Iovance Biotherapeutics Announces New LN-144 Phase 2 Clinical Data from Metastatic Melanoma Trial to be Presented at SITC Meeting

November 9, 2017

Late-Breaking Poster Shows Early Efficacy Data in Nine Patients Treated with Cryopreserved TIL Product LN-144; Comparable Safety to Non-Cryopreserved LN-144

SAN CARLOS, Calif., Nov. 09, 2017 (GLOBE NEWSWIRE) -- Iovance Biotherapeutics, Inc. (NASDAQ:IOVA), a biotechnology company developing novel cancer immunotherapies based on tumor-infiltrating lymphocyte (TIL) technology, today announced early efficacy and safety data from Cohort 2 of the ongoing Phase 2 LN-144 metastatic melanoma trial (C-144-01). These data, being presented as a late-breaking poster (Poster #515) on Friday, November 10, 2017 at the Society for Immunotherapy of Cancer (SITC) 32nd Annual Meeting in National Harbor, Maryland, show that administration of the company's Generation 2 (Gen 2) manufacturing process in nine efficacy-evaluable metastatic melanoma patients resulted in a disease control rate (DCR) of 78%, which includes 3 confirmed partial responders (PRs) and a fourth PR awaiting confirmation. These patients had four median prior therapies. The Gen 2 manufacturing process reduces the process time to 22 days and the cell product is cryopreserved for ease of administration and handling.

"The new study findings presented at SITC indicate encouraging preliminary efficacy from patients in Cohort 2 with advanced metastatic melanoma disease, who were treated with our cryopreserved TIL product LN-144," said Maria Fardis, PhD, MBA, Iovance Biotherapeutics President and Chief Executive Officer. "We are excited to be able to offer patients a TIL product manufactured with a significantly shorter process, minimizing the time a patient has to wait to receive their TIL. The cryopreservation of the product further offers the clinical sites flexibility of scheduling the patient dosing. The reduction in duration of manufacturing will reduce our manufacturing costs as well. We intend to make the decision regarding which manufacturing process to utilize for our ongoing and future clinical trials by year-end and in advance of initiation of our regulatory interactions."

In addition to the late-breaking poster, a poster will be presented on the new Gen 2 manufacturing protocol, highlighting key improvements around the current high throughput commercial manufacturing method (Poster #203). A third poster will demonstrate utility of a new reagent used for TIL expansion and effector function (Poster #357), and a fourth poster will provide data regarding investigation of key quality attributes of TIL product (Poster #194). The company will also present two posters in the Clinical Trials in Progress session that include the design of LN-145 in head and neck and cervical cancer. The details of the poster presentations are as follows:

Cellular Therapy Approaches Late-Breaking Abstract

Title: *Novel Cryopreserved Tumor Infiltrating Lymphocytes (LN-144) Administered to Patients with Metastatic Melanoma Demonstrates Efficacy and Tolerability in a Multicenter Phase 2 Clinical Trial*
Authors: Sarnaik, et al.
Poster #: 515
Presentation date: Friday, November 10, 2017

Key Takeaways:

- Preliminary efficacy data from nine patients in Cohort 2 shows a DCR of 78% including three partial responses and a fourth awaiting confirmation.
- Preliminary data to date show that the safety profile of Gen 2 LN-144 therapy is similar to Gen 1 LN-144 therapy previously presented at ASCO 2017. The most common adverse events reported were pyrexia, anaemia and nausea.

Cellular Therapy Approaches Abstracts

Title: *A Cryopreserved TIL Product, LN-144, Generated with an Abbreviated Method Suitable for High Throughput Commercial Manufacturing Exhibits Favorable Quality Attributes for Adoptive Cell Transfer*
Authors: Wardell, et al.
Poster #: 203
Presentation date: Friday, November 10, 2017

Key Takeaways:

- The Iovance Generation 2 manufacturing process produces a potentially potent TIL product with comparable quality attributes to the Generation 1 manufacturing process.
- The abbreviated 22-day expansion platform allows for the rapid generation of TIL product for patients in urgent need of therapy. The cryopreserved product also offers flexibility of patient dosing.
- The cryopreserved drug product introduces critical logistical efficiencies allowing flexibility in distribution, and overcomes traditional barriers to the wider application of TIL therapy.

