



IOVANCE Biotherapeutics Announces Clinical Data Updates for Lifileucel in Advanced Melanoma

May 13, 2020

*Median Duration of Response Not Reached at 17.0 Months
of Median Study Follow Up in C-144-01 Study*

*Oral Presentation to Include Additional Cohort 2 Data from
C-144-01 Clinical Study at ASCO 2020 Virtual Scientific Program*

SAN CARLOS, Calif., May 13, 2020 (GLOBE NEWSWIRE) -- Iovance Biotherapeutics, Inc. (NASDAQ: IOVA), a late-stage biotechnology company developing novel T cell-based cancer immunotherapies, today announced new interim data from Cohort 2 in the C-144-01 study of lifileucel in advanced melanoma. These data will be part of an oral presentation at the American Society of Clinical Oncology's (ASCO) upcoming [ASCO20 Virtual Scientific Program](#), to be held May 29-31, 2020.

"We are very excited to share our latest melanoma data at the upcoming ASCO oral presentation," said Maria Fardis, Ph.D., president and chief executive officer of Iovance Biotherapeutics. "The interim data as reported in the abstract continue to support the durability of Iovance's lifileucel TIL therapy, administered as a one-time treatment for patients with advanced melanoma. As of February 2020, the median duration of response had not been reached at 17 months of median study follow up. We look forward to providing additional updates during the oral presentation at the ASCO20 Virtual Scientific Program."

Updated interim results from Cohort 2 are available in the abstract titled, "Long-term follow up of lifileucel (LN-144) cryopreserved autologous tumor infiltrating lymphocyte therapy in patients with advanced melanoma progressed on multiple prior therapies." As of the February 2, 2020 data cut off used for the abstract submitted to ASCO20, lifileucel shows a 36.4% overall response rate (n=66) and median duration of response (DOR) was not reached at 17.0 months of median study follow up. The patients had heavily pretreated metastatic melanoma with high baseline disease burden. They have progressed on multiple prior therapies (3.3 mean prior therapies), including anti-PD1 and BRAF/MEK inhibitors. The adverse event profile was consistent with the underlying advanced disease, lymphodepletion and IL-2 regimens. The abstract is available in the ASCO Meeting Library at <https://meetinglibrary.asco.org>.

Further updates will be available during the oral presentation at the ASC20 Virtual Scientific Program. Details of the presentation are as follows:

Title: Long-term follow up of lifileucel (LN-144) cryopreserved autologous tumor infiltrating lymphocyte therapy in patients with advanced melanoma progressed on multiple prior therapies

Authors: Amod Sarnaik, *et al.*

Session Title: Melanoma/Skin Cancers

Session Type: Oral Abstract Session

Abstract Number: 10006

Location: ASCO20 Virtual Scientific Program at <https://meetings.asco.org/am/virtual-program>

Date/Time: available for on-demand viewing starting at 8:00am ET on May 29, 2020

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. After infusion, TIL reach tumor tissue, where they attack tumor cells. The company has completed dosing in the pivotal study in patients with metastatic melanoma and is currently conducting a pivotal study in patients with advanced cervical cancer. In addition, the company's TIL therapy is being investigated for the treatment of patients with locally advanced, recurrent or metastatic cancers including head and neck and non-small cell lung cancer. A clinical study to investigate Iovance T cell therapy for blood cancers called peripheral blood lymphocyte (PBL) therapy is open to enrollment. 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. We may, in some cases, use terms such as "predicts," "believes," "potential," "continue," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. The forward-looking statements include, but are not limited to, risks and uncertainties relating to the success, timing, projected enrollment, manufacturing and production capabilities, and cost of our ongoing clinical trials and anticipated clinical trials for our current product candidates (including both Company-sponsored and collaborator-sponsored trials in both the U.S. and Europe), such as statements regarding the timing of initiation and completion of these trials; the timing of and our ability to successfully submit, obtain and maintain FDA or other regulatory authority approval of, or other action with respect to, our product candidates, including those product candidates that have been granted breakthrough therapy designation ("BTD") or regenerative medicine advanced therapy designation ("RMAT") by the FDA and new product candidates in both solid tumor and blood cancers; the strength of the Company's product pipeline; the successful implementation of the Company's research and development programs and collaborations; the Company's ability to obtain tax incentives and credits; the guidance provided for the Company's future cash, cash equivalents, short term investment and restricted cash balances;

the success of the Company's manufacturing, license or development agreements; the acceptance by the market of the Company's product candidates, if approved; and other factors, including general economic conditions and regulatory developments, not within the Company's control. The factors discussed herein could cause actual results and developments to be materially different from those expressed in or implied by such statements. Actual results may differ from those set forth in this press release due to the risks and uncertainties inherent in the Company's business, including, without limitation: the COVID-19 pandemic may have an adverse effect on the Company and its clinical trials, including potential slower patient recruitment, inability of clinical trial sites to collect data, inability of the Company or its contract research organizations to monitor patients, as well as FDA availability due to competing priorities; the preliminary clinical results, which may include efficacy and safety results, from ongoing Phase 2 studies may not be reflected in the final analyses of these trials or subgroups within these trials; a slower rate of enrollment may impact the Company's clinical trial timelines; enrollment may need to be adjusted for the Company's 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 the Company's cervical cancer trial may have an adverse effect on the results reported to date; the data within these trials may not be supportive of product approval; changes in patient populations may result in changes in preliminary clinical results; the Company's ability or inability to address FDA or other regulatory authority requirements relating to its clinical programs and registrational plans, such requirements including, but not limited to, clinical, safety, manufacturing and control requirements; the Company's interpretation of communications with the FDA may differ from the interpretation of such communications by the FDA; risks related to the Company's ability to maintain and benefit from accelerated FDA review designations, including BTM and RMAT, which may not result in a faster development process or review of the Company's product candidates (and which may later be rescinded by the FDA), and does not assure approval of such product candidates by the FDA or the ability of the Company to obtain FDA approval in time to benefit from commercial opportunities; the ability or inability of the Company to manufacture its therapies using third party manufacturers or its own facility may adversely affect the Company's potential commercial launch; the results of clinical trials with collaborators using different manufacturing processes may not be reflected in the Company's sponsored trials; and additional expenses may decrease our estimated cash balances and increase our estimated capital requirements. A further list and description of the Company's risks, uncertainties and other factors can be found in the Company's most recent Annual Report on Form 10-K and the Company's subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov or www.iovance.com. The forward-looking statements are made only as of the date of this press release and the Company undertakes no obligation to publicly update such forward-looking statements to reflect subsequent events or circumstances.

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