Iovance Biotherapeutics Announces Clinical Data for Lifileucel in Combination with Pembrolizumab in Advanced Melanoma at ASCO 2021 Annual Meeting

June 4, 2021

86% Overall Response Rate (ORR) and 43% Complete Response Rate in Immune Checkpoint Inhibitor (ICI) Naïve Advanced Melanoma Patients in IOV-COM-202 Clinical Study

Initial 7 Patients Show 3 Complete Responses, 3 Partial Responses and 1 Best Response of Stable Disease

ASCO Update Conference Call and Webcast on Sunday, June 6 at 12 p.m. ET

SAN CARLOS, Calif., June 04, 2021 (GLOBE NEWSWIRE) -- Iovance Biotherapeutics, Inc. (NASDAQ: IOVA), a late-stage biotechnology company developing novel T cell-based cancer immunotherapies, today announced clinical data for lifileucel in combination with pembrolizumab in patients with advanced melanoma. The data are now available in an ePoster at the ASCO 2021 Annual Meeting.

Antonio Jimeno M.D., Ph.D., Professor of Medicine/Oncology and Otolaryngology at the University of Colorado School of Medicine stated, “Anti-PD-1 therapy has become standard of care in frontline melanoma, yet we are still looking for ways to help more patients respond and to improve upon the depth and durability of responses. The 86% Overall Response Rate (ORR) for lifileucel in combination with pembrolizumab is remarkable and suggests a potential additive effect for early-line treatment of patients with melanoma. I look forward to investigating this treatment approach in additional patients with melanoma as well as in other tumor types such as head and neck squamous cancer.”

Friedrich Graf Finckenstein, M.D., Chief Medical Officer of Iovance, stated, “We are very pleased with the initial efficacy and safety results for lifileucel in combination with pembrolizumab in patients who are naïve to anti-PD-1 therapy. We are particularly impressed by the complete response observations and noted conversion of several partial to complete responses over time. These data in melanoma also build upon our initial data for TIL in combination with pembrolizumab in head and neck cancer, supporting the broader potential for TIL in earlier anti-PD-1 naïve treatment settings across indications.”

Early data suggest the response rate of lifileucel plus pembrolizumab may be additive and confirm the potential feasibility and activity of this combination in patients with immune checkpoint inhibitor (ICI)-naïve advanced melanoma. Cohort 1A in the IOV-COM-202 study is evaluating lifileucel in combination with pembrolizumab in patients who are naïve to ICI, or anti-PD-1, therapy. Initial patients (n=7) enrolled in Cohort 1A had high tumor burden at baseline, and 71.4% had not received any prior systemic therapy.

Six of the seven patients had a confirmed objective response, representing an 86% ORR (2 complete responses (CR), 1 unconfirmed CR (uCR) who had not yet reached the confirmatory CR assessment, and 3 partial responses (PR)), with one best response of stable disease. Responses deepened over time and the CR/uCR rate was 43%. Poster data extraction was in April 2021 and the median follow up was 8.2 months. ORR was investigator-assessed per RECIST 1.1. In a subsequent data cut in May 2021, all ongoing responses continued.

The Cohort 1A results also demonstrated that lifileucel can be safely combined with pembrolizumab. The treatment-emergent adverse event (TEAE) profile was consistent with the underlying disease and known adverse event (AE) profiles of pembrolizumab, non-myeloablative lymphodepletion (NMA-LD) and IL-2. The median number of doses of IL-2 and pembrolizumab were six and 10, respectively.

Iovance Poster at ASCO 2021

Title: Safety and efficacy of lifileucel (LN-144), an autologous, tumor infiltrating lymphocyte cell therapy in combination with pembrolizumab for immune checkpoint inhibitor naïve patients with advanced melanoma.
Authors: Sajeve Samuel Thomas, *et al.*
Session Title: Melanoma/Skin Cancers
Session Type: ePoster Session
Abstract Number: 9537
Location: ASCO Meeting Library at https://meetinglibrary.asco.org/ and https://www.iovance.com/our-science/publications/
ePoster Viewing: on demand beginning Friday, June 4, 2021 at 9:00 a.m. ET

Webcast and Conference Call
Iovance will host a webcast and conference call on Sunday, June 6, at 12:00 p.m. ET to discuss ASCO clinical data updates for lifileucel alone and in combination with pembrolizumab in patients with advanced melanoma. Iovance senior leadership, together with Dr. Omid Hamid of The Angeles Clinic, will present a summary of the ASCO data from Cohort 1A in the IOV-COM-202 study as well as the upcoming oral presentation of updated Cohort 2 data from the C-144-01 clinical study.

The conference call dial-in numbers are 1-844-646-4465 (domestic) or 1-615-247-0257 (international) and the access code is 4858337. The live webcast can be accessed in the Investors section of the company’s website at http://www.iovance.com. The archived webcast will be available for a year in the Investors section at www.iovance.com.

About Iovance Biotherapeutics, Inc.
Iovance 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 (NSCLC). 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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Source: Iovance Biotherapeutics, Inc.