Iovance Biotherapeutics Announces U.S. Food and Drug Administration Acceptance of the Biologics License Application of Lifileucel for the Treatment of Advanced Melanoma

May 26, 2023

Priority Review Granted with
Prescription Drug User Fee Act (PDUFA) Action Date of November 25, 2023

First Potential Approval of an Individualized, One-Time Cell Therapy
for Patients with Advanced Melanoma

SAN CARLOS, Calif., May 26, 2023 (GLOBE NEWSWIRE) -- Iovance Biotherapeutics, Inc. (NASDAQ: IOVA), a biotechnology company focused on innovating, developing, and delivering novel polyclonal tumor infiltrating lymphocyte (TIL) therapies for patients with cancer, today announced that the U.S. Food and Drug Administration (FDA) accepted its Biologics License Application (BLA) for lifileucel for patients with advanced melanoma. The FDA granted lifileucel Priority Review and assigned November 25, 2023 as the target action date for a decision under the Prescription Drug User Fee Act (PDUFA). The FDA is not currently planning to hold an advisory committee meeting to discuss this application and, after a preliminary review, has not at this time identified any potential review issues.

Lifileucel is a TIL therapy intended for patients with advanced 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. Under the FDA's guidance, Priority Review allows for an six-month review from the time of BLA acceptance for treatments that, if approved, are substantially safer or more effective than standard of care therapies. The FDA also previously granted a Regenerative Medicine Advanced Therapy (RMAT) designation for lifileucel in advanced melanoma.

Frederick Vogt, Ph.D., J.D., Interim President and Chief Executive Officer of Iovance, stated, "The BLA acceptance is a significant milestone in our mission to deliver lifileucel as the first individualized, one-time cell therapy for a solid tumor. The FDA's commitment to a six-month Priority Review validates the unmet need and urgency for new treatment options for patients with advanced melanoma who have progressed on or after standard of care therapies. I am grateful for the patients and physicians who took part in all our clinical trials, as well as the Iovance team for their outstanding work on our first BLA filing. We look forward to continuing our collaboration with the FDA during the BLA review cycle, while continuing to execute our pre-commercialization activities and advancing our robust TIL pipeline."

The BLA submission for lifileucel is supported by positive data from the C-144-01 clinical trial in patients with advanced melanoma who progressed on or after prior anti-PD-1/L1 therapy and targeted therapy, where applicable. If lifileucel receives accelerated approval, the randomized Phase 3 TILVANCE-301 trial in frontline advanced melanoma can serve as the confirmatory study to support full approval. TILVANCE-301 is expected to be well underway at the time of approval.

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 approve our BLA submission for lifileucel in metastatic melanoma; 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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