Iovance Biotherapeutics Announces Results of a Subgroup Analysis of Patients in the Lifileucel Metastatic Melanoma Study who are Primary Refractory to Anti-PD-1/L1 Therapy

November 21, 2019

- 41 percent objective response rate (ORR) as assessed by the investigator in 42 patients who were primary refractory to anti-PD-1/L1 therapy -

- Median duration of response (DOR) was not reached as assessed by investigator at 12 months of study follow-up for the primary refractory subgroup -

SAN CARLOS, Calif., Nov. 21, 2019 (GLOBE NEWSWIRE) -- Iovance Biotherapeutics, Inc. (NASDAQ: IOVA), a late-stage biotechnology company developing novel T cell-based cancer immunotherapies, today announced results of a subgroup analysis of Cohort 2 of the Phase 2 lifileucel metastatic melanoma study C-144-01 in patients who were primary refractory to prior anti-PD-1/L1 therapy. An abstract with details of the analysis was accepted as a late-breaking poster at the 16th International Congress of the Society for Melanoma Research (SMR) being held Nov. 20-22 in Salt Lake City.

Highlights from the poster, presented by study investigator Omid Hamid, M.D., Chief of Translational Research and Immunotherapy and Director of Melanoma Therapeutics at the Angeles Clinic and Research Institute of Los Angeles, on Thursday, Nov. 21, 2019, include:

- In 42 primary refractory patients enrolled in Cohort 2 of C-144-01 study, defined as having had the best response of progressive disease (PD) on their first anti-PD-1/L1 treatment, an objective response rate (ORR) of 41 percent, as assessed by the investigator, was observed
- Median duration of response (DOR) was not reached at 12 months of study follow-up (range: 2.8+ to 21.2+ months)
- 71 percent of responders who are primary refractory to anti PD-1/L1 therapy remain on study

“Patients who are primary refractory to prior anti-PD-1/L1 therapy have very limited therapeutic options and yet form a large population of diagnosed metastatic melanoma patients,” commented Maria Fardis, Ph.D., MBA, president and chief executive officer of Iovance. “Tumor infiltrating lymphocyte (TIL) therapy developed by Iovance has shown strong efficacy for patients with relapsed or refractory metastatic melanoma. In the subgroup analysis conducted for primary refractory patients in our Cohort 2 of the C-144-01 study, TIL demonstrates excellent efficacy and durability of response thus far. We are very pleased to see that the Iovance TIL may offer a therapeutic option for this patient population.”

Cohort 2 in the ongoing C-144-01 study includes consecutively dosed post-PD-1 patients with Stage IIIC/IV unresectable melanoma who also have received BRAF/MEK therapy if clinically indicated. In this study, patients had experienced a mean of 3.3 lines of prior therapy including anti-PD1 blocking antibody, and the patients had a high baseline tumor burden. Primary refractory patients included 42 of the 66 dosed patients in Cohort 2 who had a best response of progressive disease to the first anti-PD-1/L1.

About the Society for Melanoma Research (SMR) 2019 Congress

SMR 2019 is a global congress that unites melanoma clinicians and researchers to focus on multidisciplinary management of melanoma/skin cancer. This is the leading meeting for cutting edge data in melanoma.

About Iovance Biotherapeutics, Inc.

Iovance Biotherapeutics intends 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 is currently conducting pivotal studies in patients with metastatic melanoma and advanced cervical cancer. In addition, the company’s TIL therapies are being investigated for the treatment of patients with locally advanced, recurrent or metastatic cancers including head and neck and non-small cell lung cancer. Clinical studies of T cell therapy for blood cancers called peripheral blood lymphocyte (PBL) therapy are being planned. 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”). 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 equivalent, and short term investment positions; 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 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 BTD 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; 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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