivering 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.



**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 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.

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