Iovance Biotherapeutics Reports Second Quarter 2017 Financial Results

August 1, 2017

- Company to Host Conference Call at 5:00pm ET Today -

SAN CARLOS, Calif. , Aug. 01, 2017 (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 2017 financial results and provided a corporate update.

"During the second quarter of 2017, we made significant progress with our robust immuno-oncology pipeline based on our TIL technology, and reached important milestones. Patient dosing is now ongoing in two of our three Phase 2 programs and we initiated dosing patients in cohort 2 of ourC-144-01 metastatic melanoma study, which allows for administration of LN-144 generated through a shorter manufacturing process," said Dr. Maria Fardis, Ph.D., MBA, Chief Executive Officer of Iovance Biotherapeutics . "In addition, we presented encouraging interim data at ASCO in June from cohort 1 ofour ongoing C-144-01 Phase 2 study in metastatic melanoma. The responses were presented by overall response rate and disease control rate in a heavily pre-treated patient population. This data also demonstrated that we can manufacture TIL at our central GMP facilities and treat a patient population with a high unmet medical need at multiple clinical sites. We plan on selecting theoptimal manufacturing process for our clinical programs based on the available data from the C-144-01 study, by the end of 2017.

Second Quarter 2017 and Recent Highlights and Anticipated Milestones

Corporate News :

- **Corporate name changed to Iovance Biotherapeutics :** In June, the Company changed its corporate name from Lion Biotechnologies, Inc. to Iovance Biotherapeutics, Inc. This new name better represents the company's leadership in the field of immuno-oncology and reflects the recent advancements in evaluating TIL therapy in new indications as well as initiatives to begin trials in Europe .
- **Seeking patents for recent advancements in TIL technology:** Iovance has filed for patent protection on its generation 2 TIL manufacturing process, methodsof using TIL therapies, as well as other technologies that can lead to production of better TIL products.

Clinical Trial Progress:

- **Patient dosing began in second cohort of C-144-01 Phase 2 metastatic melanoma study:** In May, the Company began patient dosing in the second cohort of its ongoing Phase 2 trial investigating LN-144 for the treatment of patients with metastatic melanoma. This cohort has a shorter manufacturing process, and reduces the time from excision to infusion from approximately six weeks to just over three weeks, by utilizing the company's generation 2manufacturing process which includes cryopreservation of the outbound products. Cryopreservation of the product offers greater flexibility for physicians and patients in scheduling the time of the infusion, and the shorter process increases the manufacturing flexibility leading to lower production costs.
- **Two Phase 2 trials investigating LN-145 areunderway:** In June, the Company began patient dosing in its Phase 2 trial of LN-145 for the treatment of patients with recurrent and/or metastatic squamous cell carcinoma of the head and neck. The Company is also actively screening patients in the Phase 2 trial for LN-145 in cervical cancer.
- **NewClinical Grant Agreement with Moffitt Cancer Center for trial in lung cancer:** In July, Iovance entered into a new Clinical Grant Agreement with the Moffitt Cancer Center to fund a Phase 1 clinical trial of TIL therapy in combination with nivolumab in metastatic non-small cell lung cancer (NSCLC) in an effort to continue to understand the potential power of TIL technology to treat various cancers in areas of high unmetmedical need.

Manufacturing Updates:

- **Technology transfer initiated at PharmaCell in the Netherlands (now Lonza) forgeneration 1 and 2 TIL manufacturing processes**: In anticipation of the initiation of clinical studies in Europe in early 2018, a technology transfer for both the generation 1 and 2 TIL manufacturing processes was commenced at PharmaCell.
- **Increasing manufacturing capacity:** Manufacturing at Wuxi, in suites capable of manufacturing late-stage clinical and commercial products, was initiated in May.

Regulatory News :

- **Expansion of clinical trials globally:** The Company engaged local health authorities in Europe to seek feedback in support of submission of a Clinical Trial Authorisation for melanoma and cervical cancer studies in that region.

Data Presentations:

- **Interim data presented at ASCO highlighting first cohort in ongoing C-144-01 study:** The Company presented a poster at the 2017 American Society of Clinical Oncology (ASCO) Annual Meeting in June 2017 with data from 16 patients enrolled in the first cohort of its ongoing Phase 2 study of LN-144 for the treatment of metastatic melanoma. The data reported showed clinically-meaningful outcomes, of the evaluable patients, with a 29% ORR including one complete response continuing beyond 15 months post-administration of a single TIL treatment, and 77% of patients reported a reduction in target tumor size. The Phase 2 study was conducted in a heavily pre-treated patient group, all of which had received prior anti-PD-1 therapy and88% with prior anti-CTLA-4 checkpoint inhibitors, with a medianof three prior therapies. For the full data, please view the release here.
- **Data to be presented at the upcoming European Society for MedicalOncology (ESMO) 2017 Congress in Madrid, Spain in September 2017 :** Data will be presented at the upcoming ESMO congress demonstrating phenotypic and functional characterization of TIL grown from lymphoma tumors.

