Iovance Biotherapeutics Reports First Quarter 2024 Financial Results and Corporate Updates

May 9, 2024

Strong Momentum for Amtagvi™ (Lifileucel) U.S. Launch Following U.S. Food and Drug Administration (FDA) Approval

100+ Amtagvi Patients Enrolled Across More Than 40 Current Authorized Treatment Centers (ATCs), with ~50 Total ATCs On Track by End of May and 70+ Total ATCs by Year-End 2024

Amtagvi Regulatory Submissions on Track in the European Union (EU), United Kingdom (UK), and Canada in 2024

SAN CARLOS, Calif., May 09, 2024 (GLOBE NEWSWIRE) -- Iovance Biotherapeutics, Inc. (NASDAQ: IOVA), a commercial biotechnology company focused on innovating, developing, and delivering novel polyclonal tumor infiltrating lymphocyte (TIL) therapies for patients with cancer, today reported first quarter 2024 financial results and corporate updates.

Frederick Vogt, Ph.D., J.D., Interim President and Chief Executive Officer of Iovance, stated, “The first quarter of 2024 was transformative for Iovance following our first FDA approval and our strong start for the U.S. commercial launch of Amtagvi™ for patients with advanced melanoma. Immediate demand for Amtagvi is very high and continues to significantly increase across initial ATCs. As of today, more than 100 patients have already enrolled for Amtagvi therapy. We have successfully manufactured and delivered Amtagvi to many ATCs where commercial patients are being treated. We expect our launch momentum to remain strong and continue to build as we ramp up the U.S. launch throughout 2024 with the authorization of additional ATCs. We also continue to execute across our broad clinical pipeline. As a fully integrated company, Iovance is well positioned to remain the global leader in innovating, developing, and delivering TIL cell therapy for patients with cancer.”

Recent and First Quarter 2024 Highlights and Corporate Updates

Amtagvi™ (Lifileucel) U.S. Approval and Launch Highlights in Advanced Melanoma

- The U.S. FDA approved Amtagvi (lifileucel) on February 16, 2024, as the first treatment option for advanced melanoma after anti-PD-1 and targeted therapy. Amtagvi is also the first and only FDA-approved T cell therapy for a solid tumor indication.
- Since approval, more than 100 patients have enrolled for Amtagvi therapy. The first patients have been successfully treated and the balance are moving through the stages of the journey, which includes surgery for cell collection, manufacturing, and the Amtagvi treatment regimen.
- Onboarding is complete at more than 40 U.S. ATCs, up from 30 initial ATCs at approval. Iovance remains on track to onboard approximately 50 ATCs by the end of May 2024 and expects to have more than 70 ATCs onboarded by the end of 2024.
- Manufacturing turnaround time has been on-target with initial launch expectations of approximately 34 days from inbound to return shipment to ATCs. The commercial manufacturing experience to date is consistent with prior clinical experience.
- The U.S. launch of Amtagvi, and additional sales of Proleukin® used with the treatment regimen, are expected to drive significant revenue for Iovance in 2024.
- Amtagvi was added as a preferred second-line or subsequent therapy in the National Comprehensive Cancer Network® guidelines for treatment of cutaneous melanoma.
- Reimbursement remains strong and on track at the ATCs with progress toward coverage policies successful in many cases. As anticipated, more than 75% of enrolled Amtagvi patients are covered by private payers. To date, payers covering more than 200 million lives have already authorized Amtagvi treatment for their patients, setting a strong precedent for reimbursement success.

