Iovance Biotherapeutics Provides Cervical Cancer Program Updates Following End of Phase 2 Meeting with U.S. Food and Drug Administration (FDA)

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FDA agreed that the ongoing single-arm Phase 2 innovaTIL-04 study may be sufficient to support registration of LN-145 in advanced cervical cancer

SAN CARLOS, Calif., July 02, 2019 (GLOBE NEWSWIRE) -- Iovance Biotherapeutics, Inc. (NASDAQ: IOVA), a late-stage biotechnology company developing novel cancer immunotherapies based on tumor-infiltrating lymphocyte (TIL) technology, today provided an update on the regulatory path for LN-145 in advanced cervical cancer. Based on an End of Phase 2 meeting held with the U.S. Food and Drug Administration (FDA), the FDA has acknowledged that the ongoing innovaTIL-04 study of TIL therapy LN-145 may be sufficient to support registration in the treatment of patients with advanced cervical cancer. The study is being enrolled with a prospective definition of objective response rate (ORR) read out by a Blinded Independent Review Committee (BIRC) as the primary endpoint. In accordance with the FDA's recommendation, the new version of the protocol will further define the patient population. Iovance plans to include in the Biologics License Application (BLA), patients who have progressed following initial systemic therapy for recurrent or metastatic disease, which constitutes almost all of the more advanced patients enrolled to date. In addition, the company announced that the innovaTIL-04 study is expected to enroll a total of 75 to 100 patients in order to support a BLA submission.

"The FDA's agreement to consider acceptability of the ongoing study in patients with cervical cancer significantly accelerates our path to BLA submission for LN-145," said Maria Fardis, Ph.D., president and chief executive officer of Iovance Biotherapeutics. "This feedback is encouraging. The ability to use the current study, as well as the Breakthrough Therapy designation recently granted to LN-145, allows us to plan on a path to BLA submission in the second half of 2020."

About Iovance Biotherapeutics, Inc.

Iovance Biotherapeutics intends to commercialize autologous cell therapy products that amplify the body's own immune response to eradicate solid tumors or attack blood cancers. The company is currently conducting the pivotal study innovaTIL-01 in patients with metastatic melanoma. In addition, the company's tumor infiltrating lymphocyte (TIL) therapies are being investigated for the treatment of patients with locally advanced, recurrent or metastatic cancers including cervical, head and neck, and 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 and production 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 FDA or other regulatory authority approval of, or other action with respect to, our product candidates, including those product candidates that have been granted breakthrough therapy designation ("BTD") or regenerative medicine advanced therapy designation ("RMAT") by the FDA; the strength of the Company's product pipeline; the successful implementation of the Company's research and development programs and collaborations; the Company's ability to obtain tax incentives and credits; 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, which may include efficacy and safety results, from ongoing Phase 2 studies may not be reflected in the final analyses of these trials; the rate of enrollment may impact the Company's clinical trial timelines; enrollment may need to be adjusted for the Company's trials and cohorts within those trials based on FDA and other regulatory agency input; the new version of the protocol which further defines the patient population to include more advanced patients in the Company's cervical cancer trial may have an adverse effect on the results reported to date; the data within these trials may not be supportive of product approval; 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, safety, manufacturing and control requirements; the Company's interpretation of communications with the FDA; risks related to the Company's ability to maintain and benefit from accelerated FDA review designations, including BTD and RMAT, which may not result in a faster development process or review of the Company's product candidates (and which may later be rescinded by the FDA), and does not assure approval of such product candidates by the FDA or the ability of the Company to obtain FDA approval in time to benefit from commercial opportunities; 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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