Iovance Biotherapeutics Completes Biologics License Application (BLA) Submission for Lifileucel in Advanced Melanoma

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First TIL Therapy BLA Submission to U.S. Food and Drug Administration

SAN CARLOS, Calif., March 24, 2023 (GLOBE NEWSWIRE) -- Iovance Biotherapeutics, Inc. (NASDAQ: IOVA), a late-stage biotechnology company developing novel T cell-based cancer immunotherapies, today announced it has completed its rolling Biologics License Application (BLA) submission to the U.S. Food and Drug Administration (FDA) for lifileucel. Lifileucel is a tumor infiltrating lymphocyte (TIL) therapy intended as a treatment for patients with advanced (unresectable or metastatic) melanoma who progressed on or after prior anti-PD-1/L1 therapy and targeted therapy, where applicable. There are no FDA approved therapies in this treatment setting.

Frederick Vogt, Ph.D., J.D., Interim President and Chief Executive Officer of Iovance, stated, “Completing our BLA submission for lifileucel is a critical step forward in our journey to deliver the first individualized, one-time cell therapy for a solid tumor. I would like to acknowledge the patients and physicians who participated in the C-144-01 clinical trial and the FDA review team for their commitment and support, as well as our internal team for their tremendous effort in completing the first BLA submission for Iovance. Our preparations for commercialization remain on track to support a launch later this year. We look forward to continued collaboration with the FDA as they review this new class of treatment for advanced melanoma patients with limited options.”

The BLA submission for lifileucel is supported by positive clinical data from the C-144-01 clinical trial in patients with advanced post-anti-PD1 melanoma. Following a successful pre-BLA meeting with the FDA, Iovance is pursuing accelerated approval in this indication. Iovance also reached agreement with the FDA regarding the registrational trial design for the Phase 3 TILVANCE-301 trial of lifileucel in combination with pembrolizumab in frontline advanced melanoma. TILVANCE-301 is intended to support full approval of lifileucel in post-anti-PD-1 advanced melanoma and is also designed to support registration for lifileucel in combination with pembrolizumab as therapy for advanced melanoma in the frontline setting. Startup activities for TILVANCE-301 are ongoing and the trial is expected to be well underway at the time of potential accelerated approval for lifileucel in advanced post-anti-PD-1 melanoma.

Marc Hurlbert, Ph.D., CEO of the Melanoma Research Alliance (MRA), said, “MRA congratulates Iovance for completing the BLA submission and moving closer toward making TIL therapy an option for people with advanced melanoma who have progressed following prior treatments. We hope for an FDA approval as quickly as possible for patients with significant unmet need who have no approved treatment options.”

Following receipt of the complete rolling BLA submission for lifileucel, the FDA has 60 days to determine the acceptability of the BLA for review. The rolling BLA allowed Iovance to submit portions of the BLA to the FDA on an ongoing basis, enabling the FDA to begin review as early as possible as documents were received. The rolling BLA submission and eligibility for priority review are benefits available under the FDA’s guidance on expedited programs for serious conditions, which allow for an expedited six-month review from the time of BLA acceptance. In addition, the FDA previously granted a regenerative medicine advanced therapy (RMAT) designation for lifileucel in advanced melanoma.

About Iovance Biotherapeutics, Inc.

Iovance Biotherapeutics 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. Our lead late-stage TIL product candidate, lifileucel for metastatic melanoma, has the potential to become the first approved one-time cell therapy for a solid tumor cancer. The Iovance TIL platform has demonstrated promising clinical data across multiple solid tumors. 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”). 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; whether clinical trial results from our pivotal studies and cohorts, and meetings with the FDA, may support registrational studies and subsequent approvals by the FDA; 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 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 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 (including from the prior pre-BLA meeting with the FDA); the risk that the FDA may not accept the BLA submission for lifileucel in metastatic melanoma, and even if the BLA submission is accepted for review, the FDA ultimately may not approve the BLA; 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 the acquisition of Proleukin® may not be completed in a timely manner or at all; the failure to satisfy the closing conditions to the consummation of the Proleukin® acquisition, including the receipt of all required regulatory approvals; 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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