Iovance Biotherapeutics Announces Breakthrough Therapy Designation for LN-145 for Treatment of Advanced Cervical Cancer Patients Who Have Progressed on or After Chemotherapy

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SAN CARLOS, Calif., May 22, 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 announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy designation to Iovance TIL therapy candidate LN-145 in recurrent, metastatic, or persistent cervical cancer with disease progression on or after chemotherapy.

“We are very excited that the FDA has granted LN-145 in advanced cervical cancer Breakthrough Therapy designation. Cervical cancer patients who have progressed on or after chemotherapy have limited treatment options. We hope to bring LN-145 to these patients as quickly as possible,” commented Maria Fardis, Ph.D., MBA, president and chief executive officer of Iovance. “The designation allows us to expedite our development program through more frequent interactions with the FDA and provides eligibility for rolling review and priority review.”

Breakthrough Therapy designation (BTD) is designed to expedite the development and review of therapeutic candidates intended to treat serious or life-threatening diseases in the case where preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint. The FDA decision on BTD for LN-145 in advanced cervical cancer was based on clinical data from the ongoing innovaTIL-04 (C-145-04) trial. The company will present the data on June 1, 2019, at the American Society of Clinical Oncology (ASCO) Annual Meeting.

About Iovance Biotherapeutics, Inc.

Iovance Biotherapeutics intends to commercialize lifileucel, an autologous cell therapy product using TIL technology that amplifies 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 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) 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, including efficacy and safety results, from ongoing Phase 2 studies may not be reflected in the final analyses of these trials, including new cohorts within these trials, and may not be supportive of product approval; the FDA or other regulatory authorities may potentially delay the timing of their approval of, or other action with respect to, the Company’s product candidates; 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 and safety requirements as well as manufacturing and control requirements; risks related to the Company’s ability to maintain and benefit from accelerated FDA review designations, including BTD, which may not ultimately result in a faster development process or review of the Company’s product candidates (and which may later be rescinded by the FDA if such product candidates no longer meet the conditions for qualification for the program), and does not in any way 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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