# Iovance Biotherapeutics Announces Updated Phase 2 Clinical Data from the Lifileucel Metastatic Melanoma Trial at the Society for Immunotherapy of Cancer's 33rd Annual Meeting

November 6, 2018

- *38% Objective Response Rate (ORR) demonstrated in 47 Metastatic Melanoma patients who were unsuccessfully treated with a prior PD-1 blocking antibody*
- *Median Duration of Response (DOR) of 6.4 Months*
- *Data selected for oral presentation on Sunday, November 11, 2018*

SAN CARLOS, Calif., Nov. 06, 2018 (GLOBE NEWSWIRE) -- Iovance Biotherapeutics, Inc. (NASDAQ: IOVA), a biotechnology company developing novel cancer immunotherapies based on tumor-infiltrating lymphocyte (TIL) technology, today announced that a presentation of new data from the ongoing Phase 2 lifileucel metastatic melanoma trial (C-144-01) will occur at the Society for Immunotherapy of Cancer (SITC) 33rd Annual Meeting in Washington, D.C. from November 7-11, 2018. Dr. Amod Sarnaik, from H. Lee Moffitt Cancer Center, the lead investigator in the C-144-01 study, will discuss the new data as an oral presentation on Sunday, November 11, 2018. These results will also be presented as a poster beginning November 9, 2018. The company will also host a live webcast of its melanoma program at an event for analysts and investors on Friday, November 9, 2018 from 6:30 – 8:30pm ET during the SITC meeting.

Highlights from the oral and poster presentations include:

- An ORR of 38% from 47 consecutively dosed metastatic melanoma patients, including one complete response and 17 partial responses, four of which are unconfirmed as of October 25, 2018, pending these patients' upcoming second assessments
- A median duration of response (DOR) of 6.4 months with a range of 1.3+ to 14+ months
- All patients were unsuccessfully treated with prior anti-PD-1 treatment
- Mean prior systemic therapies for all patients was 3.3

The most common treatment emergent adverse events observed in this cohort to date include chills, febrile neutropenia, anaemia, decreased platelet count, pyrexia, and hypophosphataemia. Two grade 5 events occurred. One was deemed not related to lifileucel by the investigator and the other possibly related.

"The ORR from the ongoing study in post PD-1 metastatic melanoma patients treated with lifileucel continues to be well above the outcomes from the current standard of care for late-stage melanoma patients. In particular, the DOR of greater than six months is very encouraging," said Dr. Maria Fardis, Ph.D., MBA, president and chief executive officer of Iovance Biotherapeutics. "We are pleased that Dr. Sarnaik can share updated data from the C-144-01 study with the oncology community at SITC."

As previously reported, an End of Phase 2 meeting with the FDA was held. During this meeting, the FDA acknowledged the potential acceptability of a single-arm cohort for registration. FDA has further acknowledged that conduct of a randomized Phase 3 trial may not be feasible in its intended population of advanced melanoma patients who have been treated with at least one systemic therapy including a PD-1 blocking antibody and if BRAF V600 mutation positive, a BRAF inhibitor or BRAF inhibitor with MEK inhibitor and is not required for initial registration of lifileucel. Literature suggests that available care for these patients offers approximately 10% ORR. A new cohort of 80-100 patients in C-144-01 will be enrolled with a prospective definition of the primary endpoint of ORR to be read out by a Blinded Independent Review Committee to support registration of lifileucel. This new cohort, which the company refers to as Cohort 4, will be initiated in early 2019 and is expected to be fully enrolled by late 2019/early 2020. BLA submission to FDA is expected in the second half of 2020.

The details of the SITC presentations are as follows:

**Concurrent Session 302: Clinical Trials Session, Oral Presentation**

**Title:** *Safety and efficacy of cryopreserved autologous tumor infiltrating lymphocyte therapy (LN-144, lifileucel) in advanced metastatic melanoma patients following progression on checkpoint inhibitors*
Author: Amod Sarnaik, MD – H. Lee Moffitt Cancer Center & Research
**Presentation date:** Sunday, November 11, 2018
**Presentation time:** 8:10 am ET

**Poster Presentation**

**Title:** *Safety and efficacy of cryopreserved autologous tumor infiltrating lymphocyte therapy (LN-144, lifileucel) in advanced metastatic melanoma patients following progression on checkpoint inhibitors*
Author: Amod Sarnaik, MD – H. Lee Moffitt Cancer Center & Research
**Dates and times:** The poster will be displayed both on Friday, November 9, 2018 from 8 a.m. – 8 p.m. ET and Saturday, November 10, 2018 8:00 a.m. – 8:30 pm ET.

**Location:** Hall E
**Poster number:** 022
**Presentation:** Dr. Sarnaik will moderate the poster presentation on Saturday, November 10, 2018 from 12:20 pm – 1:50 pm and 7:00 pm – 8:30 pm, local time

**About Iovance Biotherapeutics, Inc.**
Iovance Biotherapeutics, Inc. (the Company) is a clinical-stage biotechnology company focused on the development of cancer immunotherapy products for the treatment of various cancers. The Company's lead product candidate is an adoptive cell therapy using TIL technology being investigated for the treatment of patients with metastatic melanoma, recurrent and/or metastatic squamous cell carcinoma of the head and neck, recurrent, metastatic or persistent cervical cancer and locally advanced or metastatic non-small cell lung cancer. For more information, please visit http://www.iovance.com.

**Forward-Looking Statements**
Certain matters discussed in this press release are "forward-looking statements". The Company 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 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 obtain and maintain U.S. Food and Drug Administration or other regulatory authority approval of, or other action with respect to, our product candidates; the strength of Company's product pipeline; the successful implementation of the Company's research and development programs and collaborations; 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 and accompanying presentations due to the risks and uncertainties inherent in the Company's business, including, without limitation: the FDA may not agree with the Company's interpretation of the results of its clinical trials; later developments with the FDA that may be inconsistent with already completed FDA meetings; regulatory authorities may potentially delay the timing of FDA or other regulatory authority approval of, or other action with respect to, the Company's product candidates (specifically, the Company's description of FDA interactions are subject to FDA's interpretation, as well as FDA's authority to request new or additional information); the Company may not be able to obtain or maintain FDA or other regulatory authority approval of its product candidates; the Company's ability to address FDA or other regulatory authority requirements relating to its clinical programs and registrational plans, such requirements including, but not limited to, clinical and safety requirements as well as manufacturing and control requirements; that the preliminary clinical results, including efficacy and safety results, from the ongoing Phase 2 studies described may not be reflected in the final analyses of these trials or new cohorts within these trials; and the results obtained in the Company's ongoing clinical trials referred to in this release may not be indicative of results obtained in future clinical trials or supportive of product approval. 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.

**Investor Relations Contact:**
Sarah McCabe
Stern Investor Relations, Inc.
212-362-1200
sarah@sternir.com

**Media Relations Contact:**
John Capodanno
FTI Consulting
212-850-5705
john.capodanno@fticonsulting.com

Iovance Biotherapeutics, Inc.