



IOVANCE Biotherapeutics Announces Updated Phase 2 Clinical Data from the Lifileucel Metastatic Melanoma Trial at the Society for Immunotherapy of Cancer 34th Annual Meeting

November 8, 2019

- Cohort 2 objective response rate (ORR) as determined by independent review committee (IRC) was 35 percent, which aligns well with the investigator assessed ORR of 36 percent -
- Median duration of response (DOR) was not reached as assessed by IRC or investigator at 11.3 months of study follow-up; median DOR was not reached at a longer study follow-up of 12.8 months as assessed by investigator for 66 patients in Cohort 2 of C-144-01 study -

SAN CARLOS, Calif., Nov. 08, 2019 (GLOBE NEWSWIRE) -- IOVANCE Biotherapeutics, Inc. (NASDAQ: IOVA), a late-stage biotechnology company developing novel T cell-based cancer immunotherapies, today announced that new data from Cohort 2 of the ongoing Phase 2 lifileucel metastatic melanoma study (C-144-01) were presented Friday, Nov. 8, 2019, at the Society for Immunotherapy of Cancer (SITC) 34th Annual Meeting in National Harbor, Maryland (Abstract P865).

Highlights from the poster presentation include:

- An objective response rate (ORR) of 35 percent as assessed by IRC as compared to 36 percent as assessed by investigator
- Median DOR was not reached as assessed by either IRC (range: 1.6+ to 21.2+ months) or investigator (range: 2.2 to 21.2+ months) at 11.3 months median follow up. In addition, based on the most recent data cut from the study, median DOR was not reached as assessed by investigator at 12.8 months of median study follow-up.
- An overall concordance rate of 89.4 percent between investigator assessment and IRC assessment (n=66)

"We are pleased to see continued evidence of durability with lifileucel therapy as patients are evaluated with longer term follow-up," commented Maria Fardis, Ph.D., MBA, president and chief executive officer of IOVANCE Biotherapeutics. "In addition, concordance between IRC assessment and investigator reported results is highly favorable in this metastatic disease setting as compared with the published literature. These results continue to show that lifileucel offers a potential therapeutic option for the metastatic melanoma patients enrolled in this study. We continue to enroll patients in the pivotal cohort of the study, Cohort 4, which is expected to serve as the basis for an expected Biologics License Application (BLA) submission for lifileucel in late 2020."

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. The adverse event profile of lifileucel treatment in the C-144-01 study continued to be consistent with the underlying advanced disease and the profile of the lymphodepletion and IL-2 regimens.

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; 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; 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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