Iovance Biotherapeutics Reports Third Quarter 2017 Financial Results

October 31, 2017

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

SAN CARLOS, Calif., Oct. 31, 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 third quarter 2017 financial results and provided a corporate update.

"In the third quarter of 2017 we continued to make significant progress in the clinic as the first patient was dosed with LN-145 in the Phase 2 trial for cervical cancer. Regulatory progress was demonstrated with the FDA granting Fast Track designation for LN-144 for the treatment of advanced melanoma and approval of a CTA by the competent authority in the Netherlands for the Phase 2 trial of LN-145 in cervical carcinoma," said Dr. Maria Fardis, Ph.D., MBA, President and Chief Executive Officer of Iovance Biotherapeutics. "On the corporate front, we successfully completed a common stock offering adding approximately $54.0 million in net proceeds to the cash reserves. In the fourth quarter of 2017, we look forward to sharing new clinical data from Cohort 2 of the C-144-01 metastatic melanoma trial and nonclinical data at the upcoming SITC meeting."

Third Quarter 2017 and Recent Highlights and Anticipated Milestones

Corporate News:

- **Appointed New Chief Financial Officer (CFO):** In August, Tim Morris was appointed CFO of Iovance. Mr. Morris brings over 22 years of experience related to the biopharmaceutical industry.

- **Completion of Public Offering:** In September, the Company completed a public offering of 8,846,154 shares of its common stock at a price of $6.50 per share, before underwriting discounts. The shares of common stock issued and sold in the offering at the closing include 1,153,846 shares issued upon the exercise in full by the underwriters of their option to purchase additional shares. The net proceeds from the offering, after deducting the underwriting discounts and commissions and other estimated offering expenses payable by Iovance, are approximately $54.0 million.

Clinical Trial Progress:

- **C-144-01 Phase 2 Trial in Metastatic Melanoma**: In October, preliminary data from Cohort 2 of the ongoing C-144-01 Phase 2 trial of LN-144 was accepted as a late-breaking abstract to be presented at the Society for Immunotherapy of Cancer (SITC) 2017 Annual Meeting.

- **First Patient Dosed in C-145-04 Phase 2 Trial in Cervical Cancer:** In August, the first patient was dosed in the C-145-04 Phase 2 trial of LN-145 for the treatment of patients with recurrent, metastatic or persistent cervical carcinoma.

Manufacturing Updates:

- **Partnership with TrakCel for Personalized Patient Product Management:** In September, Iovance commenced a partnership with TrakCel Ltd. to build a scheduling and logistics tool that automates the supply chain for Iovance's adoptive cell therapy products that utilize its TIL technology. The TrakCel Solution will electronically link Iovance with clinical sites, contract manufacturing organizations and couriers to schedule and track TIL therapies for each patient. The TrakCel Solution is intended to help manage capacity utilization and throughput as well as providing efficiencies in the delivery of TIL treatment.

Regulatory Updates:

- **Fast Track Designation Granted for LN-144:** In August, the U.S. Food and Drug Administration (FDA) granted Fast Track designation for LN-144, the Company's adoptive cell therapy using its TIL technology, for the treatment of advanced melanoma.
- **European Clinical Trial Applications (CTAs):** Iovance initiated the submission of CTAs in multiple countries in Europe starting in August 2017 in support of Phase 2 clinical trials of LN-145 in cervical carcinoma and LN-144 in metastatic melanoma. In September, the Company received the first approval from the competent authority in the Netherlands, for LN-145 for the treatment of patients with cervical carcinoma. Subsequent to the end of the quarter, the Company received CTA approvals in Hungary for metastatic melanoma and the United Kingdom for cervical carcinoma and metastatic melanoma.

Research Update and Data Presentations:

- **Research Collaboration Agreement with Ohio State University:** In September, the Company entered into a collaboration with the Ohio State University. The collaboration will initially focus on hematologic malignancies in areas of poor prognostic cancers with high unmet medical need, which include acute myeloid leukemia (AML) and chronic lymphocytic leukemia (CLL).
- **Poster Presentation at European Society for Medical Oncology (ESMO):** In August, the Company announced a poster presentation at the ESMO 2017 Congress in September with data that demonstrates the ability to produce TIL from lymphoma that have similar functionality as TIL generated from melanoma.

Third Quarter 2017 Financial and Operating Results

As of September 30, 2017, the Company held $163.4 million in cash and cash equivalents and short-term investments, compared to $166.5 million as of December 31, 2016.

The Company is 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-GAAP Net Loss Attributable to Common Stockholders

GAAP net loss attributable to common stockholders for the quarter ended September 30, 2017 was $22.1 million, or ($0.35) per share, compared to GAAP net loss of $68.2 million or ($1.15) per share for the quarter ended September 30, 2016.

Non-GAAP net loss attributable to common stockholders for the quarter ended September 30, 2017 was $19.5 million, or ($0.31) per share, compared to non-GAAP net loss of $10.1 million, or ($0.17) per share for the quarter ended September 30, 2016. The non-GAAP net loss for the quarters ended September 30, 2017 and September 30, 2016 excludes $2.6 million and $8.6 million of non-cash stock-based compensation, and a non-cash deemed dividend of $49.5 million which was recorded in the quarter ended September 30, 2016. The deemed dividend will only impact the prior years' quarter's financial statements.

GAAP net loss attributable to common stockholders for the nine months ended September 30, 2017 was $66.2 million, or ($1.06) per share, compared to GAAP net loss attributable to common stockholders of $86.7 million or ($1.64) per share for the nine months ended September 30, 2016. Non-GAAP net loss for the nine months ended September 30, 2017 was $57.0 million, or ($0.91) per share, compared to non-GAAP net loss of $21.4 million or ($0.40) per share for the nine months ended September 30, 2016.

