# Iovance Biotherapeutics Reports Third Quarter and September Year-to-Date 2019 Financial Results

November 4, 2019

- Late-breaking abstract at Society for Immunotherapy of Cancer (SITC) meeting to feature Independent Review Committee (IRC) read results from Cohort 2 of C-144-01 melanoma trial -

- Investigational New Drug (IND) application cleared for newly developed peripheral blood lymphocyte (PBL) therapy, IOV-2001 -

- Company to host conference call at 4:30 p.m. EST today -

SAN CARLOS, Calif., Nov. 04, 2019 (GLOBE NEWSWIRE) -- Iovance Biotherapeutics, Inc. (NASDAQ: IOVA), a late-stage biotechnology company developing novel T cell-based cancer immunotherapies, today reported financial results from the third quarter and nine months ending September 30, 2019, and provided a corporate update.

“We continue making great progress in developing tumor infiltrating lymphocyte (TIL) therapy, which could become the first approved cell therapy product for solid tumor indications,” commented Maria Fardis, Ph.D., MBA, president and chief executive officer of Iovance Biotherapeutics. “Our pivotal studies in metastatic melanoma and advanced cervical cancer are on track to complete enrollment in early 2020. We expect to submit for regulatory approval for TIL therapies lifileucel and LN-145 in late 2020. These therapies have the potential to impact the lives of thousands of patients in the U.S. with melanoma or cervical cancer that have exhausted current treatment options. Furthermore, we are very pleased to have a new IND active in order to investigate the polyclonal blood-based T cell, or PBL therapy (IOV-2001), in chronic lymphocytic leukemia (CLL). This candidate was developed based on Iovance research efforts focused on the generation of novel cell therapy products. We anticipate the initiation of IOV-CLL-01, an Iovance-sponsored trial with IOV-2001 PBL product, before the end of 2019.”

**Recent Achievements and Upcoming Milestones**

Clinical

- Completion of enrollment of registration-enabling Cohort 4 in the C-144-01 melanoma study is expected in the first quarter of 2020. A late-breaking abstract on Independent Review Committee (IRC)-read results from Cohort 2 will be presented at the upcoming Society for Immunotherapy of Cancer (SITC) meeting.
- To further expand on evaluating TIL for a broader cervical patient population, we have amended this protocol and added new cohorts. The pivotal cohort, Cohort 1, will treat 75 patients, as planned, who are second line metastatic cervical cancer patients that have progressed during or following systemic therapy. Completion of enrollment of Cohort 1, the pivotal cohort, of the C-145-04 cervical cancer study is expected before mid-2020. Iovance has added new cohorts to the C-145-04 study in order to investigate TIL therapy in broader treatment settings. Enrollment in these additional cohorts will not impact the timing of the completion of the pivotal cohort nor the size of the registration program. The C-145-04 study has been amended to collect additional data on early-line patients as well as late-line patients. These additional cohorts also allow access to TIL therapy when enrollment in the registration Cohort 1 is completed.
- To further its strategy of the study of TIL therapy in additional solid tumors, Iovance and Yale University have initiated an Investigator Sponsored Trial with LN-145 in patients with metastatic triple negative breast cancer (TNBC). The IND has been accepted by the FDA and the trial is expected to begin enrollment in 2020.

Regulatory

- An IND application for IOV-2001, PBL therapy for patients with CLL, was accepted by the U.S. Food and Drug Administration (FDA) and the study has been cleared to proceed. IOV-CLL-01 is a company sponsored study currently active at one clinical site. Patient dosing is planned before the end of 2019. IOV-CLL-01 is a Phase 1/2 study evaluating safety and efficacy of IOV-2001 in patients with relapsed or refractory CLL or small lymphocytic lymphoma (SLL). The study is expected to enroll up to 70 patients.

Research

- Three preclinical abstracts highlighting Iovance TIL therapy will be presented at the upcoming Society for Immunotherapy of Cancer (SITC) 34th Annual Meeting. These presentations will include three poster abstracts covering expansion of TIL from core biopsies, transient genetic knockdown of PD1 in TIL and Gen 2 TIL manufacturing results from several solid tumor types. SITC meeting takes place from Nov. 6-10, 2019, at the Gaylord National Hotel and Convention Center in National Harbor, Maryland. The SITC meeting abstract titles are listed at https://sitc.sitcancer.org/2019/abstracts/titles.
- Iovance entered into a collaboration with Lytix Biopharma, to study the activity of LTX-315, an oncolytic peptide, in conjuction with TIL therapy.
- The company intends to expand its hematologic research to include *mantle cell lymphoma* (MCL).

Manufacturing

- 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, of 93 percent. The manufacturing success rate is comparable with rates published for the approved cell therapy treatments.

Corporate

- The company has been granted a total of seven U.S. patents for compositions and methods of treatment in a broad range of cancers related to its 22-day Gen 2 manufacturing process.

