

# Updated Results of Studies in Advanced Cervical Cancer and Melanoma Support Long-Term Efficacy of Iovance Tumor Infiltrating Lymphocyte (TIL) Therapy

May 31, 2019

Complete Response rate of 11 percent observed in the LN-145 study in cervical cancer

Median duration of response has not been reached at 7.4 month median follow-up in the ongoing study of LN-145 in advanced cervical cancer

#### Median duration of response has not been reached at 8.8 month median follow-up in the ongoing study of lifileucel in advanced melanoma

SAN CARLOS, Calif., May 31, 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 updated data from studies of TIL therapy LN-145 in patients with advanced cervical cancer and TIL therapy lifileucel in advanced melanoma. At 7.4-month median follow-up in the ongoing study of LN-145 in advanced cervical cancer, an 11 percent complete response rate (CR) was seen. Furthermore, the median duration of response (DOR) had not been reached. At 8.8-month median follow-up in the ongoing study of lifileucel in advanced melanoma, median duration of response had not been reached. Updated data from the ongoing innovaTIL-04 and innovaTIL-01 studies will be presented at the 55th Annual Meeting of the American Society of Clinical Oncology (ASCO).

"As we continue to observe the effects of lovance TIL therapy, we have not yet reached a median DOR for our TIL product in either our melanoma or cervical trial," commented Maria Fardis, Ph.D., president and chief executive officer of lovance Biotherapeutics. "We are also extremely encouraged to see CRs in our cervical cancer study as the study continues over time, demonstrating the potential for deep responses after one treatment. The same phenomenon was noted in our melanoma trial as well with two CRs now being reported at ASCO in a heavily pre-treated melanoma patient population."

"The duration of response of current second line treatments for advanced cervical cancer are in the range of three to five months and options are limited," commented Emese Zsiros, M.D., Ph.D., faculty researcher at the Department of Gynecologic Oncology of the Roswell Park Comprehensive Cancer Center and Iovance LN-145 study investigator. "The observation in the study of LN-145 that median DOR has not yet been reached at a median of 7.4 months following treatment provides evidence that this therapy could provide a clinically meaningful improvement over currently available options for patients with advanced cervical cancer."

As of May 14, 2019, data from the innovaTIL-04 study in 27 patients with recurrent, metastatic or persistent cervical cancer demonstrated an objective response rate of 44 percent (3 complete responses and 9 partial responses) and a disease control rate of 85 percent. At 7.4-month median follow-up, 10 patients maintained a response and the median DOR had not been reached (range 2.6+ to 9.2+ months). The mean patient age was 45 years and study participants had experienced a mean of 2.4 prior lines of therapy. Study data will be presented on Saturday, June 1 (Abstract #2538, Poster 182).

As of May 8, 2019, results from Cohort 2 in the ongoing innovaTIL-01 study demonstrated an ORR of 38 percent (2 complete responses and 23 partial responses) in 66 consecutively dosed post-PD-1 patients with Stage IIIC/IV unresectable melanoma. In this study, patients had experienced a mean of 3.3 lines of prior therapy including anti-PD1 blocking antibody, and the patients had a high baseline tumor burden. The disease control rate was 80 percent. At 8.8-month median follow-up, median DOR had not been reached (range 1.4+ to 19.8+ months). Study data will be presented on Saturday, June 1 (Abstract #2518, Poster 162).

## About lovance Biotherapeutics, Inc.

lovance 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.jovance.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 inhere 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 and RMAT, 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 <u>www.sec.gov</u> or <u>www.iovance.com</u>. The forward-looking statements to reflect subsequent events or circumstances.

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