



IOVANCE Biotherapeutics Announces Clinical Data Updates for Lifileucel in Advanced Melanoma During American Association for Cancer Research (AACR) 2021 Annual Meeting

April 9, 2021

Median Duration of Response Not Reached at 28.1 Months of Median Study Follow Up in Cohort 2 of C-144-01 Study

36.4% Overall Response Rate; Continued Deepening of Responses

SAN CARLOS, Calif., April 09, 2021 (GLOBE NEWSWIRE) -- Iovance Biotherapeutics, Inc. (NASDAQ: IOVA), a late-stage biotechnology company developing novel T cell-based cancer immunotherapies, today announced data from Cohort 2 in the C-144-01 study of lifileucel in advanced melanoma. These data will be part of an oral presentation in a Clinical Trials Plenary Session at the upcoming [American Association for Cancer Research \(AACR\) 2021 Annual Meeting](#).

"We are very excited to report our latest Cohort 2 melanoma data in an oral presentation at AACR," said Maria Fardis, Ph.D., President and Chief Executive Officer of Iovance Biotherapeutics. "The long term follow up data show that median duration of response was not reached at 28.1 months of median study follow up. Furthermore, overall response rate remained at 36.4 percent and we saw a continued deepening of response in 17 percent of the patients. The data continue to demonstrate durability and depth of our lifileucel TIL therapy response after a one-time treatment, in a difficult to treat patient population with advanced melanoma. We are honored that AACR has chosen our melanoma Cohort 2 data to be featured in a clinical trials plenary session."

Jason Chesney, M.D., Ph.D., Director, James Graham Brown Cancer Center, University of Louisville and C-144-01 study investigator stated, "Melanoma patients who have progressed on immune checkpoint and BRAF/MEK inhibitors are among the most challenging patients for oncologists to treat. The updated results of the C-144-01 study continue to demonstrate that autologous tumor infiltrating lymphocytes (TILs; lifileucel) induce durable clinical responses in 36 percent of patients in the study. This study also creates opportunities for additional trials of TILs in many other cancer types and in combination with immunomodulatory agents."

The Cohort 2 data are available in the abstract titled, "Lifileucel (LN-144), a cryopreserved autologous tumor infiltrating lymphocyte (TIL) therapy in patients with advanced (unresectable or metastatic) melanoma: durable duration of response at 28-month follow up." Data highlights as of the December 14, 2020 data cut extract used for the abstract submitted to AACR were as follows:

- Lifileucel showed a 36.4% overall response rate (4.5% complete responses and 31.8% partial responses) and median duration of response (DOR) was not reached at 28.1 months of median study follow up as assessed by investigators (n=66).
- The Cohort 2 patients had heavily pretreated metastatic melanoma with high baseline disease burden. They have progressed on multiple prior therapies (3.3 mean prior therapies), including anti-PD1 and BRAF/MEK inhibitors if BRAFV600 mutation positive.
- The adverse event profile was consistent with the underlying advanced disease, lymphodepletion and IL-2 regimens, with no additional adverse events emerging over time.

The abstract is available in the AACR Online Meeting Planner at www.aacr.org and on the Iovance website at www.iovance.com/our-science/publications. The data from the abstract will be highlighted in additional detail at the AACR 2021 Annual Meeting. Details of the oral presentation are as follows:

Abstract Title: Lifileucel (LN-144), a cryopreserved autologous tumor infiltrating lymphocyte (TIL) therapy in patients with advanced (unresectable or metastatic) melanoma: durable duration of response at 28-month follow up

Authors: Jason Alan Chesney, MD, PhD, et al.

Abstract Number: 5329

Presentation Number: CT008

Session Title: Immunooncology and Cell Therapy Trials

Session Date and Time: Saturday, April 10, 2021, 4:45 PM - 5:00 PM ET

Location: AACR Virtual Annual Meeting 2021 at www.aacr.org

In addition to the oral presentation, three Iovance poster presentations at AACR will highlight the design of clinical trials in progress in solid tumors and chronic lymphocytic leukemia or small lymphocytic lymphoma (CLL/SLL). These posters are intended to educate physicians about study design and will not include clinical data. Posters will be available from 8:30 a.m. ET on Saturday, April 10 through Monday, June 21, 2021 in the Virtual ePoster Hall at www.aacr.org and on the Iovance website at www.iovance.com/our-science/publications.

