Idera Pharmaceuticals to Provide Multiple Presentations on Intratumoral IMO-2125 at the 2016 Society for Immunotherapy of Cancer (SITC) Annual Meeting

November 9, 2016 12:31 PM EST

CAMBRIDGE, Mass. and EXTON, Pa., Nov. 09, 2016 (GLOBE NEWSWIRE) -- Idera Pharmaceuticals, Inc. (NASDAQ:IDRA), a clinical-stage biopharmaceutical company developing toll-like receptor and RNA therapeutics for patients with cancer and rare diseases, today announced that new data from the Phase 1/2 clinical trial for intratumoral IMO-2125, a TLR9 agonist, being evaluated for the treatment of late-stage metastatic melanoma, will be presented at the 2016 Society for Immunotherapy of Cancer (SITC) Annual Meeting in National Harbor, MD, November 9-13, 2016.

Oral Presentations

Date: Wednesday, November 9, 2016, Presentation Time: 11:15 AM E.T.
Session Title: Clinical New Agents in Development
Presentation Title: IMO-2125, An Investigational Intratumoral Toll-Like Receptor 9 Agonist, Modulates the Tumor Microenvironment to Enhance Anti-Tumor Activity
Presenter: Mark J. Cornfeld, M.D. M.P.H., Vice President, Oncology Medical Lead, Idera Pharmaceuticals
Location: Gaylord National Hotel & Convention Center, Cherry Blossom Ballroom

Date: Friday, November 11, 2016, Presentation Time: 3:15 PM E.T.
Session Title: State of the Art Immunotherapies: Challenges and Opportunities
Presentation Title: Reactivating the anti-tumor immune response by targeting innate and adaptive immunity in a phase I/II study of intratumoral IMO-2125 in combination with systemic ipilimumab in patients with anti-PD-1 refractory metastatic melanoma
Presenter: Presenter: Cara Haymaker, Ph.D., Instructor, The University of Texas MD Anderson Cancer Center
Location: Gaylord National Hotel & Convention Center, Maryland Ballroom

Poster Presentation
Date: Saturday, November 12, 2016: Presentation Time: 11:45 AM E.T. – 1:00 PM E.T.
Session Title: Immunotherapy
Poster Number: 216
Presentation Title: Reactivating the anti-tumor immune response by targeting innate and adaptive immunity in a phase I/II study of intratumoral IMO-2125 in combination with systemic ipilimumab in patients with anti-PD-1 refractory metastatic melanoma
Presenter: Cara Haymaker, Ph.D., Instructor, The University of Texas MD Anderson Cancer Center
Location: Gaylord National Hotel & Convention Center, Prince George's Exhibition Hall AB

A copy of the slides from Dr. Cornfeld's presentation will be made available on Idera's corporate website at http://www.iderapharma.com/our-approach/key-publications/ on Wednesday, November 9 at 11:15 AM E.T. Copies of Dr. Haymaker's presentation and related poster will be also be made available on Idera's corporate website on Friday, November 11 at 3:15 PM E.T., in accordance with the embargo policies set forth by SITC.

"As we noted in late September, we are extremely excited by the initial clinical outcomes we have generated with intratumoral IMO-2125, in combination with ipilimumab," stated Joanna Horobin, M.B., Ch.B., Idera's Chief Medical Officer. "The translational data from this trial is adding to our understanding of how IMO-2125 positively modulates the tumor microenvironment and enabling previously cold tumors an opportunity for regression and ultimately successful outcomes for patients. The translational research from this trial is critical to further this understanding as well as to help guide the direction of IMO-2125's development."

These early results are from the phase 1 portion of study IMO-2125-204 (NCT02644967) in which cohorts of patients with metastatic melanoma unresponsive to PD-1 inhibitor therapy are being administered escalating doses of IMO-2125 ranging from 4 mg/kg through 32 mg/kg. IMO-2125 is injected intra-tumorally into a designated tumor lesion together with a standard dosing regimen of ipilimumab. The trial has recently been amended to also study the combination of IMO-2125 and pembrolizumab given intravenously. Following determination of the recommended phase 2 doses (RP2D) additional patients will be treated in an expansion phase 2 portion of the study. The primary objective of the phase 1 portion of the trial is to characterize the safety and determine a RP2D of IMO-2125 when administered intra-tumorally in combination with ipilimumab or pembrolizumab. The primary objective of the phase 2 portion is to assess the clinical activity of IMO-2125 in each combination at the respective RP2Ds. Assessment will be based on the immune-related response criteria (irRC) and additionally the traditional RECIST criteria. Serial biopsies are being taken of selected injected and non-injected tumor lesions to assess immune changes and correlate with clinical response assessments. The trial will enroll approximately 60 patients. The study is being conducted at The University of Texas MD Anderson Cancer Center and is being led by Adi Diab, MD, Assistant Professor, Department of Melanoma Medical Oncology, Division of Cancer Medicine, MD Anderson as part of a strategic research alliance announced by Idera and MD Anderson in 2015.

