Iovance Biotherapeutics Announces Approval of First Clinical Trial Application by Competent Authority in Netherlands for a Phase 2 Trial of LN-145 for the Treatment of Patients with Cervical Cancer

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SAN CARLOS, Calif., Sept. 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 the approval of the Company's Clinical Trial Application (CTA), by the competent authority (CA) in the Netherlands, for a Phase 2 trial of LN-145 for the treatment of patients with recurrent, metastatic or persistent cervical carcinoma. Iovance initiated the submission of CTAs in multiple countries in Europe starting in August 2017 in support of clinical trials in cervical carcinoma and metastatic melanoma.

"We intend to use the data from our Phase 2 trials in support of global registration for TIL therapy to treat patients with melanoma and cervical carcinoma. We are very enthusiastic to have our first CTA approved by the CA and look forward to initiating our trials in Europe to offer TIL therapy to these metastatic melanoma and cervical carcinoma patients in addition to those in the US. The encouraging data generated by the National Cancer Institute showing responses in three of the nine cervical cancer patients treated with TIL therapy, with two continuing to have a complete response at 46 months and 54 months of follow up, supports the potential for LN-145 in the treatment of cervical cancer," said Dr. Maria Fardis, PhD, MBA, President and Chief Executive Officer of Iovance Biotherapeutics.

LN-145 is an adoptive cell transfer (ACT) therapy that utilizes an autologous TIL manufacturing process. C-145-04 is a Phase 2, multicenter, single-arm, open-label interventional study that will enroll up to 47 patients and will assess the safety and efficacy of LN-145 for the treatment of patients with recurrent, metastatic, or persistent cervical carcinoma. The cell transfer therapy used in this study involves patients receiving a non-myeloablative (NMA) lymphocyte depleting preparative regimen, followed by infusion of autologous TIL and the administration of a regimen of up to six doses of IL-2.

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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