Iovance Biotherapeutics Expands Pipeline of TIL Therapies into Lung Cancer

December 13, 2017

Moffitt Cancer Center Phase 1 Study Combining TIL and Nivolumab Initiated in NSCLC Patients

Iovance/MedImmune Clinical Collaboration to Initiate with Start of Phase 2 Study in PD-1/PDL-1 Naïve NSCLC Patients 1H 2018

SAN CARLOS, Calif., Dec. 13, 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 patient enrollment has begun in a study combining TIL and nivolumab in advanced non-small cell lung cancer (NSCLC) patients in collaboration with researchers at H. Lee Moffitt Cancer Center and Research Institute (Moffitt), Stand Up to Cancer and other partners. The company also announced that a Phase 2 study in PD-1/PDL-1 naïve NSCLC patients, sponsored by Iovance, in collaboration with MedImmune, the global biologics research and development arm of AstraZeneca, will initiate in the first half of 2018. The study with MedImmune will allow for enrollment of NSCLC patients for treatment with LN-145 alone or in combination with durvalumab.

"Lung cancer is the leading cause of death in cancer and the second most common cancer in the United States. Five-year survival for NSCLC remain under 20% despite recent advances in the field," said Dr. Maria Fardis, PhD, MBA, President and Chief Executive Officer of Iovance Biotherapeutics. "The Phase 1 TIL and nivolumab combination study is being conducted in collaboration with the Moffitt Cancer Center, Stand Up To Cancer, as well as support from Bristol-Myers Squibb and Prometheus Laboratories,[1] and speaks to the potential application of TIL technology in lung cancer. MedImmune is a leader in development of immuno-oncology therapy and we look forward to initiating our clinical collaboration with them for this unique combination therapy in the first half of next year."

The initiated Phase 1 study (NCT03215810) is designed to enroll up to 18 patients with advanced NSCLC.

NSCLC is associated with high mutational load in the tumor. Results of TIL growth from this tumor type has been reported by Iovance at the SITC 31st Annual Meeting in 2016. Impact of treatment of NSCLC with TIL alone, as well as in combination with durvalumab, will be explored in PD-1/PDL-1 naïve patients in the Iovance Phase 2 study to be conducted in collaboration with MedImmune. The Phase 2 multicenter study will enroll up to 24 patients and be composed of two cohorts to assess the efficacy and safety of LN-145 alone and in combination with anti-PD-L1 inhibitor durvalumab in patients with locally advanced or metastatic NSCLC.

About Lung Cancer
Lung cancer is the leading cause of human cancer deaths worldwide, with approximately 1.7 million deaths reported in 2015, of which 80% to 85% were attributed to non-small cell lung cancer (NSCLC). In 2017, there were an estimated 222,500 new cases and 155,870 deaths due to lung and bronchus cancer in the United States. In men and women, the lifetime risk of developing lung cancer is about 1 in 14 and 1 in 17, respectively, including both smokers and nonsmokers.

Forward-Looking Statements
Certain matters discussed in this press release are "forward-looking statements". The Company 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 the Company's ongoing clinical trials and anticipated clinical trials for its current product candidates, including statements regarding the timing of initiation and completion of the trials; the timing of and its ability to obtain and maintain U.S. Food and Drug Administration or other regulatory authority approval of, or other action with respect to, its 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.

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.

[1] More details about the collaboration can be found at: https://www.moffitt.org/newsroom/press-release-archive/2017/stand-up-to-cancer-awards-moffitt-267-million-to-study-new-lung-cancer-immunotherapy/

Investor Relations Contact:
Sarah McCabe
Stern Investor Relations, Inc.
212-362-1200

sarah@sternir.com

Media Contact:
Evan Smith
FTI Consulting
212-850-5622
evan.smith@fticonsulting.com

Iovance Biotherapeutics, Inc.