# Iovance Biotherapeutics Announces Positive Clinical Data for Lifileucel in Advanced Melanoma

May 26, 2022

*Positive Results in Advanced Melanoma Patients, Including a 29% Objective Response Rate (ORR) in Cohort 4 of the C-144-01 Study*

*Biologics License Application (BLA) Submission Planned for August 2022*

*Conference Call and Webcast Today at 5:00 p.m. ET*

SAN CARLOS, Calif., May 26, 2022 (GLOBE NEWSWIRE) -- Iovance Biotherapeutics, Inc. (NASDAQ: IOVA), a late-stage biotechnology company developing novel T cell-based cancer immunotherapies (tumor infiltrating lymphocyte, TIL, and peripheral-blood lymphocyte, PBL), today reported clinical results from its C-144-01 clinical study in patients with advanced (unresectable or metastatic) melanoma who progressed on prior anti-PD-1/L1 therapy, and if BRAF mutation positive, also on prior BRAF or BRAF/MEK inhibitor therapy.

In registrational Cohort 4 (n=87), the objective response rate (ORR) by an independent review committee (IRC) using RECIST 1.1 criteria was 29% (95% confidence interval (CI): 19.5%, 39.4%) with three complete responses and 22 partial responses. The median duration of response (DOR) in Cohort 4 by IRC was 10.4 months with a median study follow-up of 23.5 months. These data demonstrate that one-time treatment with lifileucel therapy may provide meaningful benefit in heavily pre-treated patients. Cohort 4's findings are supported by Cohort 2 (n=66), where the ORR by IRC was 35% (95% CI: 23.5%, 47.6%) with five complete responses and 18 partial responses. The median DOR in Cohort 2 was not reached with a median study follow-up of 36.6 months. The ORR by IRC for pooled patients (n=153) from both Cohorts 2 and 4 was 31% (95% CI: 24.1%, 39.4%) and median DOR was not reached at a median study follow up of 27.6 months.

Patients in Cohort 4 exhibited higher baseline disease burden in comparison to patients in Cohort 2, including a substantially higher proportion of patients with elevated baseline lactate dehydrogenase (LDH) levels, a well-known negative prognostic factor (64.4% versus 40.9%), as well as a greater number of tumor lesions at baseline (83.9% versus 65.2% with more than three lesions). In addition, patients in Cohort 2 also had approximately half the cumulative duration of anti-PD-1 therapy before lifileucel therapy in comparison to patients in Cohort 4. Reduced duration of prior anti-PD-1 therapy was shown[1] to be associated with an increase of DOR to lifileucel. The treatment-emergent adverse event profile in both cohorts was consistent with the underlying disease and known adverse event profiles of non-myeloablative lymphodepletion and interleukin-2 (IL-2) and was also consistent between Cohorts 2 and 4.

Iovance plans to present additional data from Cohorts 2 and 4 at a medical meeting in the second half of 2022. The planned BLA submission for lifileucel in advanced melanoma using these data remains on track for August 2022.

Frederick Vogt, Ph.D., J.D., Interim President and Chief Executive Officer of Iovance, stated, "We are pleased to report positive results for lifileucel from the registrational Cohort 4 data from the C-144-01 study. Iovance is proceeding towards submission of a BLA in August 2022 using these results as well as the potentially supportive results from Cohort 2 of the C-144-01 study. We thank our patients, their families, and our investigators, employees, shareholders, and advocates for their support. We look forward to reporting further progress with our lifileucel BLA and launch preparations in 2022."

Friedrich Graf Finckenstein, M.D., Chief Medical Officer of Iovance, commented, "Treatment of melanoma patients after failure of anti-PD-1 therapy remains a critical unmet medical need without an approved therapeutic option. Available care for metastatic melanoma patients in this setting is chemotherapy, which has been reported to offer a four to ten percent response rate with a very short median duration of response. We are excited about the results from registrational Cohort 4 of the C-144-01 study and the potential of lifileucel as a new treatment option for these patients."

**Webcast and Conference Call**

Iovance will host a conference call today at 5:00 p.m. ET to discuss the updates for 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 conference ID is #5945054. 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.

[1]Larkin, J.M.G., et al., Lifileucel (LN-144), a Cryopreserved Autologous Tumor Infiltrating Lymphocyte (TIL) Therapy in Patients with Advanced Melanoma: Evaluation of Impact of Prior Anti–PD-1 Therapy, ASCO Annual Meeting, June 6, 2021. Presentation.

**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; 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.

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