Iovance Biotherapeutics Reports Fourth Quarter and Full-Year 2019 Financial Results and Provides Corporate Update

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SAN CARLOS, Calif., Feb. 25, 2020 (GLOBE NEWSWIRE) -- Iovance Biotherapeutics, Inc. (NASDAQ: IOVA), a late-stage biotechnology company developing novel T cell-based cancer immunotherapies (tumor-infiltrating lymphocyte, TIL and peripheral-blood lymphocyte, PBL), today reported fourth quarter and year-end 2019 financial results and provided a corporate update.

“During 2019 we made tremendous progress in advancing Iovance TIL and PBL products,” said Maria Fardis, Ph.D., MBA, Iovance President and Chief Executive Officer. “We conducted two planned pivotal programs for lifileucel in melanoma and LN-145 in cervical, initiated patient dosing in earlier lines of therapy and received clearance from FDA on a new IND to proceed to dose patients with our PBL product, IOV-2001. In anticipation for commercialization of Iovance TIL, we are building our internal manufacturing capability and expanding our commercial team and infrastructure. With the first potential cell therapy in solid tumors, as well as a broad TIL platform, Iovance is poised to become the leader in development, manufacturing, and commercialization of TIL cell therapy for solid tumors.”

2019 Highlights and 2020 Updates

Clinical

- **Initiation and completion of patient dosing in the pivotal melanoma program, cohort 4 in the C-144-01 trial:** Patient dosing in the pivotal cohort 4 of the C-144-01 study was initiated in March 2019 and completed in January 2020, three months ahead of schedule. Iovance intends to submit a biologics license application (BLA) to FDA subsequent to consultation with the agency in 2020.
- **Presentation of data for lifileucel in metastatic melanoma and LN-145 for metastatic cervical cancer at major medical meetings**: Several clinical data presentations continued to demonstrate efficacy and safety of lifileucel in metastatic melanoma (from C-144-01 study) and LN-145 in recurrent, metastatic, or persistent cervical cancer (from C-145-04 study).
  -- Melanoma update
  - The data for the C-144-01 study in melanoma demonstrated a 36.4% ORR by investigator as presented at ASCO.[1]
  - In a recent data cut for the C-144-01 study, a median duration of response (DOR) was not reached at 15.5 months of median study follow up (Jan. 2020).[2]
- **Expansion of TIL treatment to earlier lines of therapy for melanoma, head and neck, and non-small cell lung cancer (NSCLC) patients**. Patient dosing in the IOV-COM-202 clinical study was initiated in May 2019 to evaluate TIL plus pembrolizumab in patients with immune checkpoint inhibitor naïve melanoma, squamous cell carcinoma of the head and neck (HNSCC), and NSCLC. In the fourth cohort, LN-145 alone is offered to relapsed/refractory NSCLC patients.

Regulatory

- **Receipt of Breakthrough Therapy designation (BTD), Fast Track designation and holding End of Phase 2 Meeting for LN-145 in cervical cancer**: LN-145 was granted Fast Track and BTD from FDA in recurrent, metastatic or persistent cervical cancer with disease progression on or after chemotherapy. Following an end of Phase 2 meeting, the ongoing C-145-04 clinical study was expanded to dose 75 patients to support registration of LN-145. Additional cohorts in earlier and later line cervical cancer patients were added to study C-145-04 in anticipation of a changing landscape in this indication, specifically, a cohort allowing patients post anti-PD-1 was added.
- **Clearance of the investigational new drug (IND) application by FDA and initiation of patient dosing for PBL (IOV-2001) therapy in the first hematologic indication, CLL**: An IND application for IOV-2001 was accepted by FDA in the blood cancer indication, relapsed or refractory CLL or small lymphocytic lymphoma (SLL). The first patient was dosed in a Phase 1/2 study (IOV-CLL-01 study).

Manufacturing

- **Continuation of high manufacturing success rate**: The Gen 2 TIL therapy manufacturing process continues to be robust with a demonstrated success rate, as measured from the receipt of the starting material to the shipment of TIL product, of well over 90 percent in approximately 300 patients.
- **Clinical introduction of Gen 3 TIL therapy**: A proprietary 16-day, third generation TIL therapy manufacturing process (Gen 3) entered the clinic for initial evaluation in the expanded C-145-03 clinical study in head and neck cancer patients with significant unmet need, for which shorter time to TIL infusion may offer a potential benefit.
- **Clinical introduction of PD-1 selected TIL therapy (LN-145-S1)**: A proprietary, selected TIL product LN-145-S1, aimed

at taking further advantage of TIL's ability to recognize the tumor, is also entering the clinic for initial evaluation in the expanded C-145-03 study in head and neck cancer, and subsequently in a new cohort in the IOV-COM-202 study.

Corporate

- **Iovance manufacturing facility on track for commercial production in 2022**: Iovance began construction of a state-of-the-art, 136,000 square foot commercial-scale production facility in Philadelphia for its TIL therapies in June 2019. The new facility is expected to be completed by year-end 2021 to support commercial supply in 2022, with capacity to meet demand for thousands of patients in multiple cancers. Iovance expects to invest approximately $85 million over three years for equipment and construction of the facility.
- **The National Cancer Institute (NCI), with support from Iovance, received an award for TIL therapy technology transfer**: NCI won the Federal Laboratory Consortium's 2020 Excellence In Technology Transfer Award for "New, First-in-class Immunotherapy, for Treatment of Recurrent, Metastatic Cervical Cancer" for its collaboration with Iovance. Iovance supported NCI's application for the award and remains a CRADA partner for ongoing research in TIL therapy. [3]
- **New Iovance patents issued**: Iovance has been granted or allowed a total of 10 U.S. patents for compositions and methods of treatment in a broad range of cancers related to its 22-day Gen 2 manufacturing process.

