Iovance Biotherapeutics was Granted Fast Track Designation for LN-145 for Cervical Cancer

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SAN CARLOS, Calif., Feb. 26, 2019 (GLOBE NEWSWIRE) -- Iovance Biotherapeutics, Inc. (NASDAQ:IOVA), a biotechnology company developing novel cancer immunotherapies based on tumor-infiltrating lymphocyte (TIL) technology, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for LN-145 for the treatment of patients with recurrent, metastatic or persistent cervical cancer who have progressed while on or after chemotherapy. LN-145 is the Company's adoptive cell therapy produced using its proprietary TIL manufacturing technology.

"We are pleased to have received Fast Track designation for LN-145 for the treatment of cervical cancer in patients who have failed chemotherapy treatment," commented Maria Fardis, Ph.D., MBA, president and chief executive officer of Iovance Biotherapeutics. "The designation is an important positive step for the development of LN-145 in a serious and unmet medical need patient population. We are excited about the clinical data for LN-145 in cervical cancer patients and look forward to a closer collaboration with the FDA as we advance the clinical development of LN-145 for the treatment of cervical cancer."

The Fast Track designation from the FDA is designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need, which includes providing a therapy that may be potentially better than the available ones. With the Fast Track designation for LN-145, Iovance is expected to have more frequent meetings and communication with the FDA and is eligible, if relevant criteria are met upon submission, for a Rolling Review of the Biologic License Application (BLA) and potentially Accelerated Approval.[1]

The Company had previously reported preliminary data from the Phase 2 study of LN-145 for cervical cancer (C-145-04) in October 2018 for 15 patients yielding an overall response rate (ORR) of 27%. Patients in the study had a median of five prior therapies. The most common treatment-emergent adverse events included chills, pyrexia and anaemia. The protocol for the cervical cancer study has since been amended to limit the number of prior therapies to no more than three and to exclude patients who have been treated with prior immunotherapy. The study is actively recruiting patients at 32 clinical sites in the United States and Europe. The company anticipates providing an update on this study at an upcoming medical meeting in 2019.

About Iovance Biotherapeutics, Inc.

Iovance Biotherapeutics, Inc. is a clinical-stage biotechnology company focused on the development of cancer immunotherapy products for the treatment of various cancers. The company's lead product candidate is an adoptive cell therapy using TIL technology being investigated for the treatment of patients with metastatic melanoma, recurrent and/or metastatic squamous cell carcinoma of the head and neck, recurrent, metastatic or persistent cervical cancer and locally advanced or metastatic 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 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 (specifically, the Company's description of FDA interactions are subject to FDA's interpretation, as well as FDA's authority to request new or additional information); 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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- https://www.fda.gov/forpatients/approvals/fast/ucm405399.htm

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