Iovance Biotherapeutics Announces First Patient Dosed with PD-1 Inactivated Tumor Infiltrating Lymphocyte (TIL) Therapy

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First Genetically Modified (TALEN®-edited) Iovance TIL Therapy with Inactivated PD-1 Expression

SAN CARLOS, Calif., Oct. 10, 2022 (GLOBE NEWSWIRE) -- Iovance Biotherapeutics, Inc. (NASDAQ: IOVA), a late-stage biotechnology company developing novel T cell-based cancer immunotherapies, announced that the first patient was dosed, and completed the safety observation period, in the IOV-GM1-201 trial of Iovance's genetically modified, PD-1 inactivated TIL therapy, IOV-4001. IOV-GM1-201 is a Phase 1/2, first-in-human study investigating the safety and efficacy of IOV-4001 in patients with previously treated metastatic non-small cell lung cancer (NSCLC) or advanced melanoma.

Friedrich Graf Finckenstein, M.D., Chief Medical Officer of Iovance, stated, "Dosing the first patient with IOV-4001 is an important first step in providing proof-of-concept for delivering genetically modified TIL therapy to solid tumor patients with significant unmet needs and few treatment options. We look forward to dosing the next patient. This trial may also support our broader platform of genetically modified Iovance TIL therapies to potentially address difficult-to-treat solid tumor cancers."

To inactivate the gene coding for the PD-1 protein, IOV-4001 utilizes the gene-editing TALEN® technology licensed from Cellectis (Euronext Growth: ALCLS - NASDAQ: CLLS), a clinical-stage biotechnology company using its pioneering gene-editing platform to develop potentially life-saving cell and gene therapies. This single genetic modification in IOV-4001 may enhance the antitumor activity of the TIL mechanism to directly target and kill tumor cells.

Jason Chesney, M.D., Ph.D., Director and Endowed Professor, UofL Health – Brown Cancer Center, University of Louisville, and an IOV-GM1-201 principal investigator, stated, "I am excited about the potential for gene-editing to open new doors for TIL therapy in patients with solid tumor cancers that do not respond well to current treatment options. As the first multicenter clinical trial to investigate a genetically modified TIL therapy, the IOV-GM1-201 trial may pave the way for a promising new treatment approach to cancer."

PD-1 is a checkpoint protein found on T cells that normally acts as an "off switch" to help to prevent T cells from attacking other cells in the body. It works by binding to PD-L1, a protein found on both normal and cancerous cells, thereby shutting down an attack by a T cell. As a TIL therapy that is genetically modified to remove this important barrier for T cells to attack cancer, IOV-4001 has the potential to become an optimized, next generation TIL therapy for several solid tumor cancers. A poster on preclinical data was presented at the American Association for Cancer Research (AACR) 2022 Annual Meeting.

IOV-GM1-201 is actively enrolling adult participants with advanced NSCLC or unresectable or metastatic melanoma. For more information, eligibility criteria, and trial locations, please visit www.clinicaltrials.gov (NCT05361174) 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, 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.

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