Iovance Biotherapeutics Provides Update on Biologics License Application Submission for Lifileucel in Advanced Melanoma

November 18, 2022

BLA Submission Ongoing with U.S. Food and Drug Administration

SAN CARLOS, Calif., Nov. 18, 2022 (GLOBE NEWSWIRE) -- Iovance Biotherapeutics, Inc. (NASDAQ: IOVA) today announced that its ongoing rolling Biologics License Application (BLA) submission to the U.S. Food and Drug Administration (FDA) for lifileucel is expected to be completed in the first quarter of 2023.

As part of an amendment to the ongoing investigational new drug application (IND) submitted during the third quarter of 2022, Iovance received recent FDA feedback regarding supplemental assay validation information and comparability data for lifileucel. Iovance will address these FDA comments promptly and will now complete its rolling BLA submission during the first quarter of 2023.

Lifileucel is an investigational tumor infiltrating lymphocyte (TIL) therapy for patients with advanced (unresectable or metastatic) melanoma who progressed on or after prior anti-PD-1/L1 therapy, and targeted BRAF/MEK inhibitor therapy where appropriate. There are no FDA approved therapies in this treatment setting.

Frederick Vogt, Ph.D., J.D., Iovance's Interim President and Chief Executive Officer stated, "We continue to make substantial progress with our ongoing BLA submission and remain close to the finish line. The FDA has provided recent valuable feedback to the IND application and remains supportive during the rolling BLA submission process. Iovance is fully committed to securing FDA approval as soon as possible to deliver the first individualized, one-time cell therapy for advanced melanoma patients, who have a significant unmet medical need."

As previously announced, Iovance held a successful pre-BLA meeting in July 2022, and the rolling BLA commenced in August 2022. A rolling BLA allows Iovance to submit portions of the BLA to the FDA on an ongoing basis, which enables the FDA to begin review as early as possible as documents are received. The rolling BLA submission and eligibility for priority review are benefits available under the FDA's guidance on expedited programs for serious conditions. The FDA previously granted a regenerative medicine advanced therapy (RMAT) designation for lifileucel in advanced melanoma.

The BLA submission for lifileucel is supported by positive clinical data from the C-144-01 clinical trial in patients with advanced melanoma. The Phase 3 trial of lifileucel in combination with pembrolizumab in frontline advanced melanoma, on track to begin in late 2022, is intended to serve as a confirmatory study and is expected to be well underway at the time of a potential approval.

Investor Webcast on Friday, November 18, 8:00 a.m. ET

Iovance will host a webcast on Friday, November 18 at 8:00 a.m. ET to discuss this corporate update. To participate in the webcast, please register at https://register.vevent.com/register/BI99a18daf00f04087b70d9c6b45008d6f. The live webcast and replay can be accessed in the Investors section of the company's website at IR.Iovance.com.

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 may support registration and approval 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 recent pre-BLA meeting with the FDA); the risk that the rolling BLA submission for lifileucel in metastatic melanoma may take longer than expected; 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.

CONTACTS

Sara Pellegrino, IRC
Senior Vice President, Investor Relations & Corporate Communications
650-260-7120 ext. 264
Sara.Pellegrino@iovance.com

Jen Saunders
Director, Investor Relations & Public Relations
267-485-3119
Jen.Saunders@iovance.com

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