- **Abstract Title:** A Phase 2, multicenter study of autologous tumor infiltrating lymphocytes (TIL) (LN-144/LN-145/LN-145-S1) in patients with solid tumors (IOV-COM-202)
- Authors:** Scott Gettinger, MD, et al.
- Abstract Number:** CT235

- Abstract Title:** A Phase 1/2 study evaluating the safety and efficacy of IOV-2001 in patients with relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) (IOV-CLL-01)

Authors: Meixiao Long, MD, PhD, et al.

Abstract Number: CT244
- Abstract Title:** A phase 2 multicenter study of autologous tumor infiltrating lymphocytes (TIL; LN-145) cell therapy in patients with metastatic non-small cell lung cancer (IOV-LUN-202)

Authors: Erminia Massarelli, MD, PhD, et al.

Abstract Number: CT246

About Iovance Biotherapeutics, Inc.

Iovance Biotherapeutics aims to improve patient care by making T cell-based immunotherapies broadly accessible for the treatment of patients with solid tumors and blood cancers. Tumor infiltrating lymphocyte (TIL) therapy uses a patient's own immune cells to attack cancer. TIL cells are extracted from a patient's own tumor tissue, expanded through a proprietary process, and infused back into the patient. Upon infusion, TIL reach tumor tissue, where they attack cancer cells. The company has completed dosing in pivotal programs in patients with metastatic melanoma and cervical cancer. In addition, the company's TIL therapy is being investigated in a registration-supporting study for the treatment of patients with locally advanced, recurrent or metastatic non-small cell lung cancer. Clinical studies are also underway to evaluate TIL in earlier stage cancers in combination with currently approved treatments, and to investigate Iovance peripheral blood lymphocyte (PBL) T cell therapy for blood cancers. 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") within the meaning of the Private Securities Litigation Reform Act of 1995 (the "PSLRA"). All such written or oral statements made in this press release, other than statements of historical fact, are forward-looking statements and are intended to be covered by the safe harbor for forward-looking statements provided by the PSLRA. Without limiting the foregoing, we may, in some cases, use terms such as "predicts," "believes," "potential," "continue," "estimates," "anticipates," "expects," "plans," "intends," "forecast," "guidance," "outlook," "may," "could," "might," "will," "should" or other words that convey uncertainty of future events or outcomes and are intended to identify forward-looking statements. Forward-looking statements are based on assumptions and assessments made in light of management's experience and perception of historical trends, current conditions, expected future developments and other factors believed to be appropriate. Forward-looking statements in this press release are made as of the date of this press release, and we undertake no duty to update or revise any such statements, whether as a result of new information, future events or otherwise. Forward-looking statements are not guarantees of future performance and are subject to risks, uncertainties and other factors, many of which are outside of our control, that may cause actual results, levels of activity, performance, achievements and developments to be materially different from those expressed in or implied by these forward-looking statements. Important factors that could cause actual results, developments and business decisions to differ materially from forward-looking statements are described in the sections titled "Risk Factors" in our filings with the Securities and Exchange Commission, including our most recent Annual Report on Form 10-K and Quarterly Reports on Form 10-Q, and include, but are not limited to, the following substantial known and unknown risks and uncertainties inherent in our business: the effects of the COVID-19 pandemic; risks related to the timing of and our ability to successfully develop, submit, 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, and our ability to successfully commercialize any product candidates for which we obtain FDA approval; preliminary and interim clinical results, which may include efficacy and safety results, from ongoing clinical trials may not be reflected in the final analyses of our ongoing clinical trials or subgroups within these trials; the risk that enrollment may need to be adjusted for our 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 our cervical cancer trial may have an adverse effect on the results reported to date; the risk that we may be required to conduct additional clinical trials or modify ongoing or future clinical trials based on feedback from the FDA or other regulatory authorities; the risk that our interpretation of the results of our clinical trials or communications with the FDA may differ from the interpretation of such results or communications by the FDA; the acceptance by the market of our product candidates and their potential reimbursement by payors, if approved; our ability or inability to manufacture our therapies using third party manufacturers or our own facility may adversely affect our potential commercial launch; the results of clinical trials with collaborators using different manufacturing processes may not be reflected in our sponsored trials; the risk that unanticipated expenses may decrease our estimated cash balances and increase our estimated capital requirements; and other factors, including general economic conditions and regulatory developments, not within our control.

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