Iovance Reports Pivotal Cohort 4 Data for Tumor Infiltrating Lymphocyte (TIL) Therapy Lifileucel from C-144-01 Clinical Study in Advanced Melanoma

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Cohort 4 Early Data Shows 32.4% ORR by Investigator Assessment at 5.3 Months of Median Study Follow up

Cohort 2 Median Duration of Response Not Reached at 18.7 Months of Median Study Follow Up and 36.4% ORR

SAN CARLOS, Calif., May 27, 2020 (GLOBE NEWSWIRE) -- Iovance Biotherapeutics, Inc. (NASDAQ: IOVA), a late-stage biotechnology company developing novel T cell-based cancer immunotherapies, today announced initial data from pivotal Cohort 4 and updated long-term data from Cohort 2 in the C-144-01 study of lifileucel in advanced melanoma.

"We are very pleased to announce our pivotal Cohort 4 early data from the C-144-01 clinical study in advanced melanoma today," said Maria Fardis, Ph.D., President and Chief Executive Officer of Iovance Biotherapeutics. "The data from the first 68 patients in Cohort 4, with a 32.4% overall response rate (ORR) at 5.3 months of median study follow up, is highly consistent with what we have observed in Cohort 2 with comparable study follow up. For Cohort 2, median duration of response has not been reached at 18.7 months of study follow up. Available care for metastatic melanoma patients enrolled into our program is chemotherapy, which has been reported to offer a 4-10% response rate with a very short median duration of response. Together, these early data continue to support the potential benefit of the one-time administration of lifileucel TIL therapy in advanced melanoma patients."

Interim Pivotal Cohort 4 Results
Initial results from the pivotal Cohort 4 in the C-144-01 clinical study is available for 68 patients with two radiological assessments, as determined by investigator. Primary endpoint for the C-144-01 Cohort 4 study is ORR by independent review committee and secondary endpoint is ORR by investigator. Lifileucel shows a 32.4% overall response rate (1 complete response and 21 partial responses, 2 of which are yet to be confirmed with follow up visits) and a disease control rate of 72.1% as of the data cut off of 16 Mar 2020. This data is consistent with what was noted in Cohort 2 at 6 months of median study follow up. The ORR was 33% as reported in SITC 2018 abstract.

The Cohort 4 metastatic melanoma patients have a similar patient characteristic profile to Cohort 2 with high baseline disease burden. They have progressed on multiple prior therapies, including anti-PD-1 and BRAF/MEK inhibitors. The adverse event profile was consistent with Cohort 2 and with the underlying advanced disease, lymphodepletion and IL-2 regimens. Cohort 4 dosed a total of 89 patients, and additional updates on Cohort 4 will be presented at upcoming medical meetings. Iovance remains on track to submit a biologics licensing application (BLA) for lifileucel in late 2020.

Updated Cohort 2 Results
Updated results from Cohort 2 will be presented at the ASCO20 Virtual Scientific Program during an oral abstract session 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." In this Cohort 2 data, lifileucel shows a 36.4% overall response rate (2 complete responses and 22 partial responses) and a disease control rate of 80% (n=66) as assessed by investigators. Median duration of response (DOR) was not reached at 18.7 months of median study follow up (2.2 to 26.9+ months). Durable responses have been observed across a wide age range in metastatic melanoma patients who have received prior anti-CTLA-4 and BRAF targeted treatments, regardless of BRAF mutation status, and equally in patients with PD-L1 high and low status.

The Cohort 2 melanoma patients are heavily pretreated with high baseline disease burden. They have progressed on multiple prior therapies (3.3 mean prior therapies), including anti-PD-1 and BRAF/MEK inhibitors. The adverse event profile was consistent with the underlying advanced disease, lymphodepletion and IL-2 regimens.

The oral abstract session at ASCO20 will be available on demand in the ASCO Meeting Library at https://meetinglibrary.asco.org/. 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

Furthermore, Iovance will provide results from Cohort 4 as well as Cohort 2 of the C-144-01 study in metastatic melanoma as part of the BLA package. Based on the pooled analysis of Cohort 2 plus 4 (n=134), the overall response rate was 34.3%, including three complete responses, 43 partial responses (two of which are yet to be confirmed with follow up visits) and a disease control rate of 76.1%. Median DOR was not reached at 10.6 months of median study follow up.