SITC Late-Breaking Abstract Information

- Title: Safety and efficacy of lifileucel (LN-144) tumor infiltrating lymphocyte therapy in metastatic melanoma patients after progression on multiple therapies - independent review committee data update
- Author: Sarniak, A. *et al.*
- Abstract Number: P865
- Dates/Times: late-breaking abstract posters will be displayed Friday, Nov. 8, 2019, from 7 a.m. - 8 p.m. EST and Saturday, Nov. 9, 2019, from 7 a.m. - 8:30 p.m. EST

**Third Quarter 2019 Financial Results**

Net loss for the third quarter ended September 30, 2019, was $49.5 million, or $0.40 per share, compared to a net loss of $33.8 million, or $0.36 per share, for the third quarter ended September 30, 2018.

Research and development expenses were $41.6 million for the third quarter ended September 30, 2019, an increase of $13.7 million compared to $27.9 million for the third quarter ended September 30, 2018. The increase was primarily attributable to higher manufacturing costs resulting from increased capacity added to support enrollment in the pivotal and other clinical trials. In addition the increase is also due to higher personnel costs including stock-based compensation resulting from an increase in headcount as compared to the third quarter in 2018.

General and administrative expenses were $10.0 million for the third quarter 2019, an increase of $2.9 million compared to $7.1 million for the third quarter 2018. The increase was primarily attributable to increased personnel costs due to additional employees added in 2019 and additional legal fees to support the growing patent portfolio.

**Nine Months Ended September 30, 2019, Financial Results**

Net loss for the nine months ended September 30, 2019, was $134.0 million, or $1.08 per share, compared to a net loss of $91.0 million, or $1.01 per share, for the same period ended September 30, 2018.

Research and development expenses were $111.8 million for the nine months ended September 30, 2019, an increase of $39.4 million compared to $72.4 million for the same period ended September 30, 2018. The increase was primarily attributable to additional manufacturing and clinical trial costs resulting from higher enrollment in the clinical trials and increased personnel costs due to an increase in employees as compared to the same period in 2018.

General and administrative expenses were $30.0 million for the nine months ended September 30, 2019, an increase of $9.1 million compared to $20.9 million for the same period ended September 30, 2018. The increase was primarily attributable to higher personnel costs including stock-based compensation resulting from an increase in the number of employees and additional legal fees to support the patent portfolio.

**Cash, cash equivalents, short term investments and restricted cash**

At September 30, 2019, the company held $367.3 million in cash, cash equivalents, short-term investments and restricted cash compared to $468.5 million at December 31, 2018. The company anticipates that the year-end balance of cash, cash equivalents, short-term investments and restricted cash may be between $310 and $320 million.

**Webcast and Conference Call**

Iovance will host a conference call today at 4:30 p.m. ET to discuss these third quarter 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 3482317. The live webcast can be accessed in the Investors section of the company's website at http://www.iovance.com.

**About Iovance Biotherapeutics, Inc.**

Iovance Biotherapeutics intends 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. Clinical studies of T cell therapy for blood cancers called peripheral blood lymphocyte (PBL) therapy are being planned. 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; 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.

**Investor Relations Contacts:**
Annie Chang
Solebury Trout
646-378-2972
achang@troutgroup.com

Chad Rubin
Solebury Trout
646-378-2947
crubin@troutgroup.com

**Media Relations Contact:**
Rich Allan
Solebury Trout
646-378-2958
rallan@troutgroup.com

**IOVANCE BIOTECHNOLOGIES, INC.**
**Selected Consolidated Balance Sheet Data**
**(Unaudited, in thousands)**

| | September 30, 2019 | December 31, 2018 |
|---|---|---|
| Cash, cash equivalents, and short-term investments | $ 361,874 | $ 468,523 |
| Restricted cash | $ 5,450 | $ - |
| Total assets | $ 395,746 | $ 480,821 |
| Stockholders' equity | $ 355,063 | $ 466,193 |

**IOVANCE BIOTECHNOLOGIES, INC.**

**Condensed Statements of Operations**
**(unaudited, in thousands, except per share information)**

| | For the Three Months Ended September 30, | | For the Nine Months Ended September 30, | |
|---|---|---|---|---|
| | **2019** | **2018** | **2019** | **2018** |
| **Revenues** | $ - | $ - | $ - | $ - |
| **Costs and expenses*** | | | | |
| Research and development | 41,582 | 27,947 | 111,785 | 72,410 |
| General and administrative | 10,029 | 7,113 | 29,977 | 20,905 |
| Total costs and expenses | 51,611 | 35,060 | 141,762 | 93,315 |
| **Loss from operations** | (51,611) | (35,060) | (141,762) | (93,315) |
| **Other income** | | | | |
| Interest income, net | 2,124 | 1,230 | 7,774 | 2,310 |
| **Net Loss** | $ (49,487) | $ (33,830) | $ (133,988) | $ (91,005) |
| **Net Loss Per Common Share, Basic and Diluted** | $ (0.40) | $ (0.36) | $ (1.08) | $ (1.01) |
| **Weighted-Average Common Shares Outstanding, Basic and Diluted** | 124,035 | 95,077 | 122,797 | 89,927 |
| ***Includes stock-based compensation as follows** | | | | |
| Research and development | $ 3,346 | $ 2,255 | $ 8,767 | $ 6,636 |
| General and administrative | 3,252 | 3,261 | 10,103 | 8,206 |
| | $ 6,598 | $ 5,516 | $ 18,870 | $ 14,842 |

Source: Iovance Biotherapeutics, Inc.