Iovance Biotherapeutics Announces Clinical Program Update for LN-145 in Non-Small Cell Lung Cancer

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SAN CARLOS, Calif., Dec. 27, 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 a clinical program update for LN-145 TIL therapy in non-small lung cancer (NSCLC).

The U.S. Food and Drug Administration (FDA) placed a clinical hold on the IOV-LUN-202 trial on December 22, 2023, in response to a recently reported Grade 5 (fatal) serious adverse event potentially related to the non-myeloablative lymphodepletion pre-conditioning regimen. IOV-LUN-202 is investigating LN-145 in patients who have progressed on or after chemotherapy and anti-PD-1 therapy for advanced (unresectable or metastatic) non-small cell lung cancer (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. These patients have a poor prognosis, limited treatment options, and a real-world overall survival of less than six months.[1] The clinical hold for IOV-LUN-202 has no impact on any other Iovance clinical trials and is independent of the FDA's Priority Review of the biologics license application (BLA) for lifileucel in advanced melanoma. The BLA remains on track toward the Prescription Drug User Fee Act (PDUFA) action date of February 24, 2024.

Iovance will pause enrollment and the LN-145 TIL treatment regimen for new patients in IOV-LUN-202 during the clinical hold. Patients previously treated with LN-145 in the IOV-LUN-202 trial will continue to be monitored and followed according to the trial protocol. Patients who have already undergone tumor resection will continue to receive the LN-145 TIL treatment regimen with additional precautions and risk mitigations.

Preliminary data for IOV-LUN-202 was reported in July of 2023. An updated analysis in November of 2023 showed additional ongoing responses and duration of response greater than six months for 71% of the confirmed responders in the trial. These results from IOV-LUN-202 in previously treated patients with advanced NSCLC continue to support the potential benefit of one-time TIL therapy, including the opportunity for more durable responses than available second line chemotherapies. Iovance is committed to bringing TIL therapy to patients with NSCLC and to continuing activities that support regulatory approval in this indication.

Friedrich Graf Finckenstein, M.D., Chief Medical Officer of Iovance, stated, “Iovance remains dedicated to addressing a significant unmet medical need for patients with advanced NSCLC, who have poor prognosis following disease progression and limited treatment options. We will work with the FDA to safely resume enrollment in the IOV-LUN-202 trial as soon as possible.”

More than 700 patients have been treated with Iovance TIL therapies across multicenter clinical trials in solid tumor cancers, including more than 100 patients treated with LN-145 for lung cancer. In clinical trial results reported to date, treatment-emergent adverse events were consistent with the underlying disease and known adverse event profiles of non-myeloablative lymphodepletion and interleukin-2.

[1]National Cancer Database, NSCLC survival from >1 million patients assessed. Lou Y et al. Survival trends among non-small-cell lung cancer patients over a decade: impact of initial therapy at academic centers. Cancer Med. 2018.

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, or maintain U.S. Food and Drug Administration ("FDA"), European Medicines Agency ("EMA"), 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, EMA, or other regulatory authority approval; whether clinical trial results from our pivotal studies and cohorts, and meetings with the FDA, EMA, or other regulatory authorities may support registrational studies and subsequent approvals by the FDA, EMA, or other regulatory authorities, including the risk that the planned single arm Phase 2 IOV-LUN-202 trial may not support registration; 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 risk that 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, EMA, or other regulatory authorities; the risk that our interpretation of the results of our clinical trials or communications with the FDA, EMA, or other regulatory authorities may differ from the interpretation of such results or communications by such regulatory authorities (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, EMA, or other regulatory authorities may not approve or may delay approval for 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, in the U.S. and other international markets; 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 the successful development or commercialization of our products may not generate sufficient revenue from product sales, and we may not become profitable in the near term, or at all; 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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