Iovance Biotherapeutics Announces FDA Fast Track Designation for LN-144 for Treatment of Advanced Melanoma

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SAN CARLOS, Calif., Aug. 31, 2017 (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-144, the Company's adoptive cell therapy using its TIL technology, for the treatment of advanced melanoma.

"We are pleased that the FDA has granted Fast Track designation to LN-144 for the treatment of advanced melanoma. The Fast Track designation underscores that advanced melanoma remains a serious condition and that LN-144 may have the potential to address this unmet medical need," said Dr. Maria Fardis, PhD, MBA, Chief Executive Officer of Iovance Biotherapeutics. "We look forward to a closer interaction with the FDA as we advance the clinical development of LN-144 for the treatment of advanced melanoma."

C-144-01 is a Phase 2 study evaluating LN-144, Iovance's lead product, for treatment of patients with metastatic melanoma. The study is currently enrolling and is expected to enroll up to 60 patients in two cohorts: Cohort 1 allows for non-cryopreserved TIL product to be administered to patients, while Cohort 2 involves administration of a cryopreserved product. In June 2017, the Company presented a poster at the 2017 American Society of Clinical Oncology (ASCO) Annual Meeting with data from 16 patients enrolled in the first cohort of this study. The data reported showed clinically-meaningful outcomes in the evaluable patients, with a 29% Objective Response Rate (per RECIST v1.1) including one complete response continuing beyond 15 months post-administration of a single TIL treatment, and 77% of patients had reduction in target tumor size. The Phase 2 study was conducted in a heavily pre-treated patient group, all of which had received prior anti-PD-1 therapy and 88% with prior anti-CTLA-4 checkpoint inhibitors, with a median of three prior therapies.

The FDA's Fast Track process is designed to facilitate the development, and expedite the review of drugs that treat serious conditions and fill an unmet medical need. Fast Track designation allows more frequent meetings and communications with the FDA to discuss the drug's development plans and review process. The Fast Track designation also allows for a rolling review of a company's Biologic License Application (BLA).

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 tumor-infiltrating lymphocyte (TIL) technology being investigated for the treatment of patients with metastatic melanoma, recurrent and/or metastatic squamous cell carcinoma of the head and neck and recurrent and metastatic or persistent cervical cancer. For more information, please visit http://www.iovance.com.

Forward-Looking Statements
Certain matters discussed in this press release are "forward-looking statements". 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. In particular, the Company's statements regarding trends and potential future results are examples of such forward-looking statements. The forward-looking statements include risks and uncertainties, including, but not limited to, the success, timing and cost of our ongoing clinical trials and anticipated clinical trials for our current product candidates, including statements regarding the timing of initiation and completion of the 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 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. 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 circumstance.

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