Iovance Biotherapeutics Announces 33-Month Follow Up Data for Lifileucel in Advanced Melanoma at ASCO 2021 Annual Meeting

June 6, 2021

Median Duration of Response (DOR) Not Reached at 33.1 Months of Median Study Follow Up in Cohort 2 in C-144-01 Study

Early Intervention with Lifileucel Following Progression on Anti-PD-1 Therapy May Maximize Benefit

ASCO Update Conference Call and Webcast at 12 p.m. ET Today

SAN CARLOS, Calif., June 06, 2021 (GLOBE NEWSWIRE) -- Iovance Biotherapeutics, Inc. (NASDAQ: IOVA), a late-stage biotechnology company developing novel T cell-based cancer immunotherapies, today announced updated clinical data for lifileucel from Cohort 2 in the C-144-01 clinical study in patients with advanced melanoma. The data were presented in an oral presentation at the ASCO 2021 Annual Meeting.

Omid Hamid, M.D., Chief of Research/Immuno-Oncology, The Angeles Clinic & Research Institute, stated, “Anti-PD-1 therapy is a mainstay class of treatment offering several therapeutic options for metastatic melanoma. For patients who progress on anti-PD-1 therapy, there is an unfulfilled need for efficacious and durable treatment options. The latest results with lifileucel suggest that early intervention with lifileucel TIL therapy, immediately upon progression on anti-PD-1 therapy, may offer better outcomes and longer duration of response. These data offer evidence that patients have had positive treatment experiences with lifileucel, and I believe TIL therapy has the potential to become an important option within the melanoma treatment landscape.”

Friedrich Graf Finckenstein, M.D., Chief Medical Officer of Iovance, stated, “Our latest data for Cohort 2 in the C-144-01 clinical study are very exciting and continue to support the durability of responses after lifileucel in challenging to treat patients with melanoma. Median DOR has still not been reached at 33 months of median study follow up. We are also reporting the important observation that a shorter duration of prior anti-PD-1 therapy is associated with longer duration of response after lifileucel. We are committed to bringing lifileucel to patients as soon as we can.”

The long-term follow-up data for Cohort 2 in the C-144-01 clinical study continue to demonstrate durability and depth of lifileucel TIL therapy response. Median DOR was not reached at 33.1 months of median study follow up (range: 2.2 to 38.5+ months) and Overall Response Rate, or ORR, remained at 36.4% (data extraction: April 2021). Responses deepened over time and one patient converted from partial to complete response at 24 months post lifileucel infusion.

A multivariable model showed that for every six-month decrease in cumulative duration of prior anti-PD-1 therapy, DOR to lifileucel will be nearly doubled. These results suggest that early intervention with lifileucel at the time of initial progression on anti-PD-1 therapy may maximize benefit.

All patients in Cohort 2 had high baseline disease burden and were heavily pretreated (3.3 mean prior therapies), including anti-PD1 and BRAF/MEK inhibitors if BRAFV600 mutation positive. The adverse event profile was consistent with the underlying advanced disease, lymphodepletion and IL-2 regimens, with no new safety risks identified for lifileucel during long-term follow-up.

Iovance Presentation at ASCO 2021

Title: Lifileucel (LN-144), a cryopreserved autologous tumor infiltrating lymphocyte (TIL) therapy in patients with advanced melanoma: Evaluation of impact of prior anti-PD-1 therapy.
Authors: James M. G. Larkin, *et al.*
Session Title: Melanoma/Skin Cancers
Session Type: Oral Abstract Session
Abstract Number: 9505
Location: ASCO Meeting Library at https://meetinglibrary.asco.org/ and https://www.iovance.com/our-science/publications/
Session Date and Time: Sunday, June 6, 2021 from 8:00 – 11:00 a.m. ET

Webcast and Conference Call
Iovance will host a webcast and conference call on Sunday, June 6, at 12:00 p.m. ET to discuss ASCO clinical data updates for lifileucel alone and in combination with pembrolizumab in patients with advanced melanoma. Iovance senior leadership, together with Dr. Hamid, will present a summary of the ASCO data from Cohort 1A in the IOV-COM-202 study as well as the oral presentation of updated Cohort 2 data from the C-144-01 clinical study.

The conference call dial-in numbers are 1-844-646-4465 (domestic) or 1-615-247-0257 (international) and the access code is 4858337. The live webcast can be accessed in the Investors section of the company’s website at http://www.iovance.com. The archived webcast will be available for a year in the Investors section at www.iovance.com.

About Iovance Biotherapeutics, Inc.
Iovance 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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Source: Iovance Biotherapeutics, Inc.