Iovance Biotherapeutics Reports Second Quarter 2020 Financial Results and Provides a Corporate Update

August 6, 2020

Enrollment Completed in Pivotal Cohort 1 of C-145-04 Cervical Cancer Study

SAN CARLOS, Calif., Aug. 06, 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 second quarter 2020 financial results and provided a corporate update.

“During a strong first half of 2020 we completed dosing and reported early data for our pivotal melanoma program for lifileucel, announced data at AACR for our collaborator Moffitt’s TIL in non-small cell lung cancer, presented updated Cohort 2 data for lifileucel at ASCO, and successfully completed a public financing,” said Maria Fardis, Ph.D., MBA, Iovance President and Chief Executive Officer. “Iovance is now in an excellent position to execute our planned commercial launch while broadening our pipeline programs. The cumulative set of positive clinical data for lifileucel continue to support our planned BLA submission for this one-time treatment for metastatic melanoma. We are also pleased to report that our cervical cancer pivotal program has recently completed enrollment in Cohort 1, and we look forward to dosing the last few patients in the coming weeks. With the first potential cell therapy in solid tumors and a broadening TIL platform, we believe Iovance is the leader in development, manufacturing, and commercialization of TIL cell therapy for cancer.”

Second Quarter 2020 Updates

Clinical:

- **TIL therapy, lifileucel, in Melanoma:** updated data from the C-144-01 trial continue to support the potential for lifileucel as a one-time treatment for advanced melanoma.
  - Updated Cohort 2 data presented at ASCO 2020 showed an ORR of 36.4% with median duration of response not reached at 18.7 months of median study follow up (n=66).
  - Early Cohort 4 data showed 32.4% ORR at 5.3 months of median study follow up (n=68).
- **TIL therapy, lifileucel, in Cervical cancer**: enrollment in the pivotal Cohort 1 is complete in the C-145-04 study of lifileucel, previously known as LN-145, for advanced cervical cancer.
- **TIL therapy in non-small cell lung cancer (NSCLC)**: active planning is underway for a registration-directed study, IOV-LUN-202, for LN-145 in NSCLC patients with defined unmet medical need.
- **T-cell based therapies in additional indications**: patient recruitment continues in the IOV-COM-202 basket study in solid tumors as well as the C-145-03 study in squamous cell carcinoma of the head and neck (SCCHN). Additional sites are being activated for the IOV-CLL-01 study in relapsed or refractory chronic lymphocytic leukemia and small lymphocytic lymphoma (CLL/SLL).

Regulatory:

- Iovance continues preparing for submission of a Biologics License Application (BLA) in late 2020 through data compilation and internal readiness activities.
- Iovance scheduled a meeting with U.S. FDA Division of Manufacturing and Product Quality (DMPQ) to align on the commercial manufacturing facility design and capacity. Full alignment was reached with the DMPQ prior to the upcoming scheduled meeting with the division.
- United States Adopted Names (USAN) council accepted and published the use of the name “lifileucel” to describe Iovance TIL therapy for cervical cancer in addition to melanoma. Lifileucel will replace the former product code LN-145 for the cervical cancer indication.

Commercial Launch Planning:

- Iovance is committed to providing individualized support for a personalized therapy through IovanceCares^{TM}, a program that will allow communication and coordination with health care providers (HCPs) for patient care throughout the lifileucel journey. All elements of the system will be managed by dedicated Iovance case managers to handle the needs of HCPs and patients. This platform will allow the hospitals to place orders for lifileucel, with Iovance to monitor and track patients’ cells during the manufacturing process through the delivery of lifileucel to the hospitals. The system will also include reimbursement support for sites.

Manufacturing:

- Construction of the Iovance Cell Therapy Center (*i*CTC) at the Navy Yard in Philadelphia remains on schedule. Clean rooms are expected to be completed in late 2020 with clinical activities to initiate in early 2021. Commercial manufacturing is on track for 2022.

Research:

- Entered into an agreement with Avid Bioservices for the GLP and GMP manufacturing of novel IL-2 analog IOV-3001.

Corporate:

- Cash position of $777.4 million at June 30 includes net proceeds of $567.4 million from a common stock public offering in June 2020. The current cash position is sufficient for Iovance to execute commercial launch and pipeline activities including a clinical program in NSCLC.
- A strong and growing organization of over 200 employees is in place across multiple locations, including an experienced commercial team with extensive cell therapy experience preparing for launch of lifileucel.
- Iovance has been granted a total of 12 U.S. patents for compositions and methods of treatment in using Iovance TIL in a broad range of cancers related to its 22-day second generation (Gen 2) manufacturing process.

Upcoming Data Presentations:

- **Three Abstracts Accepted for ESMO Virtual Congress 2020**: the following three posters will be highlighted at the upcoming ESMO Virtual Congress 2020, Scientific Weekend, to be held September 19-21, 2020
  - *In vivo* persistence of Iovance tumor-infiltrating lymphocytes LN-145 in cervical cancer patients (Abstract #3688)
  - Genetic Modification of Iovance's TIL through TALEN-mediated knockout of PD-1 as a strategy to empower TIL therapy for cancer (Abstract #3721)
  - Iovance Generation-2 Tumor-infiltrating Lymphocyte (TIL) Product Is Reinvigorated During the Manufacturing Process (Abstract #4229)

Second Quarter and First Half 2020 Financial Results

At June 30, 2020, Iovance held $777.4 million in cash, cash equivalents, short-term investments and restricted cash compared to $312.5 million at December 31, 2019. The current cash position includes net proceeds of $567.4 million from a common stock public offering in June 2020. The company anticipates that the year-end balance of cash, cash equivalents, short-term investments and restricted cash may be over $630 million. The operating expenses in the second half of 2020 are forecasted to be in the same range as the first half of 2020.

Net loss for the second quarter ended June 30, 2020, was $63.0 million, or $0.47 per share, compared to a net loss of $47.6 million, or $0.38 per share, for the second quarter ended June 30, 2019. Net loss for the six months ended June 30, 2020, was $132.6 million, or $1.02 per share, compared to a net loss of $84.5 million, or $0.68 per share, for the same period ended June 30, 2019.

Research and development expenses were $49.3 million for the second quarter ended June 30, 2020, an increase of $10.0 million compared to $39.3 million for the second quarter ended June 30, 2019. Research and development expenses were $106.2 million for the six months ended June 30, 2020, an increase of $36.0 million compared to $70.2 million for the same period ended June 30, 2019.

The increase in research and development expenses in the second quarter 2020 over the prior year period was primarily attributable to an increase in costs associated with multiple clinical trials, and growth of the internal research and development team. The increase in research and development expenses in the first half 2020 over the prior year period was primarily attributable to higher patient enrollment in clinical trials, licensing fees and growth of the internal research and development team.

General and administrative expenses were $14.4 million for the second quarter ended June 30, 2020, an increase of $3.5 million compared to $10.9 million for the second quarter ended June 30, 2019. General and administrative expenses were $28.2 million for the six months ended June 30, 2020, an increase of $8.3 million compared to $19.9 million for the same period ended June 30, 2019.

The increases in general and administrative expenses in the second quarter and first half 2020 compared to the prior year periods were primarily attributable to growth of the internal general and administrative team and higher stock-based compensation expenses.

Webcast and Conference Call

Iovance will host a conference call today at 4:30 p.m. ET to discuss the second quarter 2020 financial results and to 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 7875997. 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”) 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, filings with the Securities and Exchange Commission (“SEC”), reports to stockholders and in meetings with investors and analysts, 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. These forward-looking statements include, but are not limited to, statements regarding 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 strength of the Company’s product pipeline; and the guidance provided for the Company’s future cash, cash equivalents, short term investment, restricted cash balances, and forecasted operating expenses. These statements involve risks, uncertainties and other factors 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, including, without limitation, the following substantial known and unknown risks and uncertainties inherent in the Company’s business: the COVID-19 pandemic may have an adverse effect on the Company and its clinical trials, including potential slower patient recruitment, inability of clinical trial sites to collect data, inability of the Company or its contract research organizations to monitor patients, as well as U.S. Food and Drug Administration (“FDA”) availability due to competing priorities; our ability to achieve long-term profitability and successfully commercialize our products alone or with third parties, as well as our history of operating losses and our expectations that we will continue to incur significant operating losses; our limited operating history in our current line of business, which makes it difficult to evaluate our prospects, our business plan or the likelihood of our successfully implementing such business plan; risks related to the timing of and our ability to successfully develop, submit, obtain and maintain FDA or other regulatory authority approval of, or other action with respect to, our product candidates (including with respect to lifileucel for the treatment of metastatic melanoma, for which we expect to submit a biologics licensing application (“BLA”) to the FDA during 2020), and our ability to successfully commercialize any product candidates for which we obtain FDA approval; our limited history in conducting clinical trials, on which our future profitability is substantially dependent, and our need to rely on third parties, including contract research organizations, contract manufacturing organizations and consultants, in connection with the conduct, supervision and monitoring of our clinical trials for our product candidates; preliminary and interim clinical results, which may include efficacy and safety results, from ongoing Phase 2 studies may not be reflected in the final analyses of our ongoing clinical trials or subgroups within these trials; the risk that a slower rate of enrollment may delay the Company’s clinical trial timelines or otherwise adversely impact our clinical development activities; the risk that 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 risk that the results obtained in our ongoing clinical trials may not be indicative of results obtained in future clinical trials or that data within these trials may not be supportive of product approval, including that later developments with the FDA may be inconsistent with already completed FDA meetings; the risk that the FDA may not agree with our approach to expand our cervical cancer trial to include Cohort 2 of the C-145-04 trial; the risk that 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 risk that regulatory authorities may potentially delay the timing of FDA or other regulatory approval of, or other action with respect to, our product candidates, or 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 the Company’s interpretation of the results of its clinical trials or communications with the FDA may differ from the interpretation of such results or communications by the FDA; our ability to obtain and maintain intellectual property rights related to our product pipeline; our ability to successfully implement our research and development programs and collaborations; the acceptance by the market of our product candidates and their potential reimbursement by payors, if approved; our ability to obtain tax incentives and credits and the risk that our existing net operating loss carryforwards and research tax credits may expire or otherwise be limited in use; the success of our manufacturing, license or development agreements; risks related to the Company’s ability to maintain and benefit from accelerated FDA review designations, including breakthrough therapy designation or regenerative medicine advanced therapy designation, 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 which 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; the results of clinical trials with collaborators using different manufacturing processes may not be reflected in the Company’s sponsored trials; our dependence on additional financing to fund our operations and complete the development and commercialization of our product candidates, and the risks that raising such additional capital may restrict our operations or require us to relinquish rights to our technologies or product candidates; the risk that additional expenses may decrease our estimated cash balances and increase our estimated capital requirements; and other factors, including general economic conditions and regulatory developments, not within the Company’s control.

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IOVANCE BIOTHERAPEUTICS, INC.
Selected Condensed Consolidated Balance Sheets
(in thousands)

	June 30, 2020 (unaudited)	December 31, 2019
Cash, cash equivalents, and short-term investments	$ 771,879	$ 307,081
Restricted cash	$ 5,525	$ 5,450
Total assets	$ 817,567	$ 344,655
Stockholders' equity	$ 758,309	$ 298,971

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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2020	2019	2020	2019
Revenues	$ -	$ -	$ -	$ -
Costs and expenses*				
Research and development	49,274	39,298	106,226	70,203
General and administrative	14,353	10,867	28,211	19,948
Total costs and expenses	63,627	50,165	134,437	90,151
Loss from operations	(63,627)	(50,165)	(134,437)	(90,151)
Other income				
Interest income, net	609	2,614	1,824	5,650
Net Loss	$ (63,018)	$ (47,551)	$ (132,613)	$ (84,501)
Net Loss Per Share of Common Stock, Basic and Diluted	$ (0.47)	$ (0.38)	$ (1.02)	$ (0.68)
Weighted-Average Shares of Common Stock Outstanding, Basic and Diluted	133,162	123,567	129,848	123,491
*** Includes stock-based compensation as follows**				
Research and development	$ 5,465	$ 2,720	$ 9,783	$ 5,421
General and administrative	5,072	3,706	10,166	6,851
	$ 10,537	$ 6,426	$ 19,949	$ 12,272



Source: Iovance Biotherapeutics, Inc.