Iovance Biotherapeutics Reports Second Quarter and First Half 2023 Financial Results and Corporate Updates

August 8, 2023

FDA Priority Review of Biologics License Application (BLA) on Track for Lifileucel in Advanced Melanoma with Prescription Drug User Fee Act (PDUFA) Action Date of November 25, 2023

Preparing for Potential Commercial Launch of Lifileucel as First Approved TIL Therapy in 2023

Post-Anti-PD-1 Non-Small Cell Lung Cancer TIL Program Advances into Registrational Development

SAN CARLOS, Calif., Aug. 08, 2023 (GLOBE NEWSWIRE) -- Iovance Biotherapeutics, Inc. (NASDAQ: IOVA), a biotechnology company focused on innovating, developing and delivering novel polyclonal tumor infiltrating lymphocyte (TIL) therapies for patients with cancer, today reported second quarter and first half 2023 financial results and corporate updates.

Frederick Vogt, Ph.D., J.D., Interim President and Chief Executive Officer of Iovance, stated, “Iovance is making significant progress in executing on our goals. The Priority Review of our BLA for lifileucel in advanced melanoma remains on track and continues to progress well as we work collaboratively with FDA and approach a potential approval and launch this year. We acquired Proleukin®, which will provide revenue, streamline our supply chain and logistics, reduce our future cost of goods and lower expenses for IL-2 used with TIL therapies. We are also excited about our NSCLC pipeline, with a registrational trial and positive preliminary data in post-anti-PD-1 patients and the upcoming full data presentation for TIL therapy in combination with pembrolizumab in ICI naïve patients. We are well positioned to execute on our regulatory, pipeline, manufacturing and commercial launch activities to advance our mission to be the global leader in TIL therapy.”

Recent and Second Quarter 2023 Highlights and Corporate Updates

Iovance TIL Therapy (Lifileucel) in Advanced Melanoma
Regulatory Highlights

- The U.S. Food and Drug Administration (FDA) accepted the Biologics License Application (BLA) for lifileucel for patients with advanced melanoma. The FDA granted lifileucel Priority Review and assigned November 25, 2023, as the target action date for a decision under the Prescription Drug User Fee Act (PDUFA).
- The first patient was randomized in the registrational Phase 3 global TILVANCE-301 trial to support accelerated and full approvals of lifileucel in combination with pembrolizumab in frontline advanced melanoma. TILVANCE-301, which is also a confirmatory trial to support full approval of lifileucel in post-anti-PD-1 advanced melanoma, is expected to be well underway at the time of potential accelerated approval for lifileucel in this initial indication.

Manufacturing and Commercial Preparations

- To date, more than 600 patients have been treated with Iovance TIL therapy manufactured using proprietary Iovance processes, with a manufacturing success rate of more than 90%.
- The Iovance Cell Therapy Center (*i*CTC) is currently manufacturing TIL therapies for clinical trials while executing activities to support BLA review, including pre-approval inspection readiness, in preparation for initiating commercial supply.
- The *i*CTC facility currently has annual capacity to supply TIL therapies for 2,000+ patients, with buildable shell space to ultimately supply TIL therapies for 5,000+ patients from this facility. Iovance has additional flexibility and capacity through contract manufacturers to meet potential commercial and clinical demand.
- Several initiatives are underway ahead of potential commercialization, including on-boarding and personnel training at Authorized Treatment Centers (ATCs), patient access, education and awareness, and other commercial launch readiness activities.

Iovance TIL Therapy Programs in Advanced Non-Small Cell Lung Cancer (NSCLC)

- **Registrational Phase 2 Trial IOV-LUN-202 in Post-Anti-PD- 1 NSCLC:**
  - At a Type B Pre-Phase 3 meeting, the FDA provided positive regulatory feedback that the design of the single-arm Phase 2 IOV-LUN-202 trial may be acceptable for approval of LN-145 TIL therapy in post-anti-PD-1 NSCLC. Based on the regulatory discussions, Iovance completed a preliminary analysis and plans to enroll a total of approximately 120 patients into the registrational IOV-LUN-202 trial.
  - In a preliminary analysis of IOV-LUN-202, ORR was 26.1% by RECIST v1.1 (n=6, one complete response and five partial responses). All responses remained ongoing at the data cut off and the median duration of response (DOR) was not reached (1.4+ to 9.7+ months).

- Enrollment in IOV-LUN-202 is ongoing at more than 40 active clinical sites in the U.S., Canada and Europe, and is expected to complete in the second half of 2024.