Lifileucel Launch Expansion into New Markets and Indications

- Geographic expansion can more than double the total addressable patient population for Amtagvi in advanced melanoma. Regulatory dossiers remain on track for submission in the following markets with significant populations of advanced melanoma patients:
  - EU in the second quarter of 2024
  - UK and Canada in the second half of 2024
  - Australia and additional countries in 2025

Iovance TIL Cell Therapy Pipeline Highlights

- **Lifileucel in Frontline Advanced Melanoma**
  - The registrational Phase 3 TILVANCE-301 trial is well underway to support accelerated and full U.S. approvals of

Amtagvi in combination with pembrolizumab in frontline advanced melanoma as well as regular approval of Amtagvi in post-anti-PD-1 melanoma.
    - Global site activation and patient enrollment continue with strong momentum in the U.S., Europe, Australia, Canada, and additional countries.
    - An oral presentation of updated clinical data from Cohort 1A of the IOV-COM-202 trial, which strongly supports the rationale for TILVANCE-301 and the frontline melanoma opportunity, will be presented at the American Society of Clinical Oncology (ASCO) Annual Meeting on May 31, 2024.
- **Lifileucel in Non-Small Cell Lung Cancer (NSCLC)**
    - Enrollment resumed for new patients in the IOV-LUN-202 registrational Phase 2 trial in post-anti-PD-1 NSCLC soon after the U.S. FDA lifted a partial clinical hold in the first quarter. The IOV-LUN-202 trial includes clinical sites in the U.S., Canada, and Europe, with plans to include additional regions with strong track records for enrollment in lung cancer studies over the next few months. Enrollment has restarted with high demand and the registrational cohorts are expected to be fully enrolled in 2025.
    - At a recent Type D meeting, the FDA provided positive regulatory feedback on the proposed potency matrix for lifileucel in NSCLC. The FDA previously provided positive regulatory feedback that the design of the single-arm IOV-LUN-202 trial may be acceptable for approval of lifileucel in post-anti-PD-1 NSCLC.
- **Lifileucel in Endometrial Cancer**
    - A Phase 2 trial of lifileucel in advanced endometrial cancer patients is on track to initiate in the second quarter of 2024. The trial will enroll patients with advanced endometrial cancer who progressed after platinum-based chemotherapy and anti-PD-(L)1 therapy regardless of mismatch repair (MMR) status. This clinical program and trial design are supported by preclinical and manufacturing success data to be presented at a conference in 2024 and has received positive feedback from gynecological oncology experts.
    - In 2024, an estimated 67,880 new cases of uterine cancer (>90% of which are endometrial cancer) are expected to be diagnosed, with 13,250 deaths expected in the US.[1] There are no currently approved therapies in the emerging second-line setting after frontline post-anti-PD1 therapy and chemotherapy. Endometrial cancer represents a significant opportunity for TIL cell therapy to address an additional unmet medical need in the post-anti-PD-1 treatment setting and may address both MMR deficient and proficient patients.
- **Next Generation TIL Pipeline**
    - **IOV-4001 (PD-1 Inactivated TIL Cell Therapy):** The Phase 1 safety portion concluded in the first in human IOV-GM1-201 trial to investigate PD-1 inactivated TIL cell therapy (IOV-4001) in previously treated advanced melanoma and NSCLC, and the trial is progressing successfully into the multi-center Phase 2 efficacy stage. Iovance continues to utilize the TALEN® technology licensed from Cellectis to develop other investigational gene-edited TIL cell therapies with multiple knockout targets to potentially improve efficacy.
    - **Next Generation IL-2 for TIL Treatment Regimen:** Iovance plans to submit an Investigational New Drug application (IND) for a Phase 1/2 clinical trial of IOV-3001, a modified interleukin-2 (IL-2) fusion protein, for use in the TIL therapy treatment regimen in the third quarter of 2024. Results from non-human primate and IND-enabling studies of IOV-3001 will be presented in a poster at ASCO 2024 and demonstrate the potential for improved safety with strong effector T cell expansion.
    - **Next Generation, Cytokine-Tethered TIL Therapy:** A genetically engineered, inducible, and tethered IL-12 TIL cell therapy, designated IOV-5001, is in IND-enabling studies. In preclinical studies, IOV-5001 augmented anti-tumor activity *in vitro*, and a clinical trial of a prior generation IL-12 TIL therapy at the National Cancer Institute showed improved efficacy. An INTERACT meeting is planned with the FDA to discuss IOV-5001 in the third quarter of 2024, followed by an IND submission in early 2025.

