Iovance Biotherapeutics Announces Clinical Data in Frontline Advanced Melanoma at ASCO 2024 Annual Meeting

May 23, 2024

Lifileucel TIL Cell Therapy in Combination with Pembrolizumab Demonstrates Deep, Durable Responses in Frontline Advanced Melanoma Patients in IOV-COM-202 Clinical Study

ASCO Oral Presentation to Highlight 65% Objective Response Rate (ORR) and 30% Complete Response Rate

Nearly All Responses Remain Ongoing at a Median Follow-up of 21.7 Months in the Oral Presentation

Data in Published Abstract and Upcoming Oral Presentation Strongly Support Ongoing TILVANCE-301 Phase 3 Trial

SAN CARLOS, Calif., May 23, 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 announced updated clinical data for lifileucel in combination with pembrolizumab in frontline advanced melanoma, as well as translational data, for the upcoming 2024 ASCO Annual Meeting to be held May 31 – June 4, 2024, at McCormick Place in Chicago, IL and online.

Clinical Data in Frontline Advanced Melanoma (Cohort 1A in IOV-COM-202 Trial)

Positive results from Cohort 1A in the IOV-COM-202 trial were published in an abstract[1] and will be highlighted in an upcoming oral presentation at ASCO. Unprecedented response rates, as well as deep and durable responses, were observed in patients with frontline advanced melanoma who were naïve to immune checkpoint inhibitor (ICI) therapy. These results strongly support the ongoing Phase 3 TILVANCE-301 clinical trial.

ASCO Oral Presentation Highlights

- A recent data cut included 23 patients with a median follow up of 21.7 months.[2]
- Confirmed ORR was 65.2%, including 7 (30.4%) complete responses and 8 (34.8%) partial responses by RECIST v1.1.
- All evaluable patients demonstrated regression of their target lesions.
- Nearly all responses remained ongoing. The duration of response was 12+ months for 8 responders (53.3%) and 6+ months for 11 responders (73.3%).
- As a one-time treatment, lifileucel's safety profile was differentiated from continuous ICI combination regimens.
- Treatment-emergent adverse events were consistent with the underlying disease and known safety profiles of pembrolizumab monotherapy, nonmyeloablative lymphodepletion, and interleukin-2.

Friedrich Graf Finckenstein, M.D., Chief Medical Officer of Iovance, stated, "The compelling response rates, including a 30.4% complete response rate, and depth and durability of responses for lifileucel in combination with pembrolizumab strongly support our strategy in frontline advanced melanoma. Expanding TIL cell therapy into earlier treatment settings is a top priority for Iovance. The positive data are highly encouraging for the anticipated ORR results in our ongoing TILVANCE-301 trial. A planned early interim analysis of ORR, a dual primary endpoint in TILVANCE-301, may support an accelerated approval in the frontline setting, with full approval supported by progression free survival."

The clinical and safety data from Cohort 1A continue to reinforce the rationale for the TILVANCE-301 trial. TILVANCE-301 is a global, randomized, registrational Phase 3 trial to support accelerated and full U.S. approvals of lifileucel in combination with pembrolizumab in frontline advanced melanoma. In addition, the ORR endpoint in TILVANCE-301 supports full approval of lifileucel monotherapy (Amtagvi™) in post-anti-PD-1 melanoma. The U.S. Food and Drug Administration (FDA) has agreed to the design of the TILVANCE-301 trial, including dual-primary endpoints of ORR and progression free survival. Iovance plans to conduct an early interim analysis of ORR as the potential basis for regulatory submission and approvals.

Iovance Presentation and Posters at ASCO Annual Meeting

- 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 (Abstract 9505)
  - Session: Melanoma/Skin Cancers
    Friday, May 31, 2024, 2:45 p.m. – 5:45 p.m. CDT
- Poster: IOV-3001, a modified interleukin-2 fusion protein, for potential use in tumor-infiltrating lymphocyte cell therapy regimens (Abstract 2552)
  - 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 (Abstract 9594)
    Saturday, June 1, 2024, 1:30 p.m. – 4:30 p.m. CDT

ASCO 2024 Webcast
Iovance executives and key opinion leaders (KOLs) will discuss ASCO data highlights and perspectives on the Amtagvi commercial launch during an audio webcast on Friday, May 31, 2024 at 6:15 p.m. CDT (7:15 p.m. EDT). To listen to the live or archived audio webcast, please register at https://edge.media-server.com/mmc/p/x4v33mwt/. The live and archived webcast can be accessed in the Investors section of the Company's website, IR.Iovance.com for one year.

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.

[1]Abstract data cut off: December 22, 2023
[2]Oral presentation data cut off: April 17, 2024

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