Iovance Biotherapeutics Announces Clinical Data for Tumor Infiltrating Lymphocyte (TIL) Cell Therapy in Multiple Solid Tumors at Society for Immunotherapy of Cancer (SITC) Annual Meeting

November 9, 2021

TIL in Combination with Pembrolizumab Increases Overall Responses in Immune-Checkpoint Inhibitor-Naïve Cervical Cancer, Melanoma, and Head and Neck Cancer

21.4% Overall Response Rate (ORR) for TIL Therapy in Advanced, Immune Checkpoint Inhibitor-Treated Non-Small Cell Lung Cancer (NSCLC)

SAN CARLOS, Calif., Nov. 09, 2021 (GLOBE NEWSWIRE) -- Iovance Biotherapeutics, Inc. (NASDAQ: IOVA), a late-stage biotechnology company developing novel T cell-based cancer immunotherapies, today announced the publication of abstracts with clinical data for Iovance tumor-infiltrating lymphocyte (TIL) therapy in combination with pembrolizumab in patients with advanced cancers and for Iovance TIL cell therapy in relapsed, refractory lung cancer. Additional updates will be provided at the upcoming Society for Immunotherapy of Cancer (SITC) Annual Meeting from November 12-14, 2021 in Washington, D.C. and virtually.

Friedrich Graf Finckenstein, M.D., Chief Medical Officer of Iovance, stated, “Our latest clinical data in the SITC abstracts further support the power of our TIL platform and our ongoing TIL development across multiple solid-tumor cancers and various treatment settings. We look forward to highlighting clinical data that suggest TIL in combination with pembrolizumab may increase response rates as an early line treatment for advanced cervical cancer, melanoma, and head and neck cancer. SITC will also be our first medical meeting to present clinical results for Iovance TIL in heavily pre-treated patients with metastatic non-small cell lung cancer.”

Lifileucel in Combination with Pembrolizumab in Advanced Cancers
Early-line treatment with single-agent pembrolizumab achieved an overall response rate (ORR) of 33% in patients with advanced melanoma[1] and 17% in patients with head and neck squamous cell carcinoma (HNSCC).[2] Novel early-line combination therapies are needed to improve rate and depth of responses with manageable long-term safety. Clinical data in the SITC abstract show encouraging response rates after lifileucel plus pembrolizumab in patients with immune checkpoint inhibitor (ICI)-naïve advanced melanoma and HNSCC from the IOV-COM-202 study as well as patients from the C-145-04 clinical study who were ICI- and chemotherapy-naive. The ORR in all cohorts was assessed by investigator using RECIST 1.1 and listed in the abstract as follows (July 9, 2021 data cutoff):

- **Cervical cancer (Cohort 3 in C-145-04 cervical cancer study):** ORR was 50.0% with five out of 10 patients who had a confirmed objective response, including one complete response (CR), four partial responses (PR), and four best responses of stable disease (SD).
- **Metastatic melanoma (Cohort 1A in IOV-COM-202 study)**: ORR was 87.5% with seven out of eight patients who had a confirmed objective response, including three CRs, three PRs, one unconfirmed PR (uPR), and one best response of SD.
- **HNSCC (Cohort 2A in IOV-COM-202 study):** ORR was 42.9% with six out of 14 patients who had a confirmed objective response, including one CR, one unconfirmed CR (uCR), four PRs, and seven best responses of SD.

The treatment-emergent adverse event (TEAE) profile across all cohorts was consistent with the underlying disease and known adverse event (AE) profiles of pembrolizumab, nonmyeloablative lymphodepletion (NMA-LD), and IL-2. Additional and updated results for TIL plus pembrolizumab in cervical, melanoma and HNSCC will be available in an oral presentation at SITC.

LN-145 in Relapsed/Refractory Metastatic Non-Small Cell Lung Cancer (mNSCLC)
Clinical data in the abstract for Iovance TIL therapy LN-145 in relapsed/refractory mNSCLC demonstrated responses in heavily pretreated patients with NSCLC, regardless of PD-L1 expression, and warrant further investigation of LN-145 as a single-agent and in combination in patients with NSCLC in ongoing Iovance clinical studies IOV-LUN-202 and IOV-COM-202.

Consistent with previously announced results, the ORR was 21.4% in the full analysis set (n=28) and 25% in the efficacy-evaluable set (n=24) from the fully enrolled Cohort 3B of the ongoing basket study IOV-COM-202 (June 24, 2021 cutoff). Confirmed responses included one complete metabolic response and five PRs, including two responders with PD-L1 negative tumors. TIL was most commonly harvested from lung metastases (57.1%). All patients had progressed on prior ICI therapy, including patients with oncogene-driven tumors. The TEAE profile was consistent with the underlying NSCLC and known adverse event profiles of NMA-LD and IL-2. Additional and updated data from Cohort 3B will be available in a poster at the SITC Annual Meeting.

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 beginning on Friday, November 12, 2021 at 7 a.m. ET)
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 beginning on Friday, November 12, 2021 at 7 a.m. ET)
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 beginning on Friday, November 12, 2021 at 7 a.m. ET)
Abstract ID: 101

Conference Call and Webcast on Saturday, November 13, 2021 at 5:30pm 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 cell therapy 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, MD, Chief of Research/ImmunoOncology, The Angeles Clinic and Research Institute; Co-Director, Cutaneous Malignancy Program, Cedars Sinai CANCER
- David M. O'Malley, MD, 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, MD, Medical Oncologist at 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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[1]Robert C, et al. *N Engl J Med* 2015; 372:2521-2532.
[2]Burtness B, et al. *Lancet 2019*; 394:1915-1928.

Source: Iovance Biotherapeutics, Inc.