Iovance Biotherapeutics Announces First Patient Dosed in Cohort 4 of Pivotal InnovaTIL-01 Study of Lifileucel in Metastatic Melanoma

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- Patient dosing commenced in pivotal metastatic melanoma cohort -

- Submission for regulatory approval of lifileucel is on target for late 2020 -

SAN CARLOS, Calif., April 02, 2019 (GLOBE NEWSWIRE) -- Iovance Biotherapeutics, Inc. (NASDAQ: IOVA), a late-stage biotechnology company developing novel cancer immunotherapies based on tumor-infiltrating lymphocyte (TIL) technology, today announced that first patient has been dosed in Cohort 4, the pivotal cohort of the innovaTIL-01 (C-144-01) study of lifileucel. Cohort 4 is designed to enroll 75 patients with advanced melanoma.

“Dosing of the first patient in Cohort 4, the pivotal arm of our melanoma program, is a significant step toward registration of TIL therapy,” commented Maria Fardis, Ph.D., president and chief executive officer of Iovance. “Complete enrollment of this cohort is expected in early 2020 and we remain on track to file a Biologics License Application for regulatory approval of lifileucel in late 2020.”

InnovaTIL-01 (NCT02360579) is a pivotal phase 2 global multicenter study evaluating the safety and efficacy of Iovance’s autologous lifileucel TIL therapy for treatment of patients with metastatic melanoma. The study is currently enrolling in the United States and Europe. To date, Iovance has activated 39 clinical sites in the United States and Europe. Additional information on this study is available at https://clinicaltrials.gov/ct2/show/NCT02360579.

About Iovance Biotherapeutics, Inc.

Iovance Biotherapeutics intends to commercialize lifileucel, an autologous cell therapy product using TIL technology that amplifies the body’s own immune response to eradicate solid tumors or attack blood cancers. The company is currently conducting the pivotal study innovaTIL-01 in patients with metastatic melanoma. In addition, the company’s TIL therapies are being investigated for the treatment of patients with locally advanced, recurrent or metastatic cancers including cervical, head and neck, and non-small cell lung cancer. 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 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 obtain and maintain U.S. Food and Drug Administration (“FDA”) or other regulatory authority approval of, or other action with respect to, our product candidates; the strength of Company’s product pipeline; the successful implementation of the Company’s research and development programs and collaborations; 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, including efficacy and safety results, from ongoing Phase 2 studies may not be reflected in the final analyses of these trials, including new cohorts within these trials, and may not be supportive of product approval; the FDA or other regulatory authorities may potentially delay the timing of their approval of, or other action with respect to, the Company’s product candidates; the Company’s ability to address FDA or other regulatory authority requirements relating to its clinical programs and registrational plans, such requirements including, but not limited to, clinical and safety requirements as well as manufacturing and control requirements; risks related to the Company’s accelerated FDA review designations; and the ability of the Company to manufacture its therapies using third party manufacturers. 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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