Research and Development

- **Licensing of novel IL-2 analog (IOV-3001)**: Iovance obtained a license from Novartis to develop and commercialize an expectedly better IL-2 analog, an antibody cytokine engrafted protein, referred to as IOV-3001, as a targeted and selective IL-2 analog.
- **Licensing of TALEN® technology to develop gene edited TIL**: Under a research collaboration and exclusive worldwide license agreement with Cellectis, Iovance licensed certain Cellectis TALEN technology to develop genetically edited TIL to potentially create more potent therapeutics in several cancer indications. The worldwide exclusive license enables Iovance's use of TALEN technology addressing multiple gene targets to modify TIL for therapeutic use.

Anticipated 2020 Milestones

- Last patient dosed in the pivotal program of LN-145 for cervical cancer
- Pre-BLA Meeting with U.S. FDA
- Melanoma top-line pivotal data
- BLA submission

Fourth Quarter and Full-Year 2019 Financial Results

Net loss for the fourth quarter ended December 31, 2019, was $63.6 million, or $0.50 per share, compared to a net loss of $32.6 million, or $0.27 per share, for the fourth quarter ended December 31, 2018. Net loss for the full-year ended December 31, 2019, was $197.6 million, or $1.59 per share, compared to a net loss of $123.6 million, or $1.27 per share, for the full-year ended December 31, 2018.

Research and development expenses were $54.2 million for the fourth quarter ended December 31, 2019, an increase of $26.8 million compared to $27.4 million for the fourth quarter ended December 31, 2018. Research and development expenses were $166.0 million for the 12 months ended December 31, 2019, an increase of $66.2 million compared to $99.8 million for the prior year period. The increases in fourth quarter and full year 2019 over the prior year periods were primarily attributable to an increase in costs associated with manufacturing activities and capacity, clinical trials due to higher enrollment, and growth of the internal research and development team.

General and administrative expenses were $10.9 million for the fourth quarter 2019, an increase of $3.4 million compared to $7.5 million for the fourth quarter 2018. General and administrative expenses were $40.8 million for the 12 months ended December 31, 2019, an increase of $12.4 million compared to $28.4 million for the full year ended December 31, 2018. The increases in fourth quarter and full year 2019 over the prior year periods were primarily attributable to growth of the internal general and administrative team, as well as higher intellectual property legal costs and market research activities in preparation for commercialization.

Cash, cash equivalents, short term investments and restricted cash

At December 31, 2019, the company held $312.5 million in cash, cash equivalents, short-term investments and restricted cash compared to $468.5 million at December 31, 2018.

Webcast and Conference Call

Iovance will host a conference call today at 4:30 p.m. ET to discuss fourth quarter and full-year 2019 results and provide a corporate update. The conference call dial-in numbers are 1-844-646-4465 (domestic) or 1-615-247-0257 (international). The conference ID access number for the call is 4693108. The live webcast can be accessed in the Investors section of the company's website at http://www.iovance.com. The archived webcast will be available for a year in the Investors section at www.iovance.com.

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 has completed dosing in the pivotal study in patients with metastatic melanoma and is currently conducting a pivotal study in patients with metastatic cervical cancer. In addition, the company's TIL therapy is 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 T cell therapy for blood cancers called peripheral blood lymphocyte (PBL) therapy is open to enrollment. 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 equivalents, short term investment and restricted cash balances; 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.

[1]Sarnaik, *et al.* **ASCO 2019** - Safety and efficacy of cryopreserved autologous tumor infiltrating lymphocyte therapy (LN-144, lifileucel) in advanced metastatic melanoma patients who progressed on multiple prior therapies including anti-PD-1

[2]Iovance Corporate Overview - https://ir.iovance.com/presentations

[3]https://techtransfer.cancer.gov/news

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IOVANCE BIOTHERAPEUTICS, INC.
Selected Consolidated Balance Sheet Data
(In thousands)

	December 31, 2019	December 31, 2018
Cash, cash equivalents, short-term investments, and restricted cash	$ 312,531	$ 468,523
Total assets	$ 344,655	$ 480,821
Stockholders' equity	$ 298,971	$ 466,193

IOVANCE BIOTHERAPEUTICS, INC.
Consolidated Statements of Operations
(In thousands, except per share information)

	For the Three Months Ended December 31,		For the Years Ended December 31,	
	2019	2018	2019	2018
Revenues	$ -	$ -	$ -	$ -
Costs and expenses*				
Research and development	54,238	27,418	166,023	99,828
General and administrative	10,872	7,525	40,849	28,430
Total costs and expenses	65,110	34,943	206,872	128,258
Loss from operations	(65,110)	(34,943)	(206,872)	(128,258)
Other income				
Interest income, net	1,542	2,368	9,316	4,678
Net Loss	$ (63,568)	$ (32,575)	$ (197,556)	$ (123,580)
Net Loss Per Common Share, Basic and Diluted	$ (0.50)	$ (0.27)	$ (1.59)	$ (1.27)
Weighted-Average Common Shares Outstanding, Basic and Diluted	126,273	119,085	124,336	97,277
*** Includes stock-based compensation as follows**				
Research and development	$ 2,629	$ 2,669	$ 11,396	$ 9,305
General and administrative	2,778	2,516	12,881	10,722
	$ 5,407	$ 5,185	$ 24,277	$ 20,027

Source: Iovance Biotherapeutics, Inc.