About Toll-like Receptors and Idera's Immuno-Oncology Research Program

Toll-like receptors (TLRs) play a central role in the innate immune system, the body's first line of defense against invading pathogens, as well as damaged or dysfunctional cells including cancer cells. The innate immune system is also involved in activating the adaptive immune system, which marshals highly specific immune responses to target pathogens or tissue. Cancer cells may exploit regulatory checkpoint pathways to avoid being recognized by the immune system, thereby shielding the tumor from immune attack. Checkpoint inhibitors such as agents targeting CTLA4 or programmed cell death protein 1 (PD1) are designed to enable the immune system to recognize tumor cells. In this setting, intra-tumoral TLR9 agonist administration may increase the tumor-infiltrating lymphocytes (TILs), and thereby potentiate anti-cancer activity of checkpoint inhibitors in the injected tumor as well as systemically.

Idera's TLR9 agonists, IMO-2125 and IMO-2055, have been created using the company's proprietary chemistry-based discovery platform. IMO-2125 has been shown in various scientific presentations and publications to activate dendritic cells and induce interferon. Idera selected IMO-2125 to advance into clinical development in combination with checkpoint inhibitors based on this immunological profile. In previously completed clinical trials, subcutaneous administration of IMO-2125 was generally well tolerated in about 80 patients with hepatitis C. Idera has conducted further preclinical

research evaluating the potential of IMO-2125 to enhance the anti-tumor activity of other checkpoint inhibitors in cancer immunotherapy with data being presented at several medical conferences during the past twelve months. The posters from these presentations can be found at http://www.iderapharma.com/our-approach/key-publications.

About Metastatic Melanoma

Melanoma is a type of skin cancer that begins in a type of skin cell called melanocytes. As is the case in many forms of cancer, melanoma becomes more difficult to treat once the disease has spread beyond the skin to other parts of the body such as by through the lymphatic system (metastatic disease). Melanoma accounts for only one percent of skin cancer cases, but causes a large majority of skin cancer deaths. The American Cancer Society estimates that in 2016, there will be 76,380 new cases of melanoma in the U.S., and about 10,130 will die of this disease.

About Idera Pharmaceuticals

Idera Pharmaceuticals is a clinical-stage biopharmaceutical company developing novel nucleic acid-based therapies for the treatment of certain cancers and rare diseases. Idera's proprietary technology involves designing synthetic oligonucleotide-based drug candidates to modulate the activity of specific TLRs. In addition to its TLR programs, Idera has used its proprietary knowledge to create a third generation antisense technology platform which inhibits the production of disease-associated proteins by targeting RNA. To learn more about Idera, visit www.iderapharma.com.

Forward Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements, other than statements of historical fact, included or incorporated in this press release, including statements regarding the Company's strategy, future operations, collaborations, intellectual property, cash resources, financial position, future revenues, projected costs, prospects, plans, and objectives of management, are forward-looking statements. The words "believes," "anticipates," "estimates," "plans," "expects," "intends," "may," "could," "should," "potential," "likely," "projects," "continue," "will," and "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Idera cannot guarantee that it will actually achieve the plans, intentions or expectations disclosed in its forward-looking statements and you should not place undue reliance on the Company's forward-looking statements. There are a number of important factors that could cause Idera's actual results to differ materially from those indicated or implied by its forward-looking statements. Factors that may cause such a difference include: whether interim results from a clinical trial, such as preliminary results reported in this release, will be predictive of the final results of the trial, whether results obtained in preclinical studies and clinical trials such as the preclinical data described in this release will be indicative of the results that will be generated in future clinical trials, including in clinical trials in different disease indications; whether products based on Idera's technology will advance into or through the clinical trial process on a timely basis or at all and receive approval from the United States Food and Drug Administration or equivalent foreign regulatory agencies; whether, if the Company's products receive approval, they will be successfully distributed and marketed; and such other important factors as are set forth under the caption "Risk Factors" in the Company's Annual Report and on Form 10-Q for the period ended September 30, 2016. Although Idera may elect to do so at some point in the future, the Company does not assume any obligation to update any forward-looking statements and it disclaims any intention or obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

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