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 (the "PSLRA"). All such written or oral statements made in this press release, filings with the Securities and Exchange Commission ("SEC"), reports to stockholders and in meetings with investors and analysts, 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. These forward-looking statements include, but are not limited to, statements regarding 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 strength of the Company's product pipeline; and the guidance provided for the Company's future cash, cash equivalents, short term investment and restricted cash balances. These statements involve risks, uncertainties and other factors 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, including, without limitation, the following substantial known and unknown risks and uncertainties inherent in the Company's business: 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 U.S. Food and Drug Administration ("FDA") availability due to competing priorities; our ability to achieve long-term profitability and successfully commercialize our products alone or with third parties, as well as our history of operating losses and our expectations that we will continue to incur significant operating losses; our limited operating history in our current line of business, which makes it difficult to evaluate our prospects, our business plan or the likelihood of our successfully implementing such business plan; risks related to the timing of and our ability to successfully develop, submit, obtain and maintain FDA or other regulatory authority approval of, or other action with respect to, our product candidates (including with respect to lifileucel for the treatment of metastatic melanoma, for which we expect to submit a biologics licensing application ("BLA") to the FDA during 2020), and our ability to successfully commercialize any product candidates for which we obtain FDA approval; our limited history in conducting clinical trials, on which our future profitability is substantially dependent, and our need to rely on third parties, including contract research organizations, contract manufacturing organizations and consultants, in connection with the conduct, supervision and monitoring of our clinical trials for our product candidates; preliminary and interim clinical results, which may include efficacy and safety results, from ongoing Phase 2 studies may not be reflected in the final analyses of our ongoing clinical trials or subgroups within these trials; the interim results for Cohort 4 of our C-144-01 study in metastatic melanoma ("Cohort 4") speak only to data available as of March 16, 2020, and although such data have been reviewed by an independent investigator, they have not been reviewed by an institutional review board ("IRB") and are therefore unconfirmed (for example, the reported overall response rate for Cohort 4 is based on unconfirmed partial response rate data), and the IRB may ultimately disagree with the final data for Cohort 4, when available and submitted to it for review; the risk that a slower rate of enrollment may delay the Company's clinical trial timelines or otherwise adversely impact our clinical development activities; the risk that 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 risk that the results obtained in our ongoing clinical trials may not be indicative of results obtained in future clinical trials or that data within these trials may not be supportive of product approval, including that later developments with the FDA may be inconsistent with already completed FDA meetings; the risk that the FDA may not agree with our plan to combine the final results for Cohort 4 with the final results for Cohort 2 of our C-144-01 study in metastatic melanoma ("Cohort 2"), and that such combined data will be sufficient to support a BLA filing for lifileucel for the treatment of metastatic melanoma; the risk that the final data for Cohort 4 will not be consistent with the final data for Cohort 2; the risk that the FDA may not permit us to rely on duration of response data from Cohort 2 in place of new data from Cohort 4, in the event that patient follow-up is negatively impacted by the global COVID-19 pandemic and we are unable to generate such new data as a result; the risk that the FDA may not agree with our approach to expand our cervical cancer trial to include Cohort 2 of the C-145-04 trial; the risk that 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 risk that regulatory authorities may potentially delay the timing of FDA or other regulatory approval of, or other action with respect to, our product candidates, or 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 the Company's interpretation of the results of its clinical trials or communications with the FDA may differ from the interpretation of such results or communications by the FDA; our ability to obtain and maintain intellectual property rights related to our product pipeline; our ability to successfully implement our research and development programs and collaborations; the acceptance by the market of our product candidates and their potential reimbursement by payors, if approved; our ability to obtain tax incentives and credits and the risk that our existing net operating loss carryforwards and research tax credits may expire or otherwise be limited in use; the success of our manufacturing, license or development agreements; risks related to the Company's ability to maintain and benefit from accelerated FDA review designations, including breakthrough therapy designation or regenerative medicine advanced therapy designation, 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 which 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; our dependence on additional financing to fund our operations and complete the development and commercialization of our product candidates, and the risks that raising such additional capital may restrict our operations or require us to relinquish rights to our technologies or product candidates; the risk that additional 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 the Company's control.

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 reports that we file or furnish with the SEC from time to time. Copies of these reports are available online at www.sec.gov or www.iovance.com. The forward-looking statements in this press release should be considered in light of these risks and uncertainties.

All forward-looking statements made in this press release are based solely on information available to us as of the date of this press release and the Company undertakes no obligation to publicly update or revise such forward-looking statements, whether as a result of subsequent events, changed circumstances, new information or otherwise.

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