Iovance Biotherapeutics Reports Third Quarter and Year-to-Date 2022 Financial Results and Corporate Updates

November 3, 2022

First Biologics License Application (BLA) Submission Initiated and on Track to Complete in 4Q22

SAN CARLOS, Calif., Nov. 03, 2022 (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 2022 financial results and corporate updates.

Frederick Vogt, Ph.D., J.D., Interim President and Chief Executive Officer of Iovance, stated, “Iovance has made tremendous progress year-to-date. With our rolling BLA submission for lifileucel and six active clinical trials of TIL therapy underway, we are executing our mission to innovate, develop and deliver TIL therapy for patients with cancer. We are on track to complete our BLA submission in the fourth quarter. As we prepare for our first potential FDA approval and commercial launch and advance our pipeline and technology platforms, we believe we have multiple opportunities to create significant value for patients with cancer as well as for our shareholders.”

Third Quarter 2022 Highlights and Recent Corporate Updates

Regulatory and Clinical Updates for Iovance TIL Therapy (Lifileucel) in Advanced Melanoma

- **BLA Submission:** A rolling BLA submission for lifileucel in advanced melanoma (post-anti-PD-1 therapy) commenced in August 2022 and is anticipated to complete in the fourth quarter of 2022.

- **C-144-01 Trial Presentation and Poster at Society for Immunotherapy of Cancer (SITC):** Iovance reported positive topline clinical data from Cohorts 2 and 4 of the C-144-01 clinical trial in advanced melanoma in the second quarter of 2022. A pooled analysis and additional results for Cohorts 2 and 4 will be presented during SITC's 37 th Annual Meeting as well as a Webcast on November 10, 2022.

- **Phase 3 trial in frontline advanced melanoma:** Iovance remains on track to begin the Phase 3 trial of lifileucel in combination with pembrolizumab in frontline advanced melanoma in late 2022. The Phase 3 trial is intended to expand the opportunity for lifileucel as an earlier treatment and serve as a confirmatory study.

- **Poster at European Society for Medical Oncology (ESMO) Congress 2022:** A poster at ESMO highlighted the potential for lifileucel in advanced melanoma patients who progress after anti-LAG-3 and anti-PD-1 combination therapy. Lifileucel response rates were consistent between the overall C-144-01 study population and a C-144-01 subgroup analysis of patients treated with prior anti-LAG-3 containing therapy.

Manufacturing and Commercial Preparations

- The Iovance Cell Therapy Center (*i*CTC) is currently operating flex suites for clinical manufacturing and core suites for activities to support BLA submission and review, including pre-approval inspections, in preparation for commercial supply.

- The *i*CTC facility as currently built has annual capacity to supply TIL therapies for 2,000+ patients, with flexibility to build out existing shell space to supply 5,000+ patients.

- Contract manufacturers provide additional flexibility and capacity for Iovance to meet potential commercial and clinical demand, including a new agreement for two cGMP manufacturing suites for commercial manufacturing and supply.

- Iovance is executing several initiatives ahead of potential commercialization in 2023, including on-boarding and personnel training at authorized treatment centers (ATCs), education and awareness, and other launch readiness activities.

Clinical Pipeline

- **Iovance TIL therapy (LN-145) in mNSCLC:** Enrollment is ongoing at more than 40 active clinical sites in the U.S., Canada and Europe for the IOV-LUN-202 trial of LN-145 in patients with mNSCLC. Iovance is engaged in discussions with the FDA about the potential for IOV-LUN-202 to serve as a registrational trial for LN-145 in mNSCLC and intends to execute an updated regulatory strategy based on this dialogue and feedback.

- **Iovance PD-1 inactivated TIL therapy (IOV-4001) in previously treated advanced melanoma or mNSCLC:** the first patient was dosed, and completed the safety observation period, in the IOV-GM1-201 trial of IOV-4001, Iovance's first genetically modified TIL therapy. To inactivate the gene coding for the PD-1 protein, IOV-4001 utilizes the gene editing TALEN® technology licensed from Cellectis.

- **Lifileucel in advanced cervical cancer:** Iovance expanded Cohort 2 of the ongoing C-145-04 trial to enroll additional patients. Following FDA discussions and feedback, Cohort 2 is intended to support a BLA in cervical cancer following progression on chemotherapy and pembrolizumab.

Research Programs for Next-Generation TIL Therapies and Related Technologies

- Additional research and preclinical studies focused on optimizing TIL therapy consist of several targets for genetic modification using the gene-editing TALEN® technology, including double genetic knock-out programs, as well as approaches to increase TIL potency using CD39/69 double negative TILs and gene knock-in targets that incorporate enhancements such as tethered cytokines.

- A novel interleukin-2 (IL-2) analog (IOV-3001) is in IND-enabling studies supporting its use as part of the TIL treatment regimen following TIL infusion.

