Idera Pharmaceuticals Announces Initiation of Phase 1/2 Clinical Trial of Intra-tumoral IMO-2125 in Combination With Ipilimumab in Patients With Metastatic Melanoma

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CAMBRIDGE, Mass. and EXTON, Pa., Dec. 14, 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 commenced enrollment in a Phase 1/2 clinical trial evaluating intra-tumoral IMO-2125, a TLR9 agonist in combination with ipilimumab (an anti-CTLA4 antibody) in patients with previously treated metastatic melanoma. 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.

In this clinical trial, escalating doses of IMO-2125 ranging from 4 mg/kg through 32 mg/kg will be administered intra-tumorally into one of two selected tumor lesions, with a standard dosing regimen of ipilimumab. The primary objectives of the phase 1 portion of the trial will be to determine the maximum tolerated dose (MTD) and characterize the dose-limiting toxicities (DLTs) of IMO-2125 when administered intra-tumorally in combination with ipilimumab. The primary objective of the phase 2 portion will be to determine the efficacy of the combination utilizing the immune-related response criteria (irRC) in additional to traditional RECIST criteria. Serial biopsies will be taken of selected injected and non-injected tumor lesions to assess immune changes and response assessments. The trial will enroll approximately 45 patients. The company expects initial data from the ongoing trial to be available in 2016.

Preclinical evidence shows that IMO-2125 delivered intra-tumorally in combination with anti-CTLA-4 mAb demonstrates improved inhibition of tumor growth, regression of metastases and infiltration of the number and nature of tumor specific immune cells in injected and non-injected tumor lesions versus monotherapy with either agent. Additional pre-clinical evidence suggests that intra-tumoral IMO-2125 modulates checkpoint gene expression, including IDO1, PDL1, TIM3, LAG3 and CTLA4, in both treated and distant tumor nodules. The company is currently considering additional clinical studies to evaluate IMO-2125 in combination with other select checkpoint inhibitors.

“We are eager to demonstrate translation of the compelling preclinical data into the clinical setting with this novel approach to cancer immunotherapy with intra-tumoral IMO-2125,” stated Joanna Horobin, M.B., Ch.B, Idera’s Chief Medical Officer. “The momentum and enthusiasm among our team along with our research alliance partner, MD Anderson is very strong. This is a beginning step in a broad strategy to demonstrate a major advancement in efficacy and safety over existing treatment regimens.”

“We are anxious to understand whether the local immune changes observed in the injected tumor will be transferred to non-injected tumor lesions and that both will correlate with improved clinical efficacy for our patients,” stated Dr. Diab.

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 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 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 third generation antisense 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, including statements about potential treatments for metastatic melanoma with Idera’s IMO-2125 in combination with ipilimumab. Such statements may be identified by words such as "believe," "expect," "may," "plan," "potential," "will" and similar expressions, and are based on the company’s current beliefs and expectations. Development of drug therapies involves a high degree of risk, and only a small percentage of research and development programs undertaken may result in the commercialization of a product. Positive preclinical data does not ensure that later stage clinical trials will be successful. For more detailed information on the risks and uncertainties associated with Idera’s development activities, please review the "Risk Factors" in the Company's Annual Report as updated on Form 10-Q for the period ended September 30, 2015. Any forward-looking statements speak only as of the date of this press release and the company assumes no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

Investor and Media Contact
Robert Doody
Vice President, Investor Relations and Corporate Communications
617-679-5515 - Office
484-639-7235 - Mobile
rdoody@iderapharma.com

Idera Pharmaceuticals, Inc.