Iovance Biotherapeutics Provides Update for Lifileucel in Metastatic Melanoma

October 5, 2020

SAN CARLOS, Calif., Oct. 05, 2020 (GLOBE NEWSWIRE) -- Iovance Biotherapeutics, Inc. (NASDAQ: IOVA), a late-stage biotechnology company developing novel T cell-based cancer immunotherapies, today provided a regulatory update for its tumor-infiltrating lymphocyte (TIL) therapy lifileucel in metastatic melanoma. In preparation for the planned Biologics License Application (BLA) submission for lifileucel, the Company has been engaged in discussions with the U.S. Food and Drug Administration (FDA), including a recent Type B meeting, regarding the requirements and timing of certain information that would be provided as part of its BLA submission.

The Company believes that clinical data from its C-144-01 trial supports the potential for lifileucel as a treatment for metastatic melanoma. Iovance and the FDA have reached agreement on the duration of follow up for its pivotal Cohort 4 to support the BLA submission. As part of the Type B meeting, the Company and the FDA have not been able to agree on the required potency assays to fully define its TIL therapy, which is required as part of a BLA submission. The Company is continuing to refine the information from its current potency assays and simultaneously developing additional assays. As a result of these developments, the BLA submission is not expected by the end of 2020. The Company will continue to work closely with the FDA and now anticipates a BLA submission to occur in 2021. Additional guidance on the BLA submission timing will be provided when available.

"TIL is a first-in-class, one-time administration cell therapy targeting solid tumors. As such, definition of the product through a potency assay is an important step toward submission of the BLA," stated Maria Fardis, Ph.D., MBA, Iovance President and Chief Executive Officer. "We have agreement with the FDA regarding the amount of clinical follow up for the BLA, and we will work closely with the FDA to reach alignment on our assays. Because Iovance recognizes the significant unmet need in the melanoma patient population and believes the compelling clinical data for lifileucel will offer a new therapy for such patients, we are moving ahead with a great sense of urgency. We look forward to further collaboration with the FDA and will provide updates as they become available."

As previously announced, updated Cohort 2 data from the C-144-01 clinical trial presented at the 2020 American Society of Clinical Oncology Annual Meeting showed an overall response rate (ORR) of 36.4 percent with a median duration of response not reached at 18.7 months of median study follow up (n=66). Early Cohort 4 data previously reported by the Company showed an ORR of 32.4 percent at 5.3 months of median study follow up (n=68). Currently available treatment options for the patient population in the C-144-01 study is limited to chemotherapy, with a response rate of four to 10 percent and a very short duration of response.

Webcast and Conference Call
The Company will host a conference call today at 4:30 p.m. ET. The conference call dial-in numbers are 1-844-646-4465 (domestic) or 1-615-247-0257 (international). The conference ID access number for the call is 5866866. 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 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 metastatic 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, restricted cash balances, and forecasted operating expenses. 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, reaching agreement with the FDA on the appropriate potency assay and the timing to submit a biologics licensing application ("BLA") to the FDA), 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 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 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 that may have a material adverse effect on the Company's business and clinical development, including general economic conditions, the Covid-19 pandemic and regulatory developments, not within the Company's control.

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Source: Iovance Biotherapeutics, Inc.