Manufacturing Capacity Expansion

- The Iovance Cell Therapy Center (*i*CTC), and a nearby FDA-approved contract manufacturer, are built today for capacity for several thousands of patients annually. Capacity expansion is currently underway at *i*CTC to supply TIL cell therapies for more than 5,000 patients annually in the next few years.

Upcoming ASCO 2024 Highlights for Iovance

- Oral Presentation: Efficacy and safety of lifileucel, an autologous tumor-infiltrating lymphocyte cell therapy, and pembrolizumab in patients with immune checkpoint inhibitor-naive unresectable or metastatic melanoma: updated results from IOV-COM-202 Cohort 1A
    - Session: Melanoma/Skin Cancers, Friday, May 31, 2024, 2:45 - 5:45 p.m. CDT
- Poster: IOV-3001, a modified interleukin-2 fusion protein, for potential use in tumor-infiltrating lymphocyte cell therapy regimens
    - Session: Developmental Therapeutics – Immunotherapy - Saturday, June 1, 2024; 9:00 a.m. – 12:00 p.m. CDT
- Poster: Dynamics of circulating cytokines and chemokines during and after tumor-infiltrating lymphocyte cell therapy with lifileucel in advanced melanoma patients

- Session: Melanoma/Skin Cancers: Saturday, June 1, 2024, 1:30-4:30 p.m. CDT

Corporate Updates

- As of March 31, 2024, Iovance had cash, cash equivalents, investments, and restricted cash of approximately $362.6 million, compared to $346.3 million at December 31, 2023. The current cash position and anticipated revenue from Amtagvi and Proleukin are expected to be sufficient to fund current and planned operations well into the second half of 2025.
- Iovance is now recognizing all Proleukin revenues for commercial and clinical use and has recently commenced significant sales to distributors. In the first quarter of 2024, Iovance completed the transfer of marketing authorizations and began distribution of Proleukin. Beginning in the second quarter of 2024, Iovance expects to recognize significant incremental revenues for Proleukin as part of the Amtagvi treatment regimen.
- Iovance currently owns more than 120 granted or allowed U.S. and international patents for TIL-related technologies, including 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 and additional patent rights, including patents related to potency assays expected to provide exclusivity into 2042. More information on Iovance's patent portfolio is available on the Intellectual Property page on www.iovance.com.

First quarter 2024 Financial Results

Net loss for the first quarter ended March 31, 2024, was $113.0 million, or $0.42 per share, compared to a net loss of $107.4 million, or $0.50 per share, for the first quarter ended March 31, 2023. The net loss for the first quarter 2024 includes amortization of intangible assets acquired as part of the Proleukin transaction.

Revenue for the first quarter ended March 31, 2024, was $0.7 million from sales of Proleukin® in licensed markets outside of the U.S. Cost of sales was $7.3 million, primarily related to inventoriable costs associated with sales of Proleukin and non-cash amortization expense for the acquired intangible asset for developed technology during the first quarter of 2024. No revenue or cost of sales were incurred for the first quarter ended March 31, 2023.

Research and development expenses were $79.8 million for the first quarter ended March 31, 2024, a decrease of $2.9 million compared to $82.7 million for the first quarter of 2023. The decrease was primarily attributable to the transition to commercial Amtagvi manufacturing in the most recent quarter, partially offset by increased costs associated with the purchases of raw materials, clinical trials driven primarily by the Phase 3 TILVANCE-301 clinical trial, and the planned EU regulatory submissions for lifileucel.

Selling, general and administrative expenses were $31.4 million for the first quarter ended March 31, 2024, an increase of $3.3 million compared to $28.1 million for the first quarter of 2023. The increase was primarily attributable to increases in headcount and related costs, including stock-based compensation, to support the growth in the overall business and related corporate infrastructure, as well as costs incurred to support the commercialization of Amtagvi and Proleukin, partially offset by a decrease in legal costs.

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

Webcast and Conference Call

To listen to the live or archived audio webcast, please register at https://edge.media-server.com/mmc/p/m4tigan7. The live and archived webcast can be accessed in the Investors section of the Company's website, IR.Iovance.com for one year.

