Iovance Biotherapeutics Announces Updates to Tumor Infiltrating Lymphocyte (TIL) Therapy Clinical Programs

May 15, 2019

Patients with advanced cervical cancer treated with LN-145 had an objective response rate of 44 percent

Patients in Cohort 2 with advanced melanoma treated with lifileucel following failure of checkpoint inhibitors had objective response rate of 38 percent

First patient dosed in IOV-COM-202; the first time that Iovance TIL therapy has been administered in a PD-1/PD-L1 naive patient population

SAN CARLOS, Calif., May 15, 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 updates from ongoing clinical trials including new interim data from studies of TIL therapy LN-145 in patients with advanced cervical cancer and with TIL therapy lifileucel in advanced melanoma. These data will be presented at the 55th Annual Meeting of the American Society of Clinical Oncology (ASCO) taking place May 31 to June 4, 2019, in Chicago. In addition, the company announced that the first PD-1/PD-L1 naive patient has been dosed with TIL therapy and that it has entered into a collaboration with Genocea to evaluate the potential for an improved TIL product.

Data from the innovaTIL-04 study in patients with recurrent, metastatic or persistent cervical cancer showed an ORR of 44 percent (1 complete response, 9 partial responses and 2 unconfirmed partial responses) and a disease control rate of 89 percent. At 3.5-month median study follow-up, 11 out of 12 patients maintained a response. The mean patient age was 47 years and study participants had experienced a mean of 2.6 prior lines of therapy. The adverse event profile was generally consistent with the underlying advanced disease and the profile of the lymphodepletion and IL-2 regimens. These data will be presented on Saturday, June 1 (Abstract #2538). As a reference, ORR for Keytruda used in second line cervical cancer patients is 14 percent.[1]

“As advanced cervical cancer is typically diagnosed at a relatively young age and efficacy of existing treatment options is extremely low, there is potential to significantly impact care with an option that can bring about long-term remission and complete responses,” said Amir Jazaeri, M.D., innovaTIL-04 study investigator and associate professor of Gynecological Oncology and Reproductive Medicine at the MD Anderson Cancer Center. “The interim data from LN-145 present compelling evidence that TIL therapy, provided as a single administration, could improve upon current treatments.”

Updated results from Cohort 2 in the ongoing innovaTIL-01 study demonstrated an ORR of 38 percent (2 complete responses, 18 partial responses and 1 unconfirmed partial response) in 55 consecutively dosed post-PD-1 patients with Stage IIIC/IV unresectable melanoma. In this study, patients were heavily pretreated, with a mean of 3.1 lines of prior therapy including anti-PD1, and had high baseline tumor burden. The disease control rate was 76 percent. At 7.4-month median follow-up, responses were maintained in the majority of patients (only 4 out of 21 responders had progressed at the time of data analysis for the abstract). These data are consistent with prior results from Cohort 2, presented at the Society for Immunotherapy of Cancer (SITC) 2018 Annual Meeting, which demonstrated a 38 percent ORR in a subset of 47 of the 55 patients in Cohort 2. Adverse events resolved to baseline 2 weeks post TIL infusion. These data will be presented on Saturday, June 1 (Abstract #2518).

“We are pleased to be sharing our broader melanoma data and now Gen-2 cervical data at ASCO. The data are indicative of the efficacy of TIL therapy in multiple indications. Further, we believe that TIL therapy is a platform which may offer patients with different advanced cancers a potential therapy,” said Maria Fardis, Ph.D., president and chief executive officer of Iovance Biotherapeutics. “We will provide further updates, including duration of response data, at the ASCO meeting.”

The company today also announced that first melanoma patient has been dosed in its Phase 2 IOV-COM-202 study. This represents the first instance of a patient naive to checkpoint inhibitor treatment receiving Iovance’s TIL therapy in combination with Keytruda.

“TIL therapy represents a promising approach to further advance on the gains that have been made in cancer treatment thanks to immunotherapy and combination approaches,” commented Sajeve Thomas, M.D., Iovance study investigator and oncologist at the Orlando Heath UF Health Cancer Center. “We are encouraged to be part of evaluating new applications of Iovance TIL therapy with combinations and additional tumor types and look forward to the results in these areas.”

IOV-COM-202 is a Phase 2 global multicenter study evaluating the safety and efficacy of Iovance autologous TIL therapy in combination with pembrolizumab in patients who have not received prior immunotherapy for treatment. The study is currently enrolling in the U.S. and Europe. Additional information on this study is available at https://clinicaltrials.gov/ct2/show/NCT03645928.

To support efforts to improve the potency of TIL, Iovance has entered into a collaboration with Genocea to evaluate its ATLAS™ platform. As reported by the company at the American Association for Cancer Research (AACR) 2019 Annual Meeting, melanoma patients receiving lifileucel have a unique mutational landscape, suggesting that high mutational load solid tumors such as melanoma may benefit from treatment with a patient specific, polyclonal product such as the Iovance TIL product. The company plans to utilize the ATLAS platform to evaluate the potential for an improved TIL product.

Conference call

Management will host a conference call and live audio webcast to discuss these results on Thursday, May 16 at 8:00 a.m. EDT. To participate in the conference call, please dial 1-844-646-4465 (U.S.) or 1-615-247-0257 (international) and reference the access code 9291799. A live webcast can be accessed under “News & Events: Investor Calendar” in the Investors section of the Company’s website at www.iovance.com or at the link: https://edge.media-server.com/m6/p/wqjz5xa7. An archived webcast will be available in the Investors section of www.iovance.com for thirty days

following the call.

Details of ASCO Abstracts

- Abstract #2538. Amir Jazaeri *et al.* Safety and efficacy of adoptive cell transfer using autologous tumor infiltrating lymphocytes (LN-145) for treatment of recurrent, metastatic, or persistent cervical carcinoma. Poster display Saturday, June 1, 8:00 a.m. - 11:00 a.m. CDT.
- Abstract #2518. Amod Sarnaik *et al.* Safety and efficacy of cryopreserved autologous tumor infiltrating lymphocyte therapy (LN-144, lifileucel) in advanced metastatic melanoma patients who progressed on multiple prior therapies including anti-PD-1. Poster display Saturday, June 1, 8:00 a.m. - 11:00 a.m. CDT; poster discussion 1:15 p.m. - 2:45 p.m. CDT.

Additional information is available at the ASCO website and at https://meetinglibrary.asco.org/.

[1]https://www.keytruda.com/hcp/advanced-cervical-cancer/

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 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 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 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, including the Company's studies in advanced melanoma and advanced cervical cancer, may not be reflected or maintained 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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