# Iovance Biotherapeutics Obtains License to Develop and Commercialize a Novel IL-2 Analog

January 12, 2020

SAN CARLOS, Calif., Jan. 12, 2020 (GLOBE NEWSWIRE) -- Iovance Biotherapeutics, Inc. (NASDAQ: IOVA), a late-stage biotechnology company developing novel T cell-based cancer immunotherapies, today announced that the company has obtained a license from Novartis to develop and commercialize an antibody cytokine engrafted protein, referred to as IOV-3001. Under the agreement, Iovance will pay an upfront payment to Novartis as well as low single digit milestones involved in initiation of patient dosing in various phases of clinical development for IOV-3001 and approval of the product in the U.S., EU and Japan. Novartis is also entitled to low-to-mid single digit royalties from commercial sales of the product.

"As we progress our development efforts to commercialize TIL, we continue exploring ways to optimize the TIL treatment regimen which includes administration of IL-2," said Maria Fardis, Ph.D., MBA, Iovance's President and Chief Executive Officer. "We therefore see a great strategic and long-term fit for Iovance to pursue development of a targeted and selective IL-2 analog with better pharmacokinetic properties. This product further adds to our research efforts in making safe and more potent TIL products with the potential opportunity for chronic administration."

IOV-3001 is an engineered IL-2 CDR graft which targets IL2R beta-gamma-expressing cells and limits IL2R alpha-beta-gamma-dependent Treg activation. The protein has an improved half-life leading to a better exposure while minimizing Cmax possibly reducing the side effects associated with IL-2 protein. Iovance will focus on GMP manufacturing of IOV-3001 during 2020 and may initiate IND-enabling activities as early as 2021.

**About Iovance Biotherapeutics, Inc.**

Iovance Biotherapeutics 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. After infusion, TIL reach tumor tissue, where they attack tumor cells. The company is currently conducting pivotal studies in patients with metastatic melanoma and advanced cervical cancer. In addition, the company's TIL therapies are being investigated for the treatment of patients with locally advanced, recurrent or metastatic cancers including head and neck and non-small cell lung cancer. A clinical study to investigate Iovance's T cell therapy for blood cancers called peripheral blood lymphocyte (PBL) therapy is being initiated. 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"). We may, in some cases, use terms such as "predicts," "believes," "potential," "continue," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. The forward-looking statements include, but are not limited to, risks and uncertainties relating to the success, timing, projected enrollment, manufacturing and production capabilities, and cost of our ongoing clinical trials and anticipated clinical trials for our current product candidates (including both Company-sponsored and collaborator-sponsored trials in both the U.S. and Europe), such as statements regarding the timing of initiation and completion of these trials; the timing of and our ability to successfully submit, obtain and maintain FDA or other regulatory authority approval of, or other action with respect to, our product candidates, including those product candidates that have been granted breakthrough therapy designation ("BTD") or regenerative medicine advanced therapy designation ("RMAT") by the FDA and new product candidates in both solid tumor and blood cancers; the strength of the Company's product pipeline; the successful implementation of the Company's research and development programs and collaborations; the Company's ability to obtain tax incentives and credits; the guidance provided for the Company's future cash, cash equivalent, and short term investment positions; the success of the Company's manufacturing, license or development agreements; the acceptance by the market of the Company's product candidates, if approved; and other factors, including general economic conditions and regulatory developments, not within the Company's control. The factors discussed herein could cause actual results and developments to be materially different from those expressed in or implied by such statements. Actual results may differ from those set forth in this press release due to the risks and uncertainties inherent in the Company's business, including, without limitation: the preliminary clinical results, which may include efficacy and safety results, from ongoing Phase 2 studies may not be reflected in the final analyses of these trials or subgroups within these trials; a slower rate of enrollment may impact the Company's clinical trial timelines; enrollment may need to be adjusted for the Company's 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 the Company's cervical cancer trial may have an adverse effect on the results reported to date; the data within these trials may not be supportive of product approval; changes in patient populations may result in changes in preliminary clinical results; the Company's ability or inability to address FDA or other regulatory authority requirements relating to its clinical programs and registrational plans, such requirements including, but not limited to, clinical, safety, manufacturing and control requirements; the Company's interpretation of communications with the FDA may differ from the interpretation of such communications by the FDA; risks related to the Company's ability to maintain and benefit from accelerated FDA review designations, including BTD and RMAT, which may not result in a faster development process or review of the Company's product candidates (and which may later be rescinded by the FDA), and does not assure approval of such product candidates by the FDA or the ability of the Company to obtain FDA approval in time to benefit from commercial opportunities; the ability or inability of the Company to manufacture its therapies using third party manufacturers or its own facility may adversely affect the Company's potential commercial launch; and additional expenses may decrease our estimated cash balances and increase our estimated capital requirements. A further list and description of the Company's risks, uncertainties and other factors can be found in the Company's most recent Annual Report on Form 10-K and the Company's subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov or www.iovance.com. The forward-looking statements are made only as of the date of this press release and the Company undertakes no obligation to publicly update such forward-looking statements to reflect subsequent events or circumstances.

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Source: Iovance Biotherapeutics, Inc.