Iovance Biotherapeutics Announces First Patient Randomized in Phase 3 TILVANCE-301 Trial in Frontline Advanced Melanoma

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Global Trial of Iovance TIL Therapy Lifileucel in Combination with Pembrolizumab

SAN CARLOS, Calif., June 15, 2023 (GLOBE NEWSWIRE) -- Iovance Biotherapeutics, Inc. (NASDAQ: IOVA), a biotechnology company focused on innovating, developing, and delivering novel polyclonal tumor infiltrating lymphocyte (TIL) therapies for patients with cancer, announced that the first patient was recently randomized in TILVANCE-301, a global, multicenter, registrational Phase 3 trial comparing Iovance TIL therapy lifileucel in combination with pembrolizumab versus pembrolizumab monotherapy in frontline advanced (unresectable or metastatic) melanoma.

Friedrich Graf Finckenstein, M.D., Chief Medical Officer of Iovance, stated, “Our strategy is to offer TIL therapy across all lines of treatment for patients with advanced melanoma. Randomizing the first patient in TILVANCE-301, our first Phase 3 trial at Iovance, is an important milestone. The trial offers TIL therapy as part of an earlier treatment approach for frontline advanced melanoma, while serving as a confirmatory trial to convert an accelerated approval to full approval for lifileucel in post-anti-PD-1 melanoma. TILVANCE-301 is expected to be well underway at the time of potential accelerated approval in this initial indication. This trial may also provide important insights into the Iovance platform approach for TIL and anti-PD-1 therapy combinations in additional solid tumors.”

TILVANCE-301 builds on Iovance clinical data and decades of experience at the National Cancer Institute (NCI) on the use of TIL therapy in early line advanced melanoma patients. An oral session at the Society for Immunotherapy of Cancer (SITC) Annual Meeting in November 2021 highlighted positive results for Iovance TIL therapy in combination with pembrolizumab in patients with advanced melanoma, cervical and head and neck cancers who were naïve to prior anti-PD-1 therapy. In April 2022, Iovance announced updated positive results demonstrating a 67% ORR and durability of response for lifileucel in combination with pembrolizumab in advanced melanoma from Cohort 1A of the IOV-COM-202 trial, which have remained consistent in nearly 20 patients treated to date.

The U.S. Food and Drug Administration (FDA) previously agreed that dual primary endpoints of objective response rate (ORR) and progression free survival (PFS) in TILVANCE-301 can support accelerated and full approvals of lifileucel in frontline advanced melanoma. The FDA also agreed that TILVANCE-301, which is expected to be well underway at the time of a potential accelerated approval of lifileucel in post-anti-PD-1 melanoma, can serve as the confirmatory trial for full approval in this initial indication. The FDA granted Priority Review for lifileucel in post-anti-PD-1 melanoma and assigned November 25, 2023, as the target action date for a decision under the Prescription Drug User Fee Act (PDUFA).

About TILVANCE-301
TILVANCE-301 will randomize approximately 670 patients to investigate the safety and efficacy of lifileucel in combination with pembrolizumab (experimental arm) compared with pembrolizumab monotherapy (control arm). Trial sites are actively enrolling adult participants with unresectable or metastatic melanoma who have not received prior therapy for advanced disease. Participants randomized to the control arm who experience disease progression may be treated with lifileucel monotherapy in an optional crossover period. For more information, eligibility criteria, and trial locations, please visit www.clinicaltrials.gov (NCT05727904) or contact clinical.inquiries@iovance.com.

About Iovance Biotherapeutics, Inc.
Iovance Biotherapeutics aims to be the global leader in innovating, developing and delivering tumor infiltrating lymphocyte (TIL) cell 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, which 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, and meetings with the FDA, may support registrational studies and subsequent approvals 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 prior pre-BLA meeting with the FDA); the risk that the FDA may not approve our BLA submission for lifileucel in metastatic melanoma; 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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