Journal of Clinical Oncology Publishes Clinical Data for Cohort 2 in Iovance C-144-01 Study of Lifileucel TIL Therapy in Metastatic Melanoma

May 12, 2021

Median Duration of Response Not Reached at 18.7 Months of Median Study Follow Up

C-144-01 Study Contributes to Advancement in TIL Therapy Using Centrally Standardized Manufacturing, Allowing for Broadened Patient Access

SAN CARLOS, Calif., May 12, 2021 (GLOBE NEWSWIRE) -- Iovance Biotherapeutics, Inc. (NASDAQ: IOVA), a late-stage biotechnology company developing novel T cell-based cancer immunotherapies (tumor-infiltrating lymphocyte, TIL, and peripheral-blood lymphocyte, PBL), today announced that the *Journal of Clinical Oncology* has published a manuscript of clinical data for Cohort 2 in the C-144-01 study of lifileucel TIL therapy in metastatic melanoma. Online open access to the publication is available at https://ascopubs.org/doi/full/10.1200/JCO.21.00612.

Amod Sarnaik, Associate Professor of Cutaneous Oncology and Immunology at H. Lee Moffitt Cancer Center stated, “Effective treatment options are limited for patients with advanced melanoma who progress after immune checkpoint inhibitors and targeted therapies. Lifileucel represents a significant improvement in the treatment of advanced melanoma, particularly in the expanding post-immune checkpoint inhibitor patient population. The results from the C-144-01 clinical study, as well as the advancement of lifileucel using a centralized TIL manufacturing process, offer a new opportunity for accessible treatment for the most challenging to treat patients with metastatic melanoma.”

“With this publication we have summarized several years of our clinical development and TIL manufacturing as we strive to make TIL a broadly accessible cell therapy for patients with advanced melanoma,” said Maria Fardis, PhD, MBA, President and Chief Executive Officer of Iovance. “At the time of the data extract for publication, the overall response rate (ORR) was 36%, median duration of response (DOR) had not been reached at 18.7 months of median study follow up and median overall survival (OS) was 17.4 months. As a reference, patients treated with chemotherapy are expected to have an OS of approximately 7 months. I believe these results demonstrate the durability of one-time treatment with lifileucel. Importantly, durable responses were seen across all patient subgroups regardless of prior treatment or mutation status, including patients who were primary refractory to anti−PD-1 therapy. I would like to thank the investigators who contributed to this manuscript as well as the patients who participated in Cohort 2 of the C-144-01 clinical study.”

Publication Summary
In Cohort 2 of the C-144-01 clinical study, 66 patients received a mean of 3.3 prior therapies. As of the data extract for the publication (April 23, 2020), the ORR was 36% (2 complete responses and 22 partial responses), meeting the study primary endpoint in a patient population that had failed frontline anti−PD-1 therapy, the current standard of care. The median DOR was not reached after a median of 18.7 months of study follow-up (range 0.2 to 34.1 months) and 69% of patients had DOR of at least one-year. The median OS was 17.4 months, and one-year survival was 38% in patients with stable disease and 92% in patients with a partial or complete response.

Lifileucel also demonstrated similar ORR across Cohort 2 subgroups, including patients who were primary refractory to anti−PD-1 or anti−PD-L1 therapy (41%); patients who received anti−PD-1 or anti−PD-L1 combination as a frontline therapy (33%) or after failing frontline therapy (32%); and patients with primary resistance or acquired resistance to anti−PD-1 plus anti−CTLA-4 combination therapy (35% and 27%, respectively).

Responses to lifileucel were agnostic of PD-L1 status, BRAF mutation status, or prior anti−CTLA-4 therapy. Safety profile was consistent with known adverse events associated with advanced disease, non-myeloablative lymphodepletion, and IL-2.

About Iovance Biotherapeutics, Inc.
Iovance Biotherapeutics aims to improve patient care by making T cell-based immunotherapies broadly accessible for the treatment of patients with solid tumors and blood cancers. Tumor infiltrating lymphocyte (TIL) therapy uses a patient’s own immune cells to attack cancer. TIL cells are extracted from a patient’s own tumor tissue, expanded through a proprietary process, and infused back into the patient. Upon infusion, TIL reach tumor tissue, where they attack cancer cells. The company has completed dosing in pivotal programs in patients with metastatic melanoma and cervical cancer. In addition, the company’s TIL therapy is being investigated in a registration-supporting study for the treatment of patients with locally advanced, recurrent or metastatic non-small cell lung cancer (NSCLC). Clinical studies are also underway to evaluate TIL in earlier stage cancers in combination with currently approved treatments, and to investigate Iovance peripheral blood lymphocyte (PBL) T cell therapy for blood cancers. 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; preliminary and interim clinical results, which may include efficacy and safety results, from ongoing clinical trials may not be reflected in the final analyses of our ongoing clinical trials or subgroups within these trials; 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 new version of the protocol which further defines the patient population to include more advanced patients in our cervical cancer trial may have an adverse effect on the results reported to date; 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; 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 increase our estimated capital requirements; and other factors, including general economic conditions and regulatory developments, not within our control.

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