Iovance Biotherapeutics Presents Data at AACR Annual Meeting on T-Cell Diversity and Persistence in Patients Receiving Tumor Infiltrating Lymphocyte (TIL) Therapy Lifileucel

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- Data from cohort 2 of the innovaTIL-01 study support polyclonal approach necessary to treat metastatic melanoma -

SAN CARLOS, Calif., April 01, 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 data from an investigation of the persistence and diversity of circulating T cells from metastatic melanoma patients from the innovaTIL-01 (C-144-01) study receiving lifileucel TIL therapy. Results from an analysis of the persisting T cell clones circulating 42 days following infusion, as compared to the initial TIL product, demonstrated two phenomena: first, that TIL product from 100 percent of the evaluated patients in Cohort 2 of the innovaTIL-01 trial are persisting in circulation at 42 days post-infusion, and second, that each patient has a unique TIL product with almost no overlap between patients for expanding clones in the human body observed post-infusion. Furthermore, the small number of overlapping clones between a few patients were not associated with a clinical response. The uniqueness of the clonal profiles associated with response highlights the challenge of identifying a few T cell receptors as mediators of activity and supports using a polyclonal product such as the Iovance bulk TIL to treat high mutational load solid tumors.

“Investigation of pharmacokinetics of lifileucel TIL in metastatic melanoma patients demonstrates excellent persistence of lifileucel 42 days post-infusion. In addition, the ability of lifileucel TIL therapy to generate responses in melanoma appears to be the result of each patient’s specific populations of their TIL product targeting the patient’s unique mutated tumor antigens” commented Maria Fardis, Ph.D., MBA, president and chief executive officer of Iovance. “The results of this study suggest that high mutational load solid tumors such as melanoma are unlikely to be effectively treated with products against a single or a small number of antigens, implying a potential need for a patient specific, polyclonal product such as Iovance’s TIL product lifileucel.”

Identification of specific cancer-associated antigens responsible for an antitumor immune response continues to be an area of active research.[1,2] The ability of autologous TIL therapy to respond to the unique cancer antigens present in each individual patient may be a factor in the response rates observed with lifileucel treatment.

Study results were detailed in a late-breaking poster presentation, “Persistence of cryopreserved tumor-infiltrating lymphocyte product lifileucel (LN-144) in C-144-01 study of advanced metastatic melanoma,” at the American Association for Cancer Research (AACR) 2019 Annual Meeting. The presentation abstract and additional information is available on the AACR conference website at http://www.aacr.org.

Additional information about the registration-enabling innovaTIL-01 (C-144-01) study of lifileucel in advanced melanoma is available at https://clinicaltrials.gov/ct2/show/NCT02360579.

1. Robbins PF, *et al.,* Mining exomic sequencing data to identify mutated antigens recognized by adoptively transferred tumor-reactive T cells. *Nature Medicine.* 2013 Jun;19(6):747-52. doi: 10.1038/nm.3161.
2. Lu YC, *et al.,* Efficient identification of mutated cancer antigens recognized by T cells associated with durable tumor regressions. *Clinical Cancer Research.* 2014 Jul 1;20(13):3401-10. doi: 10.1158/1078-0432.CCR-14-0433.

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,” “suggest,” “imply,” “supports,” “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 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 implications of the Company’s clinical, correlative, and pre-clinical research activities; the timing of and our ability to obtain and maintain U.S. Food and Drug Administration (“FDA”) 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 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: investigational research results may not be supported by later studies; 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 accelerated FDA review designations; 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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