Iovance Biotherapeutics Reports Second Quarter and First Half 2022 Financial Results and Corporate Updates

August 4, 2022

First Biologics License Application (BLA) Submission on Track in August 2022

SAN CARLOS, Calif., Aug. 04, 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 second quarter and first half 2022 financial results and corporate updates.

Frederick Vogt, Ph.D., J.D., Interim President and Chief Executive Officer of Iovance, stated, “Iovance continues to solidify our global leadership across all three aspects of our mission to innovate, develop and deliver TIL therapy for patients with cancer. During the second quarter we executed toward our top priority, to submit the BLA for lifileucel in metastatic melanoma, while preparing for commercialization and advancing our robust immuno-oncology pipeline. Following our recent pre-BLA meeting in late July, we are finalizing our BLA to begin submission this month. With many opportunities to create significant value for cancer patients and our shareholders, Iovance is a true pioneer in the industry, driven by our experienced executive leadership team and talented organization with deep cell therapy experience.”

Second Quarter 2022 Highlights and Recent Corporate Updates

Regulatory

- **Iovance TIL therapy (lifileucel) in metastatic melanoma (post-anti-PD-1):** Iovance held a successful pre-BLA meeting with the U.S. Food and Drug Administration (FDA) in late July 2022. The FDA provided favorable feedback on the clinical efficacy data from Cohorts 2 and 4 of the C-144-01 clinical trial, including duration of follow up, and the potency assay matrix. The FDA agreed the clinical and safety dataset was sufficient for BLA review. Iovance will commence a rolling BLA submission for lifileucel in metastatic melanoma this month and complete the submission during the fourth quarter.

Clinical

- **Iovance TIL therapy (lifileucel) in metastatic melanoma:**
  - **Positive clinical data in advanced (post-anti-PD-1) metastatic melanoma:** Iovance reported positive clinical data from the C-144-01 clinical trial and plans to present additional results at a medical meeting in the second half of 2022.
  - **Frontline (anti-PD-1 naïve) metastatic melanoma:** Iovance remains on track to open a Phase 3 trial of lifileucel in combination with pembrolizumab in frontline metastatic melanoma in late 2022. The trial is intended to expand the opportunity for lifileucel as an earlier treatment and serve as a confirmatory study for C-144-01 clinical trial Cohort 4.
  - **Poster at American Society of Clinical Oncology (ASCO) Annual Meeting:** A translational science poster highlighting the potential for lifileucel to benefit patients with melanoma regardless of immune checkpoint inhibitor (ICI) exposure and independent of tumor biomarkers of mutational burden, single-gene mutations, or inflammation.

- **Iovance TIL therapy (LN-145) in second-line mNSCLC:** Enrollment is ongoing at more than 30 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.

- **First in human trial of genetically modified Iovance TIL therapy IOV-4001:** site activation and patient recruitment are underway in the IOV-GM1-201 clinical trial of Iovance’s first genetically modified TIL therapy, IOV-4001, for the treatment of previously treated advanced melanoma or mNSCLC. IOV-4001 leverages the gene editing TALEN® technology licensed from Cellectis to inactivate PD-1 expression.

- **Iovance TIL therapy (lifileucel) in advanced cervical cancer:** Following FDA discussions and feedback on a registration strategy to address the shift in frontline standard of care, Iovance plans to reopen Cohort 2 of the ongoing C-145-04 trial to enroll additional patients who have received prior anti-PD-1 therapy. The expanded 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

- Several targets for genetic modification using the gene-editing TALEN® technology, including double genetic knock-out programs, are advancing in preclinical development.

- Additional research and preclinical studies include approaches to increase TIL potency using CD39/69 double negative TILs and gene knock-in targets as well as development of a novel interleukin-2 (IL-2) analog (IOV-3001).

Manufacturing

- The Iovance Cell Therapy Center (*i*CTC) is currently operating flex suites for clinical manufacturing and core suites for BLA readiness activities.

- Iovance is building capacity to treat thousands of cancer patients annually, with capacity at *i*CTC for 2,000+ patients and flexibility to expand existing shell space to supply 5,000+ patients per year.

Corporate

- Iovance entered into an amendment to its license agreement with the National Institutes of Health (NIH) to include additional exclusive, worldwide patent rights to TIL products expressing IL-12, expanded rights to TIL selection technologies, and additional non-exclusive, worldwide patent rights to certain technologies related to enhancing TIL potency.

- Cash position of $430.9 million at June 30, 2022 is expected to be sufficient into 2024.

- Iovance currently owns more than 50 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.

Second Quarter and First Half 2022 Financial Results

Iovance had $430.9 million in cash, cash equivalents, investments and restricted cash at June 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, we continue to maintain a strong balance sheet through prudent investments in commercial launch preparations, internal manufacturing and pipeline expansion. Our cash position is expected to take us through several milestones to create value for patients and shareholders."

Net loss for the second quarter ended June 30, 2022, was $99.3 million, or $0.63 per share, compared to a net loss of $81.4 million, or $0.53 per share, for the second quarter ended June 30, 2021. Net loss for the six months ended June 30, 2022, was $191.0 million, or $1.21 per share, compared to a net loss of $156.8 million, or $1.04 per share, for the same period ended June 30, 2021.

Research and development expenses were $73.4 million for the second quarter ended June 30, 2022, an increase of $11.3 million compared to $62.1 million for the same period ended June 30, 2021. Research and development expenses were $141.7 million for the six months ended June 30, 2022, an increase of $23.6 million compared to $118.1 million for the same period ended June 30, 2021.

The increases in research and development expenses in the second quarter and first half of 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 $26.3 million for the second quarter ended June 30, 2022, an increase of $7.0 million compared to $19.3 million for the same period ended June 30, 2021. General and administrative expenses were $49.7 million for the six months ended June 30, 2022, an increase of $10.8 million compared to $38.9 million for the same period ended June 30, 2021.

The increase in general and administrative expenses in the second quarter and first half of 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, 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/BI25a798dba7074946a0aa3082d603bf41. 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 Data
(in thousands)

	June 30, 2022 (Unaudited)	December 31, 2021
Cash, cash equivalents, and investments	$ 424,458	$ 595,998
Restricted cash	$ 6,430	$ 6,084
Total assets	$ 610,878	$ 777,333
Stockholders' equity	$ 472,690	$ 621,659

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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2022	2021	2022	2021
Costs and expenses*				
Research and development	$ 73,406	$ 62,119	$ 141,706	$ 118,068
General and administrative	26,328	19,307	49,741	38,928
Total costs and expenses	99,734	81,426	191,447	156,996
Loss from operations	(99,734)	(81,426)	(191,447)	(156,996)
Other income				
Interest income, net	385	75	491	196
Net Loss	$ (99,349)	$ (81,351)	$ (190,956)	$ (156,800)
Net Loss Per Share of Common Stock, Basic and Diluted	$ (0.63)	$ (0.53)	$ (1.21)	$ (1.04)

Weighted-Average Shares of Common Stock Outstanding, Basic and Diluted	157,274	153,751	157,194	150,571
***Includes stock-based compensation as follows:**				
Research and development	$ 13,940	$ 8,585	$ 27,591	$ 17,787
General and administrative	8,528	5,829	17,142	13,568
Total costs and expenses	$ 22,468	$ 14,414	$ 44,733	$ 31,355

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