Corporate

- Cash position of $366.6 million at September 30, 2022 is expected to be sufficient into 2024.

- Iovance currently owns at least 60 granted or allowed U.S. and international patents for TIL compositions and methods of treatment and manufacturing in a broad range of cancers, with Gen 2 patent rights expected to provide exclusivity into 2038. More information on Iovance's patent portfolio can be found on the Intellectual Property page on www.iovance.com.

Third Quarter and Year-to-Date 2022 Financial Results

Iovance had $366.6 million in cash, cash equivalents, investments and restricted cash at September 30, 2022, compared to $602.1 million at December 31, 2021. The cash position is expected to be sufficient to fund current and planned operations into 2024.

Jean-Marc Bellemin, Chief Financial Officer of Iovance, said, "As a late-stage oncology company approaching potential commercialization, our cash position continues to support our prudent investments in commercial launch preparations, internal manufacturing and pipeline expansion into several milestones to create value for patients and shareholders."

Net loss for the third quarter ended September 30, 2022, was $99.6 million, or $0.63 per share, compared to a net loss of $86.1 million, or $0.55 per share, for the third quarter ended September 30, 2021. Net loss for the nine months ended September 30, 2022, was $290.6 million, or $1.85 per share, compared to a net loss of $242.9 million, or $1.60 per share, for the same period ended September 30, 2021.

Research and development expenses were $72.5 million for the third quarter ended September 30, 2022, an increase of $7.1 million compared to $65.4 million for the same period ended September 30, 2021. Research and development expenses were $214.2 million for the nine months ended September 30, 2022, an increase of $30.8 million compared to $183.4 million for the same period ended September 30, 2021.

The increases in research and development expenses in the third quarter and year-to-date 2022 over the prior year periods were primarily attributable to growth of the internal research and development team, including stock-based compensation expense, as well as facility-related and internal research program costs, which were partially offset by lower clinical and manufacturing costs driven by completion of enrollment of pivotal clinical trials.

General and administrative expenses were $27.9 million for the third quarter ended September 30, 2022, an increase of $7.0 million compared to $20.9 million for the same period ended September 30, 2021. General and administrative expenses were $77.6 million for the nine months ended September 30, 2022, an increase of $17.8 million compared to $59.8 million for the same period ended September 30, 2021.

The increase in general and administrative expenses in the third quarter and year-to-date 2022 compared to the prior year periods were primarily attributable to growth of the internal general and administrative and commercial teams, including stock-based compensation expense, and facility-related costs associated with the build-out of the new corporate headquarters, as well as costs associated with pre-commercial activities.

For additional information, please see the Company's Selected Condensed Consolidated Balance Sheet and Statement of Operations below.

Webcast and Conference Call

To participate in the conference call, please register at https://register.vevent.com/register/BI4721983fb77a4615b46f4ab97c051712. The live and archived webcast can be accessed in the Investors section of the Company's website, IR.Iovance.com. The archived webcast will also be available for one year.

About Iovance Biotherapeutics, Inc.

Iovance Biotherapeutics aims to be the global leader in innovating, developing and delivering tumor infiltrating lymphocyte (TIL) 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; whether clinical trial results from our pivotal studies and cohorts may support registration and approval by the FDA; 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 changing landscape of care for cervical cancer patients may impact our clinical trials in this indication; 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 (including from the recent pre-BLA meeting with the FDA); the risk that the rolling BLA submission for lifileucel in metastatic melanoma may take longer than expected; 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 Sheet Information
(In thousands)

	September 30, 2022	December 31, 2021
	(Unaudited)	
Cash, cash equivalents, and investments	$ 360,173	$ 595,998
Restricted cash	$ 6,430	$ 6,084
Total assets	$ 545,924	$ 777,333
Stockholders' equity	$ 393,736	$ 621,659

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,	
	2022	2021	2022	2021
Costs and expenses*				
Research and development	$ 72,502	$ 65,355	$ 214,208	$ 183,423
General and administrative	27,893	20,887	77,634	59,815
Total costs and expenses	100,395	86,242	291,842	243,238

Loss from operations	(100,395)	(86,242)	(291,842)	(243,238)
Other income				
Interest income, net	777	120	1,268	316
Net Loss	$ (99,618)	$ (86,122)	$ (290,574)	$ (242,922)
Net Loss Per Share of Common Stock, Basic and Diluted	$ (0.63)	$ (0.55)	$ (1.85)	$ (1.60)
Weighted Average Shares of Common Stock Outstanding, Basic and Diluted	157,817	155,508	157,404	152,221
*** Includes stock-based compensation as follows:**				
Research and development	$ 11,272	$ 11,504	$ 38,863	$ 29,291
General and administrative	8,508	7,802	25,650	21,370
	$ 19,780	$ 19,306	$ 64,513	$ 50,661

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