Idera Presents Preclinical Data Demonstrating Enhanced Systemic Anti-Tumor Activity from Combination Treatment with Intra-tumoral IMO-2125 and IDO-1 Inhibitor at AACR Annual Meeting 2016

April 19, 2016 11:30 AM EDT

CAMBRIDGE, Mass. and EXTON, Pa., April 19, 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 new preclinical data demonstrating enhanced systemic anti-tumor activity in preclinical cancer models with intra-tumoral administration of IMO-2125 in combination with an inhibitor of the immunosuppressive enzyme, indoleamine-pyrrole 2,3-dioxygenase (IDO1). IMO-2125 is a synthetic oligonucleotide-based agonist of Toll-like receptor 9 discovered and developed by Idera. IDO is one of several immune checkpoints involved in tumor immune escape. IDO-1 inhibitors are currently in clinical development. These data are being presented at the AACR Annual Meeting 2016 in New Orleans, LA.

"There is an extensive body of evidence which demonstrates that modulating the tumor microenvironment is critical to a successful outcome in cancer immunotherapy", stated Sudhir Agrawal, D.Phil., President of Research at Idera Pharmaceuticals. "In preclinical models, previously we have seen compelling systemic anti-tumor effects with intra-tumoral IMO-2125 monotherapy, in combination with inhibitors of CTLA-4, PD-1, and now, IDO."

In the presentation, entitled "Creating the tumor microenvironment for effective immunotherapy: Anti-tumor activity of intra-tumoral IMO-2125, a TLR9 agonist is further enhanced by inhibition of indoleamine-pyrrole 2,3-dioxygenase (IDO)," Idera scientists presented data further supporting the hypothesis that intra-tumoral IMO-2125 changes the tumor microenvironment by increasing tumor-infiltrating lymphocytes (TILs) and generating a favorable tumor microenvironment. Changes in IDO checkpoint inhibitor expression were also observed.

In the current studies, IMO-2125 (alone and in combination with an IDO-1 inhibitor) increased TIL infiltration and decreased the growth of treated and distant tumors, providing evidence of an enhanced systemic antitumor immune response compared to either