Iovance Biotherapeutics Reports Third Quarter and Year-to-Date 2021 Financial Results and Corporate Updates

November 4, 2021

Advancing TIL Platform in Multiple Solid Tumors and Treatment Settings

SAN CARLOS, Calif., Nov. 04, 2021 (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 third quarter and year-to-date 2021 financial results and corporate updates.

Frederick Vogt, Ph.D., J.D., Interim President and Chief Executive Officer of Iovance, stated, “During 2021, we have continued to report long-term clinical data demonstrating the durability of one-time treatment with lifileucel in metastatic melanoma while broadening the potential for TIL cell therapy to address more patients in additional indications and treatment settings. We look forward to highlighting our TIL cell therapy platform at the upcoming Society for Immunotherapy of Cancer annual meeting. Our top priority remains our ongoing work to address feedback from the U.S. Food and Drug Administration (FDA) regarding the potency assays for lifileucel to support our planned biologics license application (BLA) submission. We remain increasingly confident in the broad potential for TIL as the next class of paradigm-shifting therapy for cancer patients with significant unmet need.”

Third Quarter 2021 Highlights and Recent Corporate Updates

Regulatory

- **Potency assays for lifileucel:** Following FDA feedback regarding the potency assays for lifileucel, Iovance has continued ongoing work developing and validating its potency assays and has engaged in discussions with the FDA during the second half of 2021. The anticipated BLA submission for lifileucel continues to be planned for the first half of 2022. Resolution of the potency assay for lifileucel in melanoma is also a key step towards our regulatory plans in other indications.
- **U.S. FDA Fast Track designation for lifileucel in combination with pembrolizumab in metastatic melanoma**: The FDA granted Fast Track designation for lifileucel in combination with pembrolizumab for the treatment of metastatic melanoma based on the unmet medical need and potential advantages for this combination over available care. Fast Track designation allows for potential Accelerated Approval and Priority Review as well as more frequent interactions with the FDA.

Clinical

- **TIL therapy in combination with pembrolizumab in advanced solid tumor cancers:** Iovance is investigating TIL in combination with pembrolizumab in earlier treatment settings in metastatic melanoma, cervical cancer, non-small cell lung cancer (NSCLC), and head and neck squamous cell carcinoma (HNSCC) patients who are naïve to therapy with immune checkpoint inhibitors (ICI). Data for certain indications for TIL in combination with pembrolizumab will be highlighted in an oral presentation at the upcoming SITC annual meeting. Early clinical data previously presented in metastatic melanoma (ASCO 2021) and HNSCC (SITC 2020) suggest that the response rate for TIL in combination with pembrolizumab may be increased in patients who are ICI-naïve.
- **TIL therapy in NSCLC**:
  - **LN-145 clinical data in metastatic NSCLC (mNSCLC)**: Detailed results from Cohort 3B in the IOV-COM-202 study will be highlighted in a poster presentation at the SITC annual meeting. As previously reported, clinical data for LN-145 showed a 21.4% overall response rate (ORR) and 64.3% disease control rate in heavily pretreated mNSCLC patients who received one or more prior systemic therapies, including anti-PD-1 therapy.
  - **LN-145 in second-line mNSCLC:** Enrollment is ongoing and more than 20 clinical sites are activated in the U.S. and Canada for the IOV-LUN-202 study of LN-145 in patients with mNSCLC.

Research

- Iovance continues to advance the next generation of TIL and related therapies and technologies. Late preclinical programs in investigational new drug (IND)-enabling studies include a novel IL-2 analog (IOV-3001) as well as a genetically modified TIL (IOV-4001). IOV-4001 leverages TALEN technology licensed from Cellectis S.A. to inactivate PD-1 expression by the TIL product.
- Iovance and the National Institutes of Health (NIH) extended their Cooperative Research and Development Agreement (CRADA) through August 2024. The CRADA focuses on emerging areas of translational and clinical research for TIL therapies.

Manufacturing

- **TIL manufacturing success:** To date, more than 500 patients have been dosed with Iovance TIL products with more than a 90 percent manufacturing success rate.
- **Iovance Cell Therapy Center (*i*CTC)**: Clinical manufacturing of TIL commenced at the *i*CTC in September of 2021. Commercial manufacturing remains on track to commence with a potential regulatory approval. The *i*CTC achieved LEED Gold Certification through the U.S. Green Building Council (USGBC).

Corporate

- Cash position of $660.8 million at September 30, 2021 is expected to be sufficient well into 2023.
- A strong organization of more than 300 employees with an average of more than 3.5 years of cell therapy experience is in place to advance research, development, manufacturing, and commercial launch preparations.
- Iovance continues to expand its intellectual property portfolio and currently owns more than 30 granted or allowed U.S. and international patents for TIL compositions and methods of treatment and manufacturing in a broad range of cancers. Iovance's Gen 2 patent rights are expected to provide exclusivity through 2038. Iovance's portfolio also includes patent applications and granted patents directed towards Gen 3 manufacturing, selected TIL products, stable and transient genetic TIL modifications, tumor digest and fragment compositions and methods (including cryopreservation), and combinations of checkpoint inhibitors and TIL products.

Third Quarter and Year-to-Date 2021 Financial Results

Iovance has $660.8 million in cash, cash equivalents, investments and restricted cash at September 30, 2021 compared to $635.0 million at December 31, 2020. The cash position is expected to be sufficient to fund current and planned operations well into 2023.

Jean-Marc Bellemin, Chief Financial Officer, stated, "With the continued strength of our balance sheet and focused investment on pipeline development and launch preparations, we are well positioned to execute our operating plan with no immediate need to raise additional capital. Following completion of the *i*CTC, we have also concluded our initial $85 million investment in constructing the facility."

