

Idera Pharmaceuticals Enters Into a Strategic Clinical Research Alliance With MD Anderson Cancer Center to Advance Clinical Development of Intratumoral TLR9 Agonist in Combination With Checkpoint Inhibitors

June 8, 2015 12:00 PM EDT

- Intratumoral TLR9 Agonist Provides a Novel Approach to Immuno-Oncology -

- First Clinical Trial of IMO-2125 and Checkpoint Inhibitors to be Initiated 2H 2015 -

CAMBRIDGE, Mass. and EXTON, Pa., June 8, 2015 (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 the company has entered into a strategic clinical research alliance with The University of Texas MD Anderson Cancer Center to advance clinical development of intratumoral TLR9 agonist in combination with checkpoint inhibitors. IMO-2125 is a TLR9 agonist which has been evaluated subcutaneously in over 80 human subjects, was well tolerated, and was shown to induce immune responses.

The company intends to initiate the first trial of the research alliance, a Phase 1/2 study to assess the safety and efficacy of Intratumoral IMO-2125 in combination with ipilimumab (a CTLA4 antibody) in patients with metastatic melanoma. In this trial, escalating doses of IMO-2125 will be administered intratumorally into a lesion, with a standard dosing regimen of ipilimumab. The primary objectives of the trial will be to determine the maximum tolerated dose (MTD) and characterize the dose-limiting toxicities (DLTs) of IMO-2125 when administered intratumorally in combination with ipilimumab, as well as to determine the efficacy of the combination utilizing the immune-related response criteria (irRC). The company has already filed and received FDA feedback to a Pre-Investigational New Drug Application (PIND) for IMO-2125 and intends to submit an Investigational New Drug application (IND) and initiate the clinical study in the second half of this year. The trial will enroll approximately 45 patients. The company expects data to be available in 2016. The study will be led by Adi Diab, MD, Assistant Professor, Department of Melanoma Medical Oncology, Division of Cancer Medicine, MD Anderson. Additional trials as part of the broader, clinical research alliance are currently in the planning stages.

"This type of clinical research alliance is important to MD Anderson's work toward eliminating cancer," said Patrick Hwu, M.D., division head, Cancer Medicine at MD Anderson. "The study to be headed by Dr. Diab will add to our overall efforts in finding new therapies for our patients."

"Being chosen as a strategic research alliance partner by MD Anderson, a world-leading cancer research center to advance the clinical development of intratumoral TLR9 agonists in combination with check-point inhibitors is an important step forward for Idera's oncology program. We look forward to evaluating in the clinical setting if our targeted intratumoral approach can meaningfully improve patient outcomes," stated Vincent Milano, Chief Executive Officer of Idera Pharmaceuticals. "The pre-clinical data we presented at the American Association for Cancer Research (AACR) Immunotherapy conference in December demonstrated that the combination of intratumoral TLR9 agonist and systemically administered ipilimumab induced potent anti-tumor activity in both the treated and distant tumors and we look forward to seeing if we can replicate those results in the clinical setting."

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, intratumoral 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 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 from these studies to be presented at an oncology conference in the second half of 2015.

About Idera Pharmaceuticals

Idera Pharmaceuticals is a clinical-stage patient focused biopharmaceutical company developing novel therapeutic approaches for the treatment of cancer and rare diseases. Idera's proprietary technology involves creating novel nucleic acid therapeutics. Idera's immunotherapy approach is based on the modulation of Toll-like receptors (TLRs). In addition to its TLR modulation programs, Idera is developing gene silencing oligonucleotides (GSO) technology that it has created to inhibit 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 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 on Form 10-Q for the period ended March 31, 2015. 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.

CONTACT: Investor and Media Contact Robert Doody Vice President, Investor Relations and Corporate Communications 484-639-7235 rdoody@iderapharma.com

Idera Pharmaceuticals Logo

Idera Pharmaceuticals