Iovance Biotherapeutics' Investigational New Drug Application (IND) Allowed to Proceed for TALEN®-Edited Tumor Infiltrating Lymphocyte (TIL) in Unresectable or Metastatic Melanoma and Stage III or IV Non-Small Cell Lung Cancer (NSCLC)

March 15, 2022

Clinical Study Expected to Begin in 2022 to Investigate the Safety and Efficacy of IOV-4001 to Deliver TIL and PD-1 Inhibition within a Single Cancer Therapy

First Genetically Modified Iovance TIL Therapy Leverages TALEN® technology Licensed from Cellectis to Inactivate PD-1 Expression

SAN CARLOS, Calif., March 15, 2022 (GLOBE NEWSWIRE) -- Iovance Biotherapeutics, Inc. (NASDAQ: IOVA), a late-stage biotechnology company developing novel T cell-based cancer immunotherapies, today announced that the U.S. Food and Drug Administration (FDA) has allowed an Investigational New Drug Application (IND) to proceed for its first genetically modified TIL therapy, IOV-4001, for the treatment of unresectable or metastatic melanoma and stage III or IV NSCLC.

IOV-4001 leverages 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, to inactivate the gene coding for the PD-1 protein. By removal of 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 clinical study of IOV-4001 in patients with metastatic melanoma or stage III or IV NSCLC is expected to begin in 2022.

Frederick Vogt, Ph.D., J.D., Interim President and Chief Executive Officer of Iovance, stated, "IND allowance for IOV-4001 in two advanced cancers is an exciting milestone in the evolution of our TIL platform as we incorporate the gene editing TALEN® technology to develop next generation TIL therapies. IOV-4001 provides a significant opportunity to deliver the combination of TIL and immune checkpoint inhibition within a single genome-edited TIL therapy in multiple solid tumor types. We look forward to bringing IOV-4001 into the clinic and to advancing additional next generation TIL therapies."

A poster highlighting preclinical activity, clinical-scale manufacturing process development, and characterization of IOV-4001 will be presented at the upcoming American Association for Cancer Research (AACR) 2022 Annual Meeting. In the AACR abstract, anti-tumor activity of IOV-4001 was superior to non-edited TIL, as well as non-edited TIL in combination with anti-PD-1, in a murine model.

About the TALEN® Research Collaboration and Exclusive Worldwide Licensing Agreement

In January 2020, Iovance Biotherapeutics and Cellectis entered into a research collaboration and exclusive worldwide license agreement whereby Iovance licensed certain TALEN® technology from Cellectis. The worldwide exclusive license enables Iovance to use certain TALEN® technology addressing multiple gene targets to modify TIL for therapeutic use in several cancer indications. Iovance plans to initiate a clinical study of the first TALEN®-edited TIL therapy, IOV-4001 (PD-1 inactivated TIL), in 2022. In addition, Iovance has a burgeoning preclinical pipeline of TALEN®-edited TIL therapies, including double-knock out programs.

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.

About Cellectis

Cellectis is a clinical-stage biotechnology company using its pioneering gene-editing platform to develop life-saving cell and gene therapies. Cellectis utilizes an allogeneic approach for CAR-T immunotherapies in oncology, pioneering the concept of off-the-shelf and ready-to-use gene-edited CAR T-cells to treat cancer patients, and a platform to make therapeutic gene editing in hemopoietic stem cells for various diseases. As a clinical-stage biopharmaceutical company with over 22 years of expertise in gene editing, Cellectis is developing life-changing product candidates utilizing TALEN®, its gene editing technology, and PulseAgile, its pioneering electroporation system to harness the power of the immune system in order to treat diseases with unmet medical needs. Cellectis' headquarters are in Paris, France, with locations in New York, New York and Raleigh, North Carolina. Cellectis is listed on the Nasdaq Global Market (ticker: CLLS) and on Euronext Growth (ticker: ALCLS). For more information, visit www.cellectis.com. Follow Cellectis on social media: @cellectis, LinkedIn and YouTube.

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 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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Source: Iovance Biotherapeutics, Inc.