GAAP and Non-GAAP Expenses

GAAP research and development (R&D) expenses were $17.8 million for the quarter ended September 30, 2017, an increase of $9.3 million compared to the quarter ended September 30, 2016. The increase in R&D expense is due to increased spending on clinical activities and manufacturing. In addition, R&D-associated stock based expenses were $1.1 million for the three months ended September 30, 2017 and $4.3 million for the nine months ended September 30, 2017. Non-GAAP R&D expenses were $16.7 million for the quarter ended September 30, 2017, an increase of $8.9 million, compared to $7.8 million for the quarter ended September 30, 2016.

GAAP general and administrative (G&A) expenses were $4.6 million for the quarter ended September 30, 2017, a decrease of $5.9 million compared to the quarter ended September 30, 2016. Non-GAAP G&A expenses were $3.0 million for the quarter ended September 30, 2017, an increase of $0.5 million, compared to $2.5 million for the quarter ended September 30, 2016.

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 items included in GAAP presentations but excluded for purposes of determining non-GAAP financial measures for the periods presented in this press release are: (i) 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, and (ii) the one-time non-cash deemed dividend related to the conversion feature of the Series B Preferred Stock. 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.

2017 Year End Guidance for Cash, Cash Equivalents and Short-Term Investments

Iovance anticipates the cash, cash equivalents and short-term investments as of December 31, 2017, to be in excess of $141.0 million.

Webcast and Conference Call

Iovance will host a conference call today at 4:30 p.m. ET to discuss these third 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 1423064. 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/q7762k6j.

A replay of the call will be available one hour after the end of the call on October 31, 2017 until 8:00 p.m. ET on November 30, 2017. To access the replay, please dial 1-855-859-2056 (domestic) or 1-404-537-3406 (international). The conference ID number for the replay is 1423064. 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 events or 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 of our ongoing clinical trials and anticipated clinical trials for our 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; 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 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 events or circumstance.

Investor Relations Contact:
Sarah McCabe
Stern Investor Relations, Inc.
212-362-1200
sarah@sternir.com

Media Relations Contact:
Evan Smith
FTI Consulting
212-850-5622
evan.smith@fticonsulting.com

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

	September 30, 2017	*December 31, 2016*
Cash, cash equivalents and short-term investments	$ 163,380	$ 166,470
Total assets	$ 173,970	$ 171,886
Stockholders' equity	$ 165,441	$ 166,918

Condensed Consolidated Statements of Operations
(unaudited; in thousands, except per share data)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2017	**2016**	**2017**	**2016**
Revenues	$ -	$ -	$ -	$ -
Costs and expenses*				
Research and development	17,753	8,481	54,029	17,200

General and administrative	4,590	10,498	12,777	20,517
Total costs and expenses	22,343	18,979	66,806	37,717
Loss from operations	(22,343)	(18,979)	(66,806)	(37,717)
Other income				
Interest income	194	221	596	511
Net Loss	$ (22,149)	$ (18,758)	$ (66,210)	$ (37,206)
Deemed dividend related to beneficial conversion feature of convertible preferred stock	-	(49,454)	-	(49,454)
Net Loss Attributable to Common Stockholders	(22,149)	(68,212)	(66,210)	(86,660)
Net Loss Per Common Share, Basic and Diluted	$ (0.35)	$ (1.15)	$ (1.06)	$ (1.64)
Weighted-Average Common Shares Outstanding, Basic and Diluted	63,332	59,113	62,697	52,963
*** Includes stock-based compensation as follows**				
Research and development	$ 1,053	$ 640	$ 4,336	$ 1,818
General and administrative	1,566	8,005	4,872	13,963
	$ 2,619	$ 8,645	$ 9,208	$ 15,781

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2017	**2016**	**2017**	**2016**
Reconciliation of GAAP to non-GAAP Research and development				
GAAP Research and development	$ 17,753	$ 8,481	$ 54,029	$ 17,200
Less:				
Non-cash stock-based compensation (2)	(1,053)	(640)	(4,336)	(1,818)
Non-GAAP Research and development	$ 16,700	$ 7,841	$ 49,693	$ 15,382
Reconciliation of GAAP to non-GAAP General and administrative				
GAAP General and administrative	$ 4,590	$ 10,498	$ 12,777	$ 20,517
Less:				
Non-cash stock-based compensation (2)	(1,566)	(8,005)	(4,872)	(13,963)
Non-GAAP General and administrative	$ 3,024	$ 2,493	$ 7,905	$ 6,554
Non-GAAP Net loss reconciliation				
GAAP Net loss	$ (22,149)	$ (68,212)	$ (66,210)	$ (86,660)
Add back:				
Non-cash stock-based compensation (2)	2,619	8,645	9,208	15,781
Non-cash Deemed dividend related to beneficial conversion feature of convertible preferred stock (3)	-	49,454	-	49,454
Non-GAAP Net loss	$ (19,530)	$ (10,113)	$ (57,002)	$ (21,425)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2017	2016	2017	2016
Non-GAAP net loss per share reconciliation				
GAAP net loss per basic and diluted share:	$ (0.35)	$ (1.15)	$ (1.06)	$ (1.64)
Add back:				
Non-cash stock-based compensation [2]	0.04	0.15	0.15	0.30
Non-cash Deemed dividend related to beneficial conversion feature of convertible preferred stock [3]	-	0.83	-	0.94
Non-GAAP net loss per basic and diluted share	$ (0.31)	$ (0.17)	$ (0.91)	$ (0.40)
Weighted-Average Common Shares Outstanding, Basic and Diluted	63,332	59,113	62,697	52,963

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.
3. The deemed dividend related to the conversion feature of the Series B Preferred Stock was excluded for non-GAAP analysis.