Iovance Biotherapeutics Announces Preliminary Phase 2 Data for TIL Treatment in Head and Neck and Cervical Cancers

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- Three of Eight Evaluable Patients with Recurrent and/or Metastatic Squamous Cell Carcinoma of the Head and Neck Treated with LN-145 Experienced a Confirmed Partial Response
- One of Two Evaluable Patients with Recurrent, Metastatic or Persistent Cervical Carcinoma Treated with LN-145 Experienced a Confirmed Partial Response

SAN CARLOS, Calif., Jan. 24, 2018 (GLOBE NEWSWIRE) -- Iovance Biotherapeutics, Inc. (Nasdaq:IOVA), a biotechnology company developing novel cancer immunotherapies based on tumor-infiltrating lymphocyte (TIL) technology, today reported preliminary clinical results from two ongoing open-label Phase 2 studies in head and neck and cervical cancers.

The company reported preliminary data from C-145-03, a multicenter Phase 2 study to evaluate the safety and efficacy of autologous Tumor Infiltrating Lymphocytes (LN-145) for the treatment of patients with recurrent and/or metastatic squamous cell carcinoma of the head and neck. Three of the eight patients treated with LN-145 had a reduction in tumor size of at least 30% and qualified as a Partial Response (PR) as per RECIST 1.1 criteria. The Objective Response Rate (ORR) in the study is 38% to date. These patients had a median of 4 prior treatments for their cancer and had all received prior anti-PD-1 therapy. Two of eight had also received prior anti-CTLA-4. The most common side effects were pyrexia, chills, and hypotension. Iovance will continue to enroll patients in this study to the full sample size of 47 per protocol.

The company also reported preliminary data from C-145-04, a multicenter Phase 2 study to evaluate the safety and efficacy of autologous Tumor Infiltrating Lymphocytes (LN-145) for the treatment of patients with recurrent, metastatic or persistent cervical carcinoma. Two patients are currently evaluable. One treated with LN-145 had a confirmed PR and one patient had stable disease.

“These early data from the head and neck study show the potential safety and efficacy of TIL therapy in tumor types other than melanoma, and demonstrate the broad utility of TIL therapy in various solid tumors. Recently approved anti-PD-1 therapies have resulted in overall response rates of 13-16% in head and neck cancer patients with a median of 2 prior therapies or similar disposition. We are therefore excited by this early data and believe that LN-145 may offer patients who have failed prior therapies, including anti-PD-1 checkpoints, an important treatment alternative,” said Dr. Maria Fardis, PhD, MBA, president and chief executive officer of Iovance Biotherapeutics. “We are also encouraged by the preliminary data reported today in cervical cancer. Previously published data from the National Cancer Institute (NCI) had shown a response in three of nine cervical cancer patients treated with TIL therapy. Patients with metastatic cervical cancer have limited effective treatment options, with no transformative new systemic therapies having been approved over the last several decades.”

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.

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 efficacy, safety, tolerability and cost of the Gen 2 manufacturing process, 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; statements with respect to the preliminary clinical results from ongoing Phase 2 studies described above, which may not be reflected in the final analyses of this trial; whether results obtained in Company’s ongoing clinical trials, such as the studies and trials referred to in this release, will be indicative of results obtained in future clinical 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 the 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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