- **Iovance TIL Therapy in combination with anti-PD-1 in frontline advanced NSCLC:**
  - Detailed results from Cohort 3A of the IOV-COM-202 clinical trial will be presented at an oral session during the IASLC 2023 World Congress on Lung Cancer (WCLC 2023). Cohort 3A explores the combination of TIL therapy (LN-145) and pembrolizumab in anti-PD-1 naïve advanced NSCLC patients.
  - Iovance plans a meeting with the FDA in 2023 to discuss Cohort 3A results and a potential registrational trial of lifileucel in combination with pembrolizumab after standard of care chemotherapy to support accelerated approval in frontline advanced NSCLC and to serve as the confirmatory trial for IOV-LUN-202.

Additional Clinical Pipeline Highlights

- **Iovance PD-1 inactivated TIL therapy (IOV-4001) in previously treated advanced melanoma or mNSCLC:** The ongoing IOV-GM1-201 trial of Iovance's first genetically modified TIL therapy, IOV-4001, is among the first clinical trials of a genetically modified TIL cell therapy for solid tumors.
- **Lifileucel in advanced cervical cancer:** Additional patients continued to enroll in pivotal Cohort 2 in the ongoing C-145-04 trial to support a BLA in cervical cancer following progression on or after chemotherapy and pembrolizumab.

Research Programs for Next-Generation TIL Therapies and Related Technologies

- Additional programs using the gene editing TALEN® technology are on track to enter clinical development in 2024, including genetically modified TIL therapy with multiple inactivated checkpoint targets.
- Additional research and preclinical studies are exploring approaches to increase TIL potency using CD39/69 double negative TILs and stable gene incorporation 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 Updates

- Iovance completed the acquisition of worldwide rights to Proleukin® (aldesleukin) from Clinigen Limited in May of 2023. Proleukin is an interleukin-2 (IL-2) product with uses that include administration following TIL infusion to promote T-cell activity. Iovance expects Proleukin to provide revenue, secure the IL-2 supply chain and logistics surrounding TIL therapy administration, and lower cost of goods and clinical trial expenses for Proleukin used with TIL therapies.
- As of June 30, 2023, Iovance's cash position was approximately $317.3 million. In July of 2023, Iovance raised estimated net proceeds from a common stock public offering of approximately $161.4 million. Inclusive of the net proceeds from the offering, the current cash position is expected to fund Iovance's operating plan into the end of 2024.
- Iovance currently owns more than 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 is available on the Intellectual Property page on www.iovance.com.

Upcoming Medical Conferences

- **IASLC 2023 World Conference on Lung Cancer hosted by the International Association for the Study of Lung Cancer (WCLC 2023), September 9-12, 2023, Singapore**
  - **Mini Oral Presentation:** MA15.08 – Multicenter phase II trial of LN-145 TIL cell therapy plus pembrolizumab in patients with ICI-naïve metastatic NSCLC
    - **Presenter:** Adam J. Schoenfeld, MD, Medical Oncologist, Memorial Sloan Kettering Cancer Center
    - **Session:** MA15 - Bringing New Discoveries into Early Phase Clinical Trials
    - **Session Date & Time:** Tuesday, Sep 12, 2023, 11:15 AM - 11:20 AM SST (Monday, September 11, 2023, 11:15 – 11:20 PM EDT)
  - **Poster Presentation:** P2.18-02 – Successful generation of tumor-infiltrating lymphocytes (TIL) for adoptive cell therapy from mesothelioma
    - **Presenter:** Professor Dean Fennell FRCP Ph.D., Melanoma Research Programme, University of Leicester
    - **Session:** P2.18 - Mesothelioma, Thymoma, and Other Thoracic Tumors - Clinical
    - **Session Date & Time:** Monday, September 11, 2023, 6:00 PM - 7:30 PM SST (Monday, September 11, 2023, 6:00 – 7:30 AM EDT)
- **European Society for Medical Oncology ESMO CONGRESS 2023, October 20-24, 2023, Madrid, Spain**
  - **Mini Oral Presentation**: 1086MO – Lifileucel tumor-infiltrating lymphocyte (TIL) cell therapy in patients (pts) with advanced mucosal melanoma after progression on immune checkpoint inhibitors (ICI): Results from the phase 2 C-144-01 study
    - **Presenter:** Götz-Ulrich Grigoleit, Head of Department Hematology, Oncology and Immunology at Helios

Hospital Duisburg

- **Session:** Mini Oral Session – Melanoma and Other Skin Tumours
- **Session Date & Time:** Saturday, October 21, 3:20 PM - 3:25 PM CEST (9:20 AM – 9:25 AM EDT)

Second Quarter and First Half 2023 Financial Results

Iovance had $317.3 million in cash, cash equivalents, investments and restricted cash at June 30, 2023, compared to $478.3 million at December 31, 2022. With the estimated net proceeds from the common stock public offering of approximately $161.4 million raised in July of 2023, the cash position is expected to be sufficient to fund current and planned operations into the end of 2024.

