



## **Iovance Biotherapeutics Provides Regulatory Update for Lifileucel Potency Assays**

May 18, 2021

SAN CARLOS, Calif., May 18, 2021 (GLOBE NEWSWIRE) -- Iovance Biotherapeutics, Inc. (NASDAQ: IOVA), a late-stage biotechnology company developing novel T cell-based cancer immunotherapies, today announced receipt of regulatory feedback from the U.S. Food and Drug Administration (FDA) regarding its potency assays for lifileucel. Previously, the company reported the submission of assay data to the FDA and recently the FDA provided comments regarding the data package.

Following FDA feedback, Iovance will continue its ongoing work developing and validating its potency assays and plans to submit additional assay data and to meet with the FDA in the second half of 2021. The company's biologics license application (BLA) submission for lifileucel is now expected to occur during the first half of 2022.

"TIL is a first-in-class, one-time administration cell therapy and the first potential BLA for a cell therapy in solid tumors," stated Maria Fardis, Ph.D., MBA, Iovance President and Chief Executive Officer. "As such, TIL product is complex by nature and alignment with FDA on a potency assay is an important step toward BLA submission. With a regenerative medicines advanced therapy (RMAT) designation for lifileucel, FDA recognizes the unmet need for patients with metastatic melanoma who progress after anti-PD1 therapy."

### **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 (NSCLC). 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 may not be reflected in the final analyses of our ongoing clinical trials or subgroups within these trials; 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 increase our estimated capital requirements; and other factors, including general economic conditions and regulatory developments, not within our control.

### **CONTACTS**

**Iovance Biotherapeutics, Inc.:**  
Sara Pellegrino, IRC

Vice President, Investor Relations & Public Relations  
650-260-7120 ext. 264  
[Sara.Pellegrino@iovance.com](mailto:Sara.Pellegrino@iovance.com)

**Solebury Trout:**

Zara Lockshin  
646.378.2960  
[zlockshin@soleburytrout.com](mailto:zlockshin@soleburytrout.com)



Source: iovance Biotherapeutics, Inc.