Iovance Biotherapeutics Announces Updated Clinical Data for Lifileucel in Advanced Melanoma at Society for Immunotherapy of Cancer (SITC) Annual Meeting

November 7, 2022

Clinically Meaningful and Durable Activity in Largest Cell Therapy Clinical Trial in Patients with Melanoma After Progression on Immune Checkpoint Inhibitors

31% Objective Response Rate (ORR) and Median Duration of Response (mDOR) Not Reached at 27.6 Months Median Study Follow Up in C-144-01 Trial (Cohorts 2 and 4)

SAN CARLOS, Calif., Nov. 07, 2022 (GLOBE NEWSWIRE) -- Iovance Biotherapeutics, Inc. (NASDAQ: IOVA), a late-stage biotechnology company developing novel T cell-based cancer immunotherapies, today announced the publication of abstracts reporting clinical data and a trial in progress (TIP) for Iovance tumor-infiltrating lymphocyte (TIL) cell therapies for the upcoming Society for Immunotherapy of Cancer (SITC) Annual Meeting, November 8-12, 2022, in Boston, MA and virtually.

The abstract reports on pooled consecutive cohorts from the C-144-01 trial with efficacy data from a total of 153 patients with advanced melanoma enrolled in Cohort 2 (n=66) and Cohort 4 (n=87). All patients had progressed on or after immune checkpoint inhibitor therapy, and targeted BRAF/MEK therapy where appropriate. Patients were heavily pre-treated (median of 3 lines of prior therapy at baseline, range: 1-9) and had substantial disease burden at baseline. As previously reported, 100% of patients received prior anti-PD-1 therapy and more than 80% of patients received prior anti-CTLA-4 therapy.

The ORR assessed by an independent review committee (IRC) using RECIST v1.1 was 31% (95% CI: 24.1%-39.4%), with 8 complete responses (CRs) and 40 partial responses (PRs). mDOR was not reached, 42% of responses extended beyond 18 months, and 40% of responses were ongoing at the median study follow-up of 27.6 months. Median overall survival (mOS) was 13.9 months (95% CI: 10.6-17.8). In patients who achieved a response at their first assessment (6 weeks after lifileucel infusion), mOS had not been reached (95% CI: 22.5 months to NR). The treatment-emergent adverse event profile was consistent with the underlying disease and known adverse event profiles of nonmyeloablative lymphodepletion and interleukin-2 (IL-2). There are no currently approved treatments for the C-144-01 study population. Available care is chemotherapy, offering 4-10% ORR and OS of 7-8 months.[1-4]

Friedrich Graf Finckenstein, M.D., Chief Medical Officer of Iovance, stated, “Adding to the initial positive data from our topline analysis, the analyses across pooled Cohorts 2 and 4 further demonstrate the clinical efficacy and durability of lifileucel in patients with advanced melanoma. The C-144-01 trial also validates the potential for lifileucel to become a broadly accessible TIL therapy using our centralized, scalable, 22-day manufacturing process. Our rolling BLA submission for lifileucel to the U.S. FDA is currently underway and on track to complete by the end of this year.”

Additional information and patient-level detail are available in the abstract. Analyses across pooled Cohorts 2 and 4, along with key individual cohort outcomes from an updated data analysis, will be presented during a rapid oral presentation at SITC.

Iovance Posters and Presentations at SITC Annual Meeting

Title: Lifileucel TIL cell monotherapy in patients with advanced melanoma after progression on immune checkpoint inhibitors (ICI) and targeted therapy: Pooled analysis of consecutive cohorts (C-144-01 study)
Authors: A. Sarnaik, *et al*
Presentation Type: Rapid Oral Abstract and Poster
Session Date and Time: November 10, 2022, 12:33 p.m. (Concurrent Session 105 11:55 a.m. – 12:55 p.m. ET) and Poster Hall (1:00 p.m. – 9:00 p.m. ET)
Abstract ID: 789

Title: Trial in progress: A phase 1/2 open-label study (IOV-GM1-201) of TALEN-mediated PD-1–inactivated autologous tumor-infiltrating lymphocytes (TIL; IOV-4001) in patients with advanced melanoma and NSCLC
Authors: A. Betof Warner, *et al*
Presentation Type: Poster
Session Date and Time: November 10, 2022, 9:00 a.m. – 9:00 p.m. ET, Poster Hall
Abstract ID: 783

Investor Webcast on Thursday, November 10, 4:30 p.m. ET
Iovance will host a webcast on Thursday, November 10 at 4:30 p.m. ET to discuss clinical data updates for lifileucel in advanced melanoma. Iovance senior leadership will be joined by key opinion leaders and principal investigators in Iovance clinical studies. To participate in the webcast, please register at: https://ir.iovance.com/events/event-details/sitc-investor-webcast. The live and archived webcast can be accessed in the Investors section of the company’s website at www.iovance.com.

About Iovance Biotherapeutics, Inc.

Iovance Biotherapeutics aims to be the global leader in innovating, developing and delivering tumor infiltrating lymphocyte (TIL) therapies for patients with cancer. We are pioneering a transformational approach to cure cancer by harnessing the human immune system’s ability to recognize and destroy diverse cancer cells in each patient. Our lead late-stage TIL product candidate, lifileucel for metastatic melanoma, has the potential to become

the first approved one-time cell therapy for a solid tumor cancer. The Iovance TIL platform has demonstrated promising clinical data across multiple solid tumors. We are committed to continuous innovation in cell therapy, including gene-edited cell therapy, that may extend and improve life for patients with 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”) 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; whether clinical trial results from our pivotal studies and cohorts may support registration and approval by the FDA; preliminary and interim clinical results, which may include efficacy and safety results, from ongoing clinical trials or cohorts may not be reflected in the final analyses of our ongoing clinical trials or subgroups within these trials or in other prior trials or cohorts; 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 changing landscape of care for cervical cancer patients may impact our clinical trials in this indication; 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 (including from the recent pre-BLA meeting with the FDA); the risk that the rolling BLA submission for lifileucel in metastatic melanoma may take longer than expected; 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 forecasts and increase our estimated capital requirements; and other factors, including general economic conditions and regulatory developments, not within our control.

[1]Keytruda USPI accessed Mar 2022
[2]Weber et al., Lancet Oncol 2015
[3]Kirchburger et al., Eur J Cancer 2016
[4]Goldinger et al., J Clin Oncol 2018

CONTACTS

Iovance Biotherapeutics, Inc.:
Sara Pellegrino, IRC
SVP, Investor Relations & Corporate Communications
650-260-7120 ext. 264
Sara.Pellegrino@iovance.com

Jen Saunders
Director, Investor Relations & Public Relations
267-485-3119
Jen.Saunders@iovance.com

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