Net loss for the second quarter ended June 30, 2023, was $106.5 million, or $0.47 per share, compared to a net loss of $99.3 million, or $0.63 per share, for the second quarter ended June 30, 2022. Net loss for the six months ended June 30, 2023, was $213.9 million, or $0.98 per share, compared to a net loss of $191.0 million, or $1.21 per share, for the same period ended June 30, 2022.

Revenue for the six months ended June 30, 2023, was $0.2 million, comprised of product sales following the Proleukin acquisition in May of 2023. There was no revenue for six months ended June 30, 2022. Cost of sales for the six months ended June 30, 2023, was $2.1 million, including $1.9 million of non-cash amortization of the acquired intangible asset for developed technology during the second quarter. There was no cost of revenues for the six months ended June 30, 2022.

Research and development expenses were $86.3 million for the second quarter ended June 30, 2023, an increase of $12.9 million compared to $73.4 million for the same period ended June 30, 2022. Research and development expenses were $169.1 million for the six months ended June 30, 2023, an increase of $27.4 million compared to $141.7 million for the same period ended June 30, 2022.

The increases in research and development expenses in the second quarter and first half of 2023 over the prior year periods were primarily attributable to growth of the internal research and development team, as well as higher costs related to facilities, internal research programs and the Phase 3 TILVANCE trial, which were partially offset by a decrease in stock-based compensation expense.

Selling, general and administrative expenses were $21.9 million for the second quarter ended June 30, 2023, a decrease of $4.4 million compared to $26.3 million for the same period ended June 30, 2022. Selling, general and administrative expenses were $50.0 million for the six months ended June 30, 2023, an increase of $0.3 million compared to $49.7 million for the same period ended June 30, 2022.

The decrease in selling, general and administrative expenses in the second quarter of 2023 compared to prior year period was primarily attributable to the capitalization of expenses associated with the Proleukin acquisition upon the transaction close. Decreases in other costs are related to the timing of spend compared to the prior year period, including marketing, advertising, licensing and insurance costs, partially offset by costs associated with the growth in the overall business. The increase in selling, general and administrative expenses in the first half of 2023 compared to the prior year period was primarily attributable to growth of the internal general and administrative and commercial teams, offset by a decrease in legal fees and other costs.

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 and live audio webcast at 5:00 p.m. ET, please register at https://register.vevent.com/register/BI83559f749d674b71bae2cbaeb65d484b. To view the live webcast, please register at https://edge.media-server.com/mmc/p/nxy3p22t. The live and archived webcast can be accessed in the Investors section of the Company's website, IR.Iovance.com. The archived webcast will 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: preliminary and interim clinical results, which may include efficacy and safety results, from ongoing clinical trials or cohorts, including but not limited to our IOV-LUN-202 trial, 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; 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, and meetings with the FDA, may support registrational studies and subsequent approvals by the FDA, including the risk that the planned single-arm Phase 2 IOV-LUN-202 trial may not support registration; 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 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 prior pre-BLA meeting with the FDA and/or regarding our prior meetings with the FDA regarding our NSCLC clinical trials); the risk that the FDA may not approve our BLA submission for lifileucel in metastatic melanoma; 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 regarding the successful integration of the recent Proleukin acquisition; the risk that the successful development or commercialization of our products may not generate sufficient revenue from product sales, and we may not become profitable in the near term or, if at all; 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)

	June 30, 2023 (unaudited)	December 31, 2022
Cash, cash equivalents, and investments	$ 250,894	$ 471,845
Restricted cash	$ 66,430	$ 6,430
Total assets	$ 757,293	$ 663,982
Stockholders' equity	$ 578,569	$ 499,638

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,	
	2023	2022	2023	2022
Revenue				
Product revenue	$ 238	$ —	$ 238	$ —
Total revenue	238	—	238	—
Costs and expenses*				
Costs of sales	$ 2,050	$ —	$ 2,050	$ —
Research and development	86,347	73,406	169,081	141,706
Selling, general and administrative	21,927	26,328	50,049	49,741
Total costs and expenses	110,324	99,734	221,180	191,447
Loss from operations	(110,086)	(99,734)	(220,942)	(191,447)
Other income				
Interest income, net	3,081	385	6,567	491
Net Loss before income taxes	$ (107,005)	$ (99,349)	$ (214,375)	$ (190,956)
Income tax benefit	477	—	477	—
Net Loss	(106,528)	(99,349)	(213,898)	(190,956)
Net Loss Per Share of Common Stock, Basic and Diluted	$ (0.47)	$ (0.63)	$ (0.98)	$ (1.21)
Weighted-Average Shares of Common Stock Outstanding, Basic and Diluted	224,481	157,274	219,117	157,194
***Includes stock-based compensation as follows:**				
Research and development	$ 9,390	$ 13,940	$ 18,249	$ 27,591
Selling, general and administrative	7,350	8,528	14,156	17,142
Total stock-based compensation included in costs and expenses	$ 16,740	$ 22,468	$ 32,405	$ 44,733

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