Iovance Biotherapeutics Reports Second Quarter 2018 Financial Results and Provides Corporate Update

August 6, 2018

- Company to Host Conference Call at 4:30pm ET Today -

SAN CARLOS, Calif., Aug. 06, 2018 (GLOBE NEWSWIRE) -- Iovance Biotherapeutics, Inc. (NASDAQ: IOVA), a biotechnology company developing novel cancer immunotherapies based on tumor-infiltrating lymphocyte (TIL) technology, today reported its second quarter and six months ended June 30, 2018 financial results and provided a corporate update.

“The dosing of the first patient with lifileucel in Europe for the treatment of metastatic melanoma marked an important milestone for Iovance and our global development plans as we continue our mission to develop TIL therapy as a treatment option for cancer patients. In line with expansion of the TIL platform, we are initiating investigation of TIL therapy in several new indications with high unmet need, as part of our collaboration with MD Anderson,” said Dr. Maria Fardis, Ph.D., MBA, president and chief executive officer of Iovance Biotherapeutics. “We continue to advance our four company-sponsored trials and intend to provide an update regarding our melanoma program later this year.”

Recent Achievements

Manufacturing

- Initiated manufacturing at Lonza, Netherlands in support of the melanoma and cervical clinical sites in Europe.

Clinical

- Enrollment in the global Phase 2 metastatic melanoma study, C-144-01, continues and in June 2018, the company announced that it dosed the first patient with LN-144 (lifileucel) in Europe at a clinical trial site in the United Kingdom.
- As part of a collaboration program, Iovance and MD Anderson Cancer Center (MDACC) initiated two new Phase 2 clinical studies. The first, 2017-0672 (NCT03449108), is studying LN-145 manufactured by Iovance using the company’s Gen 2 manufacturing process to treat patients with soft tissue sarcoma, osteosarcoma and platinum resistant ovarian cancer. The study is active and enrolling patients. The second study is expected to be activated before the end of 2018 and will use TIL manufactured by MDACC.
- Iovance has expanded to over 70 clinical sites for its four company-sponsored studies.

Regulatory

- As of the end of July 2018, Iovance has activated sites for its two clinical trials being conducted in Europe in five countries including the Netherlands, France, Hungary, Spain and the United Kingdom.
- In early May 2018, the company was granted orphan-drug designation from the U.S. Food and Drug Administration (FDA) for autologous tumor infiltrating lymphocytes for the treatment of cervical cancer with a tumor size of greater than 2 cm in diameter.

Research

- Iovance entered into a Research Collaboration Agreement with Roswell Park Cancer Institute for a pre-clinical collaboration to explore the potential for TIL therapy in bladder and other cancers.

Second Quarter 2018 Financial Results

Net loss for the second quarter ended June 30, 2018 was $30.7 million, or $0.34 per share, compared to net loss of $23.4 million, or $0.37 per share for the same period ended June 30, 2017.

Research and development expenses were $24.6 million for the second quarter ended June 30, 2018, an increase of $6.0 million compared to $18.6 million for the second quarter ended June 30, 2017. The increase in research and development expenses was primarily attributable to a $2.8 million increase in payroll and related expenses, including stock-based compensation expenses, due to a higher number of full time employees and dedicated consultants as we expanded our research efforts and clinical development programs. In addition, a $4.5 million increase occurred due to clinical trial costs because of higher patient enrollment and the number of clinical sites in the clinical trial of lifileucel, for the treatment of metastatic melanoma, and the ongoing clinical trials of LN-145 for the treatment of cervical, head and neck and lung cancers. These increases were partially offset by a $1.0 million decrease in manufacturing costs due to higher costs in 2017 related to technical transfer activities.

General and administrative expenses were $6.8 million for the quarter ended June 30, 2018, an increase of $1.9 million compared to $4.9 million for the second quarter ended June 30, 2017. The increase was primarily attributable to a $1.6 million increase in payroll and related expenses, including stock-based compensation expenses, due to an increase in head count and higher stock prices during the quarter, and a $0.3 million increase in

professional service and legal expenses.

Six Months Ended June 30, 2018 Financial Results

Net loss for the six months ended June 30, 2018 was $ 57.2 million, or $0.65 per share, compared to net loss of $44.1 million, or $0.71 per share for the same period ended June 30, 2017.