Net loss for the third quarter ended September 30, 2021, was $86.1 million, or $0.55 per share, compared to a net loss of $58.6 million, or $0.40 per share, for the third quarter ended September 30, 2020. Net loss for the nine months ended September 30, 2021, was $242.9 million, or $1.60 per share, compared to a net loss of $191.2 million, or $1.41 per share, for the same period ended September 30, 2020.

Research and development expenses were $65.4 million for the third quarter ended September 30, 2021, an increase of $22.3 million compared to $43.1 million for the third quarter ended September 30, 2020. Research and development expenses were $183.4 million for the nine months ended September 30, 2021, an increase of $34.1 million compared to $149.3 million for the same period ended September 30, 2020.

The increase in research and development expenses in the third quarter 2021 over the prior year period was primarily attributable to an increase in costs associated with growth of the internal research and development team and increases in clinical trial costs and *i*CTC facility related costs. The increase in research and development expenses in the first nine months of 2021 over the prior year period was primarily attributable to growth of the internal research and development team and an increase in *i*CTC facility related costs.

General and administrative expenses were $20.9 million for the third quarter ended September 30, 2021, an increase of $5.0 million compared to $15.9 million for the third quarter ended September 30, 2020. General and administrative expenses were $59.8 million for the nine months ended September 30, 2021, an increase of $15.7 million compared to $44.1 million for the same period ended September 30, 2020.

The increases in general and administrative expenses in the third quarter and first nine months of 2021 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 third quarter 2021 financial results and corporate updates. The conference call dial-in numbers are 1-(844) 646-4465 (domestic) or 1-(615) 247-0257 (international) and the access code is 7286232. 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 be the global leader in innovating, developing and delivering tumor infiltrating lymphocyte (TIL) cell therapies for patients with cancer. We are pioneering a transformational approach to cure cancer by harnessing the human immune system's ability to recognize and destroy diverse cancer cells in each patient. Our lead late-stage TIL product candidate, lifileucel for metastatic melanoma, has the potential to become the first approved one-time cell therapy for a solid tumor cancer. The Iovance TIL platform has demonstrated promising clinical data across multiple solid tumors. We are committed to continuous innovation in cell therapy, including gene-edited cell therapy, that may extend and improve life for patients with cancer.
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, 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. Forward-looking statements are based on assumptions and assessments made in light of management’s experience and perception of historical trends, current conditions, expected future developments and other factors believed to be appropriate. Forward-looking statements in this press release are made as of the date of this press release, and we undertake no duty to update or revise any such statements, whether as a result of new information, future events or otherwise. Forward-looking statements are not guarantees of future performance and are subject to risks, uncertainties and other factors, many of which are outside of our control, 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. Important factors that could cause actual results, developments and business decisions to differ materially from forward-looking statements are described in the sections titled "Risk Factors" in our filings with the Securities and Exchange Commission, including our most recent Annual Report on Form 10-K and Quarterly Reports on Form 10-Q, and include, but are not limited to, the following substantial known and unknown risks and uncertainties inherent in our business: the effects of the COVID-19 pandemic; risks related to the timing of and our ability to successfully develop, submit, obtain and maintain U.S. Food and Drug Administration (“FDA”) or other regulatory authority approval of, or other action with respect to, our product candidates, and our ability to successfully commercialize any product candidates for which we obtain FDA approval; preliminary and interim clinical results, which may include efficacy and safety results, from ongoing clinical trials or cohorts may not be reflected in the final analyses of our ongoing clinical trials or subgroups within these trials or in other prior trials or cohorts; the risk that enrollment may need to be adjusted for our 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 our cervical cancer trial may have an adverse effect on the results reported to date; the risk 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 our interpretation of the results of our clinical trials or communications with the FDA may differ from the interpretation of such results or communications by the FDA; the acceptance by the market of our product candidates and their potential reimbursement by payors, if approved; our ability or inability to manufacture our therapies using third party manufacturers or our own facility may adversely affect our potential commercial launch; the results of clinical trials with collaborators using different manufacturing processes may not be reflected in our sponsored trials; the risk that unanticipated expenses may decrease our estimated cash balances and forecasts and increase our estimated capital requirements; and other factors, including general economic conditions and regulatory developments, not within our control.

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

	September 30, 2021 (Unaudited)	December 31, 2020
Cash, cash equivalents, and investments	$ 654,696	$ 629,437
Restricted cash	$ 6,084	$ 5,525
Total assets	$ 828,825	$ 768,458
Stockholders' equity	$ 698,330	$ 656,498

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2021	2020	2021	2020
Costs and expenses*				
Research and development	$ 65,355	$ 43,050	$ 183,423	$ 149,276
General and administrative	20,887	15,916	59,815	44,127
Total costs and expenses	86,242	58,966	243,238	193,403
Loss from operations	(86,242)	(58,966)	(243,238)	(193,403)
Other income				
Interest income, net	120	395	316	2,219
Net Loss	$ (86,122)	$ (58,571)	$ (242,922)	$ (191,184)
Net Loss Per Share of Common Stock, Basic and Diluted	$ (0.55)	$ (0.40)	$ (1.60)	$ (1.41)

Weighted-Average Shares of Common Stock Outstanding, Basic and Diluted	155,508	146,492	152,221	135,457

*** Includes stock-based compensation as follows**				
Research and development	$ 11,504	$ 5,282	$ 29,291	$ 15,065
General and administrative	7,802	5,424	21,370	15,590
	$ 19,306	$ 10,706	$ 50,661	$ 30,655

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