Title: *Studies of Key Quality Attributes for TIL Product, LN-144*
Authors: Ritthipichai, et al.
Poster #: 194

Presentation date: Saturday, November 11, 2017

Key Takeaways:

- Commercial manufacturing of TIL products will require a robust analytical platform to ensure consistent delivery of products meeting the critical quality attributes of cellular therapeutics.
- Study shows TIL products manufactured by Iovance are composed of greater than 99% CD45+CD3+ T cells.
- Residual melanoma cells in TIL products were below the limit of detection using a specialized assay developed for this assessment.

Immune Modulation, Cytokines, and Antibodies Abstract

Title: *The T-cell Growth Factor Cocktail IL-2/IL-15/IL-21 Enhances Expansion and Effector Function of Tumor-Infiltrating T cells in a Novel Process Developed by Iovance*
Authors: Simpson-Abelson, et al.
Poster #: 357
Presentation date: Friday, November 10, 2017

Key Takeaways:

- This study demonstrates the positive effects of adding IL-15 and IL-21 to the standard IL-2-containing cell culture in an ex vivo TIL generation protocol.

Clinical Trials (In Progress) Abstracts

Title: *A Phase 2 Study to Evaluate the Safety and Efficacy Using Autologous Tumor Infiltrating Lymphocytes (LN-145) in Patients with Recurrent and/or Metastatic Squamous Cell Carcinoma of the Head and Neck*
Authors: Leidner, et al.
Poster #: 221
Presentation date: Friday, November 10, 2017

Title: *A Phase 2, Multicenter Study to Evaluate the Efficacy and Safety Using Autologous Tumor Infiltrating Lymphocytes (LN-145) in Patients with Recurrent, Metastatic, or Persistent Cervical Carcinoma*
Authors: Jazaeri, et al.
Poster #: 220
Presentation date: Saturday, November 11, 2017

Additional information including the presentation schedule and full abstracts can be found on the conference website: http://www.sitcancer.org/2017/attendees/annual-meeting/schedule.

Forward-Looking Statements
Certain matters discussed in this press release are “forward-looking statements”. The Company may, in some cases, use terms such as “predicts,” “believes,” “potential,” “continue,” “estimates,” “anticipates,” “expects,” “plans,” “intends,” “may,” “could,” “might,” “will,” “should” or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. In particular, the Company’s statements regarding trends and potential future results are examples of such forward-looking statements. The forward-looking statements include risks and uncertainties, including, but not limited to, the efficacy, safety, tolerability and cost of the Gen 2 manufacturing process, the success, timing and cost of the Company’s ongoing clinical trials and anticipated clinical trials for its current product candidates, including statements regarding the timing of initiation and completion of the trials; the timing of and its ability to obtain and maintain U.S. Food and Drug Administration or other regulatory authority approval of, or other action with respect to, its product candidates; the strength of Company’s product pipeline; the successful implementation of the Company’s research and development programs and collaborations; the success of the Company’s license or development agreements; the acceptance by the market of the Company’s product candidates, if approved; and other factors, including general economic conditions and regulatory developments, not within the Company’s control. The factors discussed herein could cause actual results and developments to be materially different from those expressed in or implied by such statements. A further list and description of the Company’s risks, uncertainties and other factors can be found in the Company’s most recent Annual Report on Form 10-K and the Company's subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov or www.iovance.com. The forward-looking statements are made only as of the date of this press release and the Company undertakes no obligation to publicly update such forward-looking statements to reflect subsequent events or circumstance.

About Iovance Biotherapeutics, Inc.
Iovance Biotherapeutics, Inc. is a clinical-stage biotechnology company focused on the development of cancer immunotherapy products for the treatment of various cancers. The Company's lead product candidate is an adoptive cell therapy using tumor-infiltrating lymphocyte (TIL) technology being investigated for the treatment of patients with metastatic melanoma, recurrent and/or metastatic squamous cell carcinoma of the head and neck and recurrent and metastatic or persistent cervical cancer. For more information, please visit http://www.iovance.com.

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