Iovance Biotherapeutics Reports First Quarter 2023 Financial Results and Corporate Updates

May 9, 2023

First Biologics License Application (BLA) Submission Completed in March 2023

Commercial Readiness Activities on track to Support Potential Commercial Launch of Lifileucel in 2023

SAN CARLOS, Calif., May 09, 2023 (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 first quarter 2023 financial results and corporate updates.

Frederick Vogt, Ph.D., J.D., Interim President and Chief Executive Officer of Iovance, stated, “Since the beginning of 2023, we have completed our first BLA for lifileucel in advanced melanoma, and continue to execute our commercial readiness activities to launch lifileucel in 2023, while advancing our immuno-oncology pipeline. We are also on track with our integration activities for the planned acquisition of 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. Our top priorities in 2023 are to gain FDA approval and successfully launch lifileucel, continue to develop our pipeline in multiple solid tumor indications and present new data from our clinical programs.”

Recent and First Quarter 2023 Highlights and Corporate Updates

Acquisition of Proleukin®

- Under a definitive agreement between Iovance and Clinigen Limited, Iovance will acquire worldwide rights to Proleukin® (aldesleukin), an interleukin-2 (IL-2) product with uses that include administration following TIL infusion to promote T-cell activity. Iovance expects the benefits of this transaction to include immediate and future revenue, securing 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. The closing of this transaction is expected to occur in the second quarter of 2023, when all closing conditions and required regulatory approvals are achieved.

Iovance TIL Therapy (Lifileucel) in Advanced Melanoma

- **Regulatory highlights:**
  - A rolling BLA submission for lifileucel in post-anti-PD-1 advanced (metastatic or unresectable) melanoma was completed in March 2023.
  - Site activation commenced for the randomized, registrational Phase 3 global TILVANCE-301 trial to support accelerated and full approvals of lifileucel in combination with pembrolizumab in frontline advanced melanoma in the U.S., Europe, Australia and other regions. 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.

- **IOV-COM-202 (Cohort 1A) trial results in frontline advanced melanoma:**

  - A January 2023 corporate update highlighted results from nearly 20 patients treated with lifileucel in combination with pembrolizumab in Cohort 1A. The results remained consistent with previously reported efficacy and safety data, including a robust 67% ORR and durability of response in 12 patients, and continue to support the frontline melanoma opportunity for lifileucel. Study enrollment remains ongoing.

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 as currently built has annual capacity to supply TIL therapies for 2,000+ patients, with available shell space that can be built to supply TIL therapies for 5,000+ patients from this facility. Contract manufacturers provide additional flexibility and capacity for Iovance to meet potential commercial and clinical demand.

- Iovance is executing several initiatives ahead of potential commercialization, including on-boarding and personnel training at Authorized Treatment Centers (ATCs), education and awareness, and other commercial launch readiness activities.

Clinical Pipeline

- **Iovance TIL (LN-145) monotherapy in second or third line metastatic non-small-cell lung cancer (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 who have progressed on or after frontline chemo- and anti-PD1-therapy.
  - 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 second/third line mNSCLC and intends to execute an updated regulatory strategy based on this dialogue and feedback.

- **Iovance TIL (LN-145) in combination with anti-PD-1 in earlier line mNSCLC:**

  - Iovance reported positive initial results from Cohort 3A of the IOV-COM-202 clinical trial that explores the combination of TIL therapy (LN-145) and pembrolizumab as therapy for ICI naïve mNSCLC patients. The confirmed ORR by RECIST 1.1 was 47% (n=8/17), with responses observed across PD-L1 negative and positive patients.
  - Cohort 3A enrollment remains ongoing and presentation of detailed results is expected at a medical meeting in the second half of 2023.
  - A meeting with the FDA is planned in 2023 to discuss Cohort 3A results and a potential registrational trial of lifileucel in frontline advanced NSCLC.

- **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

- As of March 31, 2023, Iovance's cash position is approximately $632.7 million, which includes net proceeds from an at-the market (ATM) equity financing facility of approximately $260.1 million raised during the first quarter of 2023. This cash position is expected to fund the previously disclosed acquisition of Proleukin® and Iovance's operating plan into the second half 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.

