Iovance Biotherapeutics Announces Regulatory and Clinical Updates for TIL Therapy in Advanced Non-Small Cell Lung Cancer

July 10, 2023

Positive FDA Feedback Supports IOV-LUN-202 Trial Design for Accelerated Approval of TIL Therapy in Post-Anti-PD-1 Advanced Non-Small Cell Lung Cancer (NSCLC)

Preliminary Clinical Data in Post-Anti-PD-1 NSCLC Demonstrated a 26.1% Objective Response Rate (ORR) in Registrational IOV-LUN-202 Trial

SAN CARLOS, Calif., July 10, 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 positive regulatory and clinical updates related to its registrational single-arm Phase 2 IOV-LUN-202 trial in post-anti-PD-1 NSCLC.

NSCLC Regulatory and Clinical Update:
At a Type B Pre-Phase 3 meeting held between Iovance and the U.S. Food and Drug Administration (FDA), the FDA provided positive regulatory feedback that the design of the IOV-LUN-202 trial may be acceptable for accelerated approval of LN-145 TIL therapy for patients who have progressed on or after chemotherapy and anti-PD-1 therapy for advanced (unresectable or metastatic) NSCLC without EGFR, ROS or ALK genomic mutations and had received at least one line of an FDA-approved targeted therapy if indicated by other actionable tumor mutations. Based on this FDA feedback, Iovance completed a preliminary analysis of the IOV-LUN-202 trial. This recent data cut[1] included 23 NSCLC patients treated with LN-145. An ORR of 26.1% by RECIST v1.1 (n=6, one complete response and five partial responses) was observed, with a disease control rate of 82.6%. While still early on study, the median duration of response (DOR) was not reached. The DOR ranged from 1.4+ months to 9.7+ months. Treatment-emergent adverse events were consistent with the underlying disease and known adverse event profiles of non-myeloablative lymphodepletion and interleukin-2. Based on the regulatory discussions, Iovance plans to enroll a total of approximately 120 patients into the registrational IOV-LUN-202 trial. Enrollment is expected to be complete during the second half of 2024. As previously announced, Iovance is also preparing to meet with the FDA this year to discuss a randomized confirmatory trial of LN-145 in frontline advanced NSCLC patients. This confirmatory trial in frontline advanced NSCLC is expected to be well underway at the time of a potential approval in advanced post-anti-PD-1 NSCLC.

Lifileucel BLA Submission on Track in Advanced Melanoma:
The FDA's Priority Review of Iovance's Biologics License Application (BLA) for lifileucel in advanced melanoma remains on track and continues to progress well. The Prescription Drug User Fee Act target action date for the BLA is November 25, 2023.

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[1]Data cut date of July 6, 2023.

About Iovance Biotherapeutics, Inc.
Iovance Biotherapeutics aims to be the global leader in innovating, developing and delivering tumor infiltrating lymphocyte (TIL) cell 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: preliminary and interim clinical results, which may include efficacy and safety results, from ongoing clinical trials or cohorts, including but not limited to our IOV-LUN-202 trial, 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; 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, including the risk that the planned single-arm Phase 2 IOV-LUN-202 trial may not support registration; 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 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 and/or regarding our prior meetings with the FDA regarding our NSCLC clinical trials); 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 regarding the successful integration of the recent Proleukin acquisition; 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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