



## **IOVANCE Biotherapeutics Initiates Clinical Supply of Tumor-Infiltrating Lymphocyte (TIL) Cell Therapy Manufactured at IOVANCE Cell Therapy Center (iCTC)**

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*First Patient Infused with TIL Cell Therapy Manufactured at iCTC*

SAN CARLOS, Calif., Sept. 23, 2021 (GLOBE NEWSWIRE) -- IOVANCE Biotherapeutics, Inc. (NASDAQ: IOVA), a late-stage biotechnology company developing novel T cell-based cancer immunotherapies (tumor-infiltrating lymphocyte, TIL, and peripheral-blood lymphocyte, PBL), today reported that the IOVANCE Cell Therapy Center ([iCTC](#)) successfully manufactured and delivered the first clinical batch of TIL cell therapy LN-145. The first IOVANCE clinical study participant infused with LN-145 manufactured at *iCTC* is enrolled in a metastatic non-small cell lung cancer (mNSCLC) cohort in the IOV-COM-202 basket study in solid tumors.

Igor Bilinsky, Ph.D., Chief Operating Officer of IOVANCE, stated, "We are thrilled to announce that one of our clinical study participants has received the first infusion of our internally manufactured IOVANCE TIL cell therapy. I applaud the efforts of our IOVANCE team at *iCTC* in achieving the important construction and manufacturing milestones that led to this moment. Moving forward, we are diversifying between internal and external TIL manufacturing for clinical studies, and *iCTC* remains on track to provide commercial supply upon potential product approval. Establishing our internal manufacturing capabilities is a top priority at IOVANCE to ensure broad access to and reduce the costs of IOVANCE TIL cell therapy."

The *iCTC*, located at the Philadelphia Navy Yard, is the first centralized, scalable, state-of-the-art manufacturing facility dedicated to producing potentially life-saving TIL cell therapies for patients with solid tumor cancers. With approximately 136,000 square feet of space, the *iCTC* is among the largest cell therapy manufacturing facilities today. The *iCTC* is currently supplying IOVANCE clinical studies, and commercial manufacturing is expected to begin after initial product approval. The current capacity is expected to meet the demand for thousands of patients per year with multiple types of cancers.

Sumit Verma, Senior Vice President of Commercial Manufacturing at IOVANCE, added, "Since breaking ground two years ago, we completed construction of the *iCTC* and built our organization to lead the next chapter in manufacturing and delivering novel cell therapies for patients with cancer. Philadelphia and the Cellicon Valley ecosystem have been instrumental in our progress. At *iCTC* we have recruited an extraordinary and diverse internal team, and we continue to recruit new highly skilled employees to further support our growth and success."

### **About IOVANCE Biotherapeutics, Inc.**

IOVANCE Biotherapeutics aims to improve patient care by making T cell-based immunotherapies broadly accessible for the treatment of patients with solid tumors and blood cancers. Tumor infiltrating lymphocyte (TIL) therapy uses a patient's own immune cells to attack cancer. TIL cells are extracted from a patient's own tumor tissue, expanded through a proprietary process, and infused back into the patient. Upon infusion, TIL reach tumor tissue, where they attack cancer cells. The company has completed dosing in pivotal programs in patients with metastatic melanoma and cervical cancer. In addition, the company's TIL therapy is being investigated in a registration-supporting study for the treatment of patients with locally advanced, recurrent or metastatic non-small cell lung cancer. Clinical studies are also underway to evaluate TIL in earlier stage cancers in combination with currently approved treatments, and to investigate IOVANCE peripheral blood lymphocyte (PBL) T cell therapy for blood cancers. For more information, please visit [www.iovance.com](http://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"). All such written or oral statements made in this press release, other than statements of historical fact, are forward-looking statements and are intended to be covered by the safe harbor for forward-looking statements provided by 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," "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 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 effects of the COVID-19 pandemic; risks related to the timing of and our ability to successfully develop, submit, obtain and maintain U.S. Food and Drug Administration ("FDA") or other regulatory authority approval of, or other action with respect to, our product candidates, and our ability to successfully commercialize any product candidates for which we obtain FDA 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 enrollment may need to be adjusted for our trials and cohorts within those trials based on FDA and other regulatory agency input; the new version of the protocol which further defines the patient population to include more advanced patients in our cervical cancer trial may have an adverse effect on the results reported to date; 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 or other regulatory authorities; the risk that our interpretation of the results of our clinical trials or communications with the FDA may differ from the interpretation of such results or communications by the FDA; the acceptance by the market of our product candidates and their potential reimbursement by payors, if approved; our ability or inability to manufacture our therapies using third party manufacturers or our own facility may adversely affect our potential commercial launch; the results of clinical trials with collaborators using different manufacturing processes may not be reflected in our sponsored trials; the risk that unanticipated expenses may decrease our estimated cash balances and forecasts and increase our estimated capital requirements; and other factors, including general economic conditions and regulatory developments, not within our control.

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