Second Quarter 2017 Financial and Operating Results

As of June 30, 2017 , the Company held $129.0 million in cash and cash equivalents and short-term investments, compared to $166.5 million as of December 31, 2016 .

In connection with hiring Maria Fardis Ph.D. as the new Chief Executive Officer, on June 1, 2016 the Company granted to Dr. Fardis 550,000 non-transferrable restricted stock units as an inducement of employment pursuant to the exception to The NASDAQ GlobalMarket rules. The 550,000 restricted stock units vest in installments as follows: (i) 137,500 restricted stock units vested June 1, 2017 ; (ii) 275,000 restricted stock units vested upon the satisfaction of certain clinical and manufacturing milestones; and (iii) the remaining 137,500 restricted stock units will vest in equal monthly installments over the 36-month period after June 1, 2017 .

The Companyis providing both GAAP and non-GAAP financial information. All non-GAAP information excludes amounts related to stock-based compensation. See "Use of Non-GAAP Financial Measures" below for a description of the Company's non-GAAP Financial Measures. Reconciliation between certain GAAP and non-GAAP measures is provided at the end of this press release.

GAAP and Non-GAAPNet Loss

GAAP net loss for the quarter ended June 30, 2017 was $23.4 million , or ($0.37) per share, compared to GAAP net loss of $11.6 million or ($0.23) per share for the quarter ended June 30, 2016 .

Non-GAAP net loss for the quarter ended June 30, 2017 was $20.1 million , or ($0.32) per share, compared to non-GAAP net loss of $6.2 million , or ($0.13) per share for the quarter ended June 30, 2016 . The non-GAAP net loss for the quarters ended June 30, 2017 and June 30, 2016 excludes $3.3 million and $5.4 million of non-cash stock-based compensation, respectively.

GAAP net loss for the six months ended June 30, 2017 was $44.1 million , or ($0.71) per share, compared to GAAP net loss of $18.5 million or ($0.37) per share for the six months ended June 30, 2016 . Non-GAAP net loss for thesix months ended June 30, 2017 was $37.5 million , or ($0.60) per share, compared to non-GAAP net loss of $11.3 million or ($0.23) per share for the six months ended June 30,2016 .

GAAP and Non-GAAP Expenses

GAAP research and development (R&D) expenses were $19.7 million for the quarter ended June 30, 2017 , an increase of $15.2 million compared to the quarter ended June 30, 2016 .The increase in R&D expense is due to increased spending onclinical activities and manufacturing. In addition, R&D-associated stock based expenses were $1.9 million for the three months ended June 30, 2017 and $3.3 million for the six months ended June 30, 2017 . Non-GAAP R&D expenses were $17.8 million for the quarter ended June 30, 2017 , an increase of $13.9 million , compared to $3.9 million for the quarter ended June 30, 2016 .

GAAP general and administrative (G&A) expenses were $3.9 million for the quarter ended June 30, 2017 , a decrease of $3.4 million compared to the quarter ended June 30, 2016 . Non-GAAP G&A expenses for both quarters ended June 30, 2017 and June 30, 2016 remained unchanged at $2.5 million .

Use of Non-GAAP Financial Measures

This press release contains non-GAAP financial measures, including expenses adjusted to exclude certain non-cash expenses. These measures are not in accordance with, or an alternative to, generally accepted accounting principles, or GAAP, and may be different from non-GAAP financial measures used by other companies. The item included in GAAP presentations but excluded for purposes of determining non-GAAP financial measuresfor the periods presented in this press release relates to the non-cash stock-based compensation expense which may fluctuate from period to period based on factors including the timing and accounting of grants for stock options and changes in the Company's stock price which impacts the fair value of options granted. The Company believes the presentation of non-GAAP financial measures provides useful information to management and investors regarding various financial and business trends relating to the Company's financial condition and results of operations. When GAAP financial measures are viewed in conjunction with non-GAAP financial measures, investors are provided with a more meaningful understanding of Iovance's ongoing operating performance. In addition, these non-GAAP financial measures are among those indicators the Company uses as a basis for evaluating operational performance, allocating resources and planning and forecasting future periods. Non-GAAP financial measures are not intended to be considered in isolation or as a substitute for GAAP financial measures.To the extent this release contains historical or future non-GAAP financial measures, the Company has also provided corresponding GAAP financial measures for comparative purposes. Reconciliation between certain GAAP and non-GAAP measures is provided at the end of this press release.

