Iovance Biotherapeutics Provides Corporate, Clinical, and Regulatory Updates

January 23, 2023

Acquisition of Worldwide Rights to Proleukin® Provides Immediate and Ongoing Revenue and Secures IL-2 Supply for Clinical and Future Commercial TIL Therapy

Positive FDA Feedback on Phase 3 Confirmatory Study in Frontline Advanced (Metastatic or Unresectable) Melanoma

Positive Clinical Data in Anti-PD-1 Naïve Metastatic Non-Small Cell Lung Cancer (NSCLC)

Biologics License Application (BLA) Submission in Post-Anti-PD-1 Advanced Melanoma on Track to Complete in Q1 2023

Strengthened Cash Position to Fund Operating Plan Well into 2024

SAN CARLOS, Calif., Jan. 23, 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 provided corporate, clinical, and regulatory updates.

CORPORATE UPDATE

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 used to promote T-cell activity following TIL infusion. 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.

Terms of the agreement include an upfront payment of £166.7 million, a £41.7 million milestone payment upon first approval of lifileucel in advanced melanoma, and double-digit Proleukin® global sales royalties from Iovance to Clinigen. The transaction is expected to close in the first quarter of 2023, subject to required regulatory approvals and clearances and other customary closing conditions.

Iovance is financing the acquisition with existing cash. As of January 20, 2023, Iovance's unaudited cash position is approximately $477.0 million, which includes net proceeds from an at-the market (ATM) equity financing facility of approximately $227.1 million raised during the fourth quarter of 2022 and early 2023. In addition, Iovance has agreed to terms for a secured line of credit of up to $100 million from Quogue Capital. These proceeds are expected to fund the acquisition of Proleukin® and Iovance's operating plan well into 2024.

CLINICAL AND REGULATORY UPDATES

Lifileucel in Advanced Melanoma

TILVANCE-301 Phase 3 Confirmatory Trial: During the fourth quarter of 2022, Iovance reached agreement with the U.S. Food and Drug Administration (FDA) regarding the Phase 3 TILVANCE-301 trial of lifileucel in combination with pembrolizumab in frontline advanced melanoma. The TILVANCE-301 trial will randomize 670 patients and will investigate lifileucel in combination with pembrolizumab (experimental arm) compared with pembrolizumab monotherapy (control arm).

The FDA agreed to dual primary endpoints of objective response rate (ORR) to support accelerated approval and progression free survival (PFS) to support full approval of lifileucel in frontline advanced melanoma. The TILVANCE-301 confirmatory trial will also support full approval of lifileucel in post-anti-PD-1 advanced melanoma and is expected to be well underway at the time of potential BLA approval for lifileucel. Further details will be shared later in 2023.

Updated results from nearly 20 patients treated in Cohort 1A of the IOV-COM-202 trial of lifileucel in combination with pembrolizumab in frontline advanced melanoma remain consistent with previously reported data[1] demonstrating robust ORR by RECIST 1.1 and durability of response. Additional data will be shared later in 2023 and continue to support the opportunity for lifileucel in frontline advanced melanoma.

Lifileucel in Anti-PD-1 Naïve Metastatic Non-Small Cell Lung Cancer (NSCLC)

IOV-COM-202 Cohort 3A: Confirmed ORR by RECIST 1.1 of 47% (n=8/17) was observed in patients treated with a combination of TIL therapy (LN-145) and pembrolizumab in Cohort 3A of the IOV-COM-202 trial. Responses were observed regardless of PD-L1 status. Safety was consistent with other studies of Iovance TIL therapies in combination with pembrolizumab. Study enrollment remains ongoing.

ORR by Clinical Subset: Cohort 3A comprises three distinct clinical subsets of anti-PD-1 naïve metastatic NSCLC: 1) treatment-naïve, 2) post-chemotherapy, and 3) *EGFR*-mutant after prior treatment with tyrosine kinase inhibitors (TKI). Response rates were highest in patients who were treatment-naïve (80% ORR; n=4/5) and post-chemotherapy anti-PD-1 naïve (43% ORR, n=3/7) compared with *EGFR*-mutant after prior treatment with TKI (20% ORR, n=1/5). Two patients achieved complete responses and remain on study (post-chemotherapy anti-PD-1 naive, n=1 and *EGFR*-mutant after prior treatment with TKI, n=1). The observed differences in ORR between the patient subsets are informing the design of a subsequent potential

registration study. Detailed clinical results will be shared at a future medical meeting.

Regulatory Strategy: Iovance plans to meet with FDA in 2023 to discuss Cohort 3A results and a potential registration trial of lifileucel in frontline advanced NSCLC patients who are *EGFR* wild-type. The proposed design will be a frontline maintenance study of standard-of-care pembrolizumab and limited duration chemotherapy followed by treatment consisting of TIL therapy in combination with pembrolizumab compared with pembrolizumab monotherapy in responding patients. This design takes advantage of the findings of Cohort 3A and has the potential to offer frontline advanced NSCLC patients improved responses and PFS compared with single agent maintenance pembrolizumab.

BLA Submission

The rolling BLA submission for lifileucel in post-anti-PD-1 advanced melanoma commenced in August 2022 and is on track to complete during the first quarter of 2023.

Investor Webcast

Iovance will host a webcast on Monday, January 23, 2023, at 8:30 a.m. ET to discuss these corporate, clinical and regulatory updates. To participate in the webcast, please register at https://register.vevent.com/register/BIb01d5a16742c4d99b3dfe1b02bad8147. The live webcast and replay can be accessed in the Investors section of the company's website at ir.iovance.com.

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 registration 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 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.

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[1] Iovance Biotherapeutics Announces Regulatory and Clinical Updates for Lifileucel in Melanoma, April 5, 2022.



Source: Iovance Biotherapeutics, Inc.