American Society of Clinical Oncology (ASCO) Annual Meeting, June 2-6, 2023

- Iovance will present the following posters at ASCO 2023:
  - Abstract #TPS9607: A phase 3 study (TILVANCE-301) to assess the efficacy and safety of lifileucel, an autologous tumor-infiltrating lymphocyte cell therapy, in combination with pembrolizumab compared with pembrolizumab alone in patients with untreated unresectable or metastatic melanoma. Poster Session: June 3, 2023, 1:15 PM-4:15 PM CT

  - Abstract #2542: Effect of a novel expansion process on tumor-infiltrating lymphocyte (TIL) polyfunctionality, cytotoxicity, and expansion, while preserving cells in a less differentiated and more stem-like phenotype. Poster

Session: June 3, 2023, 8:00 AM-11:00 AM CT

First Quarter 2023 Financial Results

Iovance had $632.7 million in cash, cash equivalents, investments and restricted cash at March 31, 2023, compared to $478.3 million at December 31, 2022. With the net proceeds from the ATM equity financing facility of approximately $260.1 million raised during the first quarter of 2023, the cash position is expected to be sufficient to fund current and planned operations into the second half of 2024.

Jean-Marc Bellemin, Chief Financial Officer of Iovance, said, “Iovance is committed to prioritizing our investments and effectively managing expenses. We expect that our current cash position is sufficient to fund our operating plan into the second half of 2024, including our planned acquisition of Proleukin®, commercial launch preparations, internal manufacturing and clinical pipeline expansion.”

Net loss for the first quarter ended March 31, 2023, was $107.4 million, or $0.50 per share, compared to a net loss of $91.6 million, or $0.58 per share, for the first quarter ended March 31, 2022.

Research and development expenses were $82.7 million for the first quarter ended March 31, 2023, an increase of $14.4 million compared to $68.3 million for the first quarter of 2022. The increase in research and development expenses in the first quarter 2023 over the prior year period was primarily attributable to growth of the internal research and development team, as well as clinical trial costs, manufacturing costs to support commercial manufacturing readiness, and facility-related costs, which were partially offset by lower stock-based compensation expense.

General and administrative expenses were $28.1 million for the first quarter ended March 31, 2023, an increase of $4.7 million compared to $23.4 million for the first quarter of 2022. The increase in general and administrative expenses in the first quarter of 2023 compared to the prior year period was primarily attributable to growth of the internal general and administrative and commercial teams in preparation for launch, fees to support the Proleukin acquisition, as well as costs associated with pre-commercial activities, which were partially offset by lower stock-based compensation and marketing expenses.

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 at 4:30 p.m. ET today, please dial 1-800-715-9871 (domestic) or 1-646-307-1963 (international) and reference the access code 8957192. 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, and meetings with the FDA, may support registrational studies and subsequent approvals 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 the acquisition of Proleukin® may not be completed in a timely manner or at all; the failure to satisfy

the closing conditions to the consummation of the Proleukin® acquisition, including the receipt of all required regulatory approvals; 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)

	March 31, 2023 (unaudited)	December 31, 2022
Cash, cash equivalents, and investments	$ 626,292	$ 471,845
Restricted cash	$ 6,430	$ 6,430
Total assets	$ 824,767	$ 663,982
Stockholders' equity	$ 666,881	$ 499,638

Condensed Consolidated Statements of Operations
(in thousands, except per share information)

	For the Three Months Ended March 31,	
	2023	2022
Costs and expenses*		
Research and development	$ 82,734	$ 68,300
General and administrative	28,122	23,413
Total costs and expenses	110,856	91,713
Loss from operations	(110,856)	(91,713)
Other income		
Interest income, net	3,486	106
Net Loss	$ (107,370)	$ (91,607)
Net Loss Per Share of Common Stock, Basic and Diluted	$ (0.50)	$ (0.58)
Weighted-Average Shares of Common Stock Outstanding, Basic and Diluted	213,694	157,113
***Includes stock-based compensation as follows:**		
Research and development	$ 8,859	$ 13,651
General and administrative	6,806	8,614
Total costs and expenses	$ 15,665	$ 22,265

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