Iovance Biotherapeutics Announces Clinical Data for LN-145 in Non-Small Cell Lung Cancer at Society for Immunotherapy of Cancer (SITC) Annual Meeting

November 12, 2021

21.4% Overall Response Rate (ORR) in Heavily Pre-Treated Patients with Relapsed/Refractory Metastatic Non-Small Cell Lung Cancer (mNSCLC)

Conference Call and Webcast on Saturday, November 13 at 5:30pm ET

SAN CARLOS, Calif., and WASHINGTON, Nov. 12, 2021 (GLOBE NEWSWIRE) -- Iovance Biotherapeutics, Inc. (NASDAQ: IOVA), a late-stage biotechnology company developing novel T cell-based cancer immunotherapies, today announced additional clinical data for its tumor infiltrating lymphocyte (TIL) therapy LN-145 in patients with metastatic non-small cell lung cancer (mNSCLC) who enrolled in Cohort 3B of the ongoing basket study IOV-COM-202. The results are available in a poster at the Society for Immunotherapy of Cancer (SITC) Annual Meeting, November 12-14, 2021, Washington, D.C. and virtual.

The results demonstrate the feasibility of TIL cell therapy in heavily pre-treated patients with NSCLC, and warrant continued investigation of LN-145 as a single-agent and in combination in patients with mNSCLC in ongoing Iovance clinical studies IOV-LUN-202 and IOV-COM-202.

Adam J. Schoenfeld, M.D., medical oncologist at Memorial Sloan Kettering Cancer Center and an investigator in the IOV-COM-202 and IOV-LUN-202 studies, stated, “The clinical data for LN-145 in heavily-treated patients with metastatic non-small cell lung cancer is exciting. It represents the first experience for TIL monotherapy to show clinical benefit in metastatic non-small cell lung cancer and demonstrates the feasibility and safety shown in a multi-center study with a centralized manufacturing process. I am particularly impressed to see responses following multiple prior therapies, including tumors resistant to anti–PD-(L)1 blockade. We observed responses to LN-145 across a range of PD-L1 expression levels, clinical characteristics, and molecular features. I look forward to the ongoing IOV-LUN-202 clinical study in second-line non-small cell lung cancer, where there’s potential to see an increase in overall responses and durability among patients who are earlier in their disease and improve a treatment landscape dominated by chemotherapy.”

Following one-time treatment with LN-145 monotherapy, the overall response rate (ORR) is 21.4% in the full analysis set (n=28) and 25% in the efficacy-evaluable set (n=24), including one complete response and five partial responses (August 24, 2021 data cutoff). Two responders, including the CR, had PD-L1 negative tumors and two responders had tumors with *KRAS* mutations. One complete response and one partial response are ongoing at 20.7 months and 3.0 months, respectively, at a median study follow up of 9.8 months. The treatment-emergent adverse event profile is consistent with the underlying disease and known adverse event profiles of non-myeloablative lymphodepletion and IL-2.

The heavily pre-treated patients in Cohort 3B had received a median of 2 prior therapies. All patients had progressed on prior immune checkpoint inhibitor (ICI) therapy and all six responders received prior chemotherapy. TIL were most commonly grown and manufactured from tumor samples resected from the lung.

Friedrich Graf Finckenstein, M.D., Chief Medical Officer of Iovance, stated, “We are pleased to present our clinical data for LN-145 in metastatic non-small cell lung cancer to the physician community at SITC. There remains a very significant unmet need to increase response rates and prolong survival in the second-line non-small cell lung cancer treatment setting. The data for LN-145 in this signal-finding cohort demonstrated the potential for TIL in metastatic non-small cell lung cancer across a diverse set of patients and informed our ongoing IOV-LUN-202 clinical study in second-line lung cancer. Iovance is committed to advancing both TIL alone and TIL combinations to address multiple non-small cell lung cancer patient populations.”

Iovance is currently enrolling patients in the IOV-LUN-202 clinical study to investigate LN-145 in second-line mNSCLC where patients have progressed on prior ICI and chemotherapy. More than 20 clinical sites are currently active in the U.S. and Canada. For more information please visit Iovance.com/clinical or clinicaltrials.gov (identifier NCT04614103).

Iovance Posters and Presentations at SITC Annual Meeting (November 12-14, 2021)

Title: Phase 2 efficacy and safety of autologous tumor-infiltrating lymphocyte (TIL) cell therapy in combination with pembrolizumab in immune checkpoint inhibitor-naïve patients with advanced cancers
Authors: D O’Malley, *et al.*
Presentation Type: Oral Presentation
Date and Time: Saturday, November 13, 2021 at 4:30 p.m. ET
Abstract ID: 492

Title: First phase 2 results of autologous tumor-infiltrating lymphocyte (TIL; LN-145) monotherapy in patients with advanced, immune checkpoint inhibitor-treated, non-small cell lung cancer (NSCLC)
Authors: A Schoenfeld, *et al.*
Presentation Type: Poster (available online)
Abstract ID: 458

Title: Successful generation of tumor-infiltrating lymphocyte (TIL) product from renal cell carcinoma (RCC) tumors for adoptive cell therapy
Authors: B Halbert, *et al.*
Presentation Type: Poster (available online)
Abstract ID: 176

Title: Expansion of tumor-infiltrating lymphocytes (TIL) using static bag for the clinical manufacturing rapid expansion protocol (REP) process

Authors: K Onimus, *et al.*
Presentation Type: Poster (available online)
Abstract ID: 101

Conference Call and Webcast on Saturday, November 13, 2021 at 5:30 p.m. ET

Iovance will host a webcast and conference call on Saturday, November 13, at 5:30 p.m. ET to discuss SITC clinical data updates for Iovance TIL in relapsed, refractory lung cancer as well as Iovance TIL in combination with pembrolizumab in patients with advanced cancers.

Iovance senior leadership will be joined by the following key opinion leaders and principal investigators in Iovance clinical studies:

- Omid Hamid, M.D., Chief of Research/ImmunoOncology, The Angeles Clinic and Research Institute; Co-Director, Cutaneous Malignancy Program, Cedars Sinai CANCER
- David M. O'Malley, M.D., Professor of Obstetrics and Gynecology at The Ohio State University College of Medicine; Director of the Division of Gynecologic Oncology, The Ohio State University Comprehensive Cancer Center – Arthur G. James Cancer Hospital and Richard J. Solove Research Institute (OSUCCC – James)
- Adam J. Schoenfeld, M.D., Medical Oncologist, Memorial Sloan Kettering Cancer Center

The conference call dial-in numbers are 1-844-646-4465 (domestic) or 1-615-247-0257 (international) and the access code is 3263399. The live webcast can be accessed in the Investors section of the company's website at www.iovance.com. The archived webcast will be available for one year following the event.

About Iovance

Iovance Biotherapeutics aims to be the global leader in innovating, developing and delivering tumor infiltrating lymphocyte (TIL) cell 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.

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; 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 new version of the protocol which further defines the patient population to include more advanced patients in our cervical cancer trial may have an adverse effect on the results reported to date; 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; 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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Source: Iovance Biotherapeutics, Inc.