Webcast and Conference Call

Iovance will host a conference call today at 5:00 p.m. ET to discuss these second quarter 2017 results. 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 47307932. 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: http://edge.media-server.com/m/p/so22f2sr.

A replay of the call will be available one hour after the end of the call on August 1, 2017 until 8:00 p.m. ET on August 31, 2017 . To access the replay, please dial 1-855-859-2056 (domestic) or 1-404-537-3406 (international). Theconference ID number for the replay is 47307932. 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. (formerly Lion Biotechnologies, 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 tumor-infiltrating lymphocyte (TIL) technology being investigated for the treatment of patients with metastatic melanoma, recurrent and/or metastatic squamous cell carcinoma of the head and neck and recurrent and metastatic or persistent cervical 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 eventsor outcomes to identify these forward-looking statements. In particular, the Company's statements regarding trends and potential future results are examples of such forward-looking statements. The forward-looking statements include risks and uncertainties, including, but not limited to, the success, timing and cost ofour ongoing clinical trials and anticipated clinical trials forour current product candidates, including statements regarding the timing of initiation and completion of the 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; thestrength of Company's product pipeline; the successful implementation of the Company's research and development programs and collaborations; the success of the Company's 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. 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 eventsor circumstance.

Iovance Biotherapeutics, Inc.
Selected Consolidated Balance Sheet Data
(unaudited; inthousands)

	June 30, 2017	*December 31, 2016*
Cash, cash equivalents and short-term investments	$ 129,017	$ 166,470
Total assets	$ 138,012	$ 171,886
Stockholders' equity	$ 129,152	$ 166,918

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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2017	2016	2017	2016
Revenues	$ -	$ -	$ -	$ -
Costs and expenses*				
Research and development	19,653	4,463	36,276	8,655
General and administrative	3,928	7,264	8,188	10,082
Total costs and expenses	23,581	11,727	44,464	18,737
Loss from operations	(23,581)	(11,727)	(44,464)	(18,737)
Other income				
Interest income	204	164	403	290
Net Loss	$ (23,377)	$ (11,563)	$ (44,061)	$ (18,447)
Net Loss Per Common Share, Basic and Diluted	$ (0.37)	$ (0.23)	$ (0.71)	$ (0.37)
Weighted-Average Common Shares Outstanding, Basic and Diluted	62,457	51,082	62,371	49,807
*** Includes stock-based compensation as follows**				
Research and development	$ 1,896	$ 593	$ 3,283	$ 1,178
General and administrative	1,397	4,764	3,306	5,958
	$ 3,293	$ 5,357	$ 6,589	$ 7,136

Iovance Biotherapeutics, Inc. (1)
Reconciliation of Selected GAAP Measures to Non-GAAP
(unaudited; in thousands, except per share data)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2017	2016	2017	2016

Reconciliation of GAAP to non-GAAP Research and development				
GAAP Research and development	$ 19,653	$ 4,463	$ 36,276	$ 8,655
Less:				
Non-cash stock-based compensation [2]	(1,896)	(593)	(3,283)	(1,178)
Non-GAAP Research and development	$ 17,757	$ 3,870	$ 32,993	$ 7,477
Reconciliation of GAAP to non-GAAP General and administrative				
GAAP General and administrative	$ 3,928	$ 7,264	$ 8,188	$ 10,082
Less:				
Non-cash stock-based compensation [2]	(1,397)	(4,764)	(3,306)	(5,958)
Non-GAAP General and administrative	$ 2,531	$ 2,500	$ 4,882	$ 4,124
Non-GAAP Net loss reconciliation				
GAAP Net loss	$ (23,377)	$ (11,563)	$ (44,061)	$ (18,447)
Add back:				
Non-cash stock-based compensation [2]	3,293	5,357	6,589	7,136
Non-GAAP Net loss	$ (20,084)	$ (6,206)	$ (37,472)	$ (11,311)

	For the Three Months Ended June 30,		Forthe Six Months Ended June 30,	
	2017	**2016**	**2017**	**2016**
Non-GAAP net loss per share reconciliation				
GAAP net loss per basic and diluted share:	$ (0.37)	$ (0.23)	$ (0.71)	$ (0.37)
Add back:				
Non-cash stock-based compensation [2]	0.05	0.10	0.11	0.14
Non-GAAP net loss per basic and diluted share	$ (0.32)	$ (0.13)	$ (0.60)	$ (0.23)
Weighted-Average Common Shares Outstanding, Basic and Diluted	62,457	51,082	62,371	49,807

1. This presentation includes non-GAAP measures. The Company's non-GAAP measures are not meant to be considered in isolation or as a substitute for comparable GAAP measures and should be read only in conjunction with its financial statements prepared in accordance with GAAP.
2. All stock-based compensation was excluded for the non-GAAP analysis.

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