1. National Cancer Institute Surveillance, Epidemiology and End Results (SEER) Program. 2024 Estimates. https://seer.cancer.gov

About Iovance Biotherapeutics, Inc.

Iovance Biotherapeutics, Inc. 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. The Iovance TIL platform has demonstrated promising clinical data across multiple solid tumors. Iovance's Amtagvi™ is the first FDA-approved T cell therapy for a solid tumor indication. 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"). 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 U.S. 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 risks related to our ability to successfully commercialize our products, including Amtagvi, for which we have obtained U.S. Food and Drug Administration ("FDA") approval, and Proleukin, for which we have obtained FDA and European Medicines Agency ("EMA") approval; the risk that the EMA or other ex- U.S. regulatory authorities may not approve or may delay approval for our marketing authorization application submission for lifileucel in metastatic melanoma; the acceptance by the market of our products, including Amtagvi and Proleukin, and their potential pricing and/or reimbursement by payors, if approved (in the case of our product candidates), in the U.S. and other international markets and whether such acceptance is sufficient to support continued commercialization or development of our products, including Amtagvi and Proleukin, or product candidates, respectively; the risk whether the number of patients treated and/or ATCs is an appropriate measure of commercial success and/or recognized revenue; future competitive or other market factors may adversely affect the commercial potential for Amtagvi or Proleukin; the risk regarding our ability or inability to manufacture our therapies using third party manufacturers or at our own facility, including our ability to increase manufacturing capacity at such third party manufacturers and our own facility, may adversely affect our 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, including Amtagvi and Proleukin, may not generate sufficient revenue from product sales, and we may not become profitable in the near term, or at all; the risks related to the timing of and our ability to successfully develop, submit, obtain, or maintain FDA, EMA, or other regulatory authority approval of, or other action with respect to, our product candidates; whether clinical trial results from our pivotal studies and cohorts, and meetings with the FDA, EMA, or other regulatory authorities may support registrational studies and subsequent approvals by the FDA, EMA, or other regulatory authorities, including the risk that the planned single arm Phase 2 IOV-LUN-202 trial may not support registration; 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 risk that 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, EMA, or other regulatory authorities; the risk that our interpretation of the results of our clinical trials or communications with the FDA, EMA, or other regulatory authorities may differ from the interpretation of such results or communications by such regulatory authorities (including from our prior meetings with the FDA regarding our non-small cell lung cancer clinical trials); the risk that clinical data from ongoing clinical trials of Amtagvi will not continue or be repeated in ongoing or planned clinical trials or may not support regulatory approval or renewal of authorization; the risk that unanticipated expenses may decrease our estimated cash balances and forecasts and increase our estimated capital requirements; the effects of the COVID-19 pandemic; 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, 2024 (unaudited)	December 31, 2023
Cash, cash equivalents, and investments	$ 356,195	$ 279,867
Restricted cash	$ 6,430	$ 66,430
Total assets	$ 869,830	$ 780,351
Stockholders' equity	$ 680,024	$ 584,613

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

	For the Three Months Ended March 31,	
	2024	2023
Revenue		
Product revenue	$ 715	$ —
Total revenue	715	—
Costs and expenses*		
Cost of sales	$ 7,261	$ —
Research and development	79,783	82,734
Selling, general and administrative	31,393	28,122
Total costs and expenses	118,437	110,856
Loss from operations	(117,722)	(110,856)
Other income		
Interest income, net	3,338	3,486
Net loss before income taxes	$ (114,384)	$ (107,370)
Income tax benefit	1,408	—
Net Loss	$ (112,976)	$ (107,370)

Net Loss Per Share of Common Stock, Basic and Diluted	$ (0.42)	$ (0.50)
Weighted Average Shares of Common Stock Outstanding, Basic and Diluted	266,220	213,694
***Includes stock-based compensation as follows:**		
Research and development	$ 8,915	$ 8,859
Selling, general and administrative	8,263	6,806
Total stock-based compensation included in costs and expenses	$ 17,178	$ 15,665

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