Research and development expenses were $44.5 million for the six months ended June 30, 2018, an increase of $10.3 million compared to $34.2 million for the same period ended June 30, 2017. The increase in research and development expenses was primarily attributable to a $5.7 million increase in payroll and related expenses, including stock-based compensation expenses, primarily due to a higher number of full time employees and higher stock prices in 2018, and additional outside services contracted to perform research and development activities on our behalf, and a $7.0 million increase in costs related to our clinical trials as we expanded our clinical development programs into additional indications and added clinical trial sites in Europe. These increases were partially offset by a $2.0 million decrease in manufacturing costs due to higher costs in 2017 related to technical transfer activities.

General and administrative expenses were $13.8 million for the six months ended June 30, 2018, an increase of $3.6 million compared to $10.2 million for the same period ended June 30, 2017. The increase was primarily attributable to a $2.7 million increase in payroll and related expenses, including stock-based compensation expenses, due to a higher number of full time employees and higher stock prices in 2018, and a $0.5 million increase in legal expenses.

At June 30, 2018, the company held $276.1 million in cash, cash equivalents, and short-term investments compared to $297.1 million at March 31, 2018. During the second quarter the company used $24.0 million for operating activities. The company anticipates that the year-end balance of cash, cash equivalents and short-term investments may be between $190 to $210 million.

Webcast and Conference Call
Iovance will host a conference call today at 4:30 p.m. ET to discuss these second quarter and six months ended June 30, 2018 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 for the call is 5177499. The live webcast can be accessed under “News & Events” in the “Investors” section of the company’s website at http://www.iovance.com/ or you may use the link: https://edge.media-server.com/m6/p/xqrxbkif.

A replay of the call will be available from August 6, 2018 at 7:30 p.m. ET to August 13, 2018 at 8:30 p.m. ET. To access the replay, please dial 1-855-859-2056 (domestic) or 1-404-537-3406 (international). The reference access code is 5177499. The archived webcast will be available for thirty days in the Investors section of Iovance Biotherapeutics’ website at http://www.iovance.com.

About Iovance Biotherapeutics, Inc.
Iovance Biotherapeutics, Inc. 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”. 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. In particular, the Company’s statements regarding clinical trials in Europe and the U.S. are examples of such forward-looking statements. The forward-looking statements include, but are not limited to, risks and uncertainties relating to the success, initiation, timing, projected enrollment, progression through stages in trial design, completion, 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); 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; the Company’s cash guidance; 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. 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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IOVANCE BIOTECHNOLOGIES, INC.
Selected Consolidated Balance Sheet Data
(Unaudited, in thousands)

	June 30, 2018	December 31, 2017
Cash and cash equivalents	$ 246,017	$ 145,373
Short-term investments	$ 30,082	$ -
Total assets	$ 284,751	$ 155,373
Stockholders' equity	$ 270,569	$ 145,481

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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2018	2017	2018	2017
Revenues	$ -	$ -	$ -	$ -
Costs and expenses*				
Research and development	24,551	18,647	44,463	34,240
General and administrative	6,827	4,934	13,792	10,224
Total costs and expenses	31,378	23,581	58,255	44,464
Loss from operations	(31,378)	(23,581)	(58,255)	(44,464)
Other income				
Interest income, net	718	204	1,080	403
Net Loss	$ (30,660)	$ (23,377)	$ (57,175)	$ (44,061)
Net Loss Per Common Share, Basic and Diluted	$ (0.34)	$ (0.37)	$ (0.65)	$ (0.71)
Weighted-Average Common Shares Outstanding, Basic and Diluted	90,236	62,457	87,310	62,371
*** Includes stock-based compensation as follows**				
Research and development	$ 2,381	$ 1,742	$ 4,381	$ 2,992
General and administrative	2,841	1,551	4,945	3,597
	$ 5,222	$ 3,293	$ 9,326	$ 6,589

(1) Certain amounts within the statement of operations for the three and six months ended June 30, 2017 have been reclassified to conform with the current period presentation. These reclassifications had no impact on the Company's previously reported financial position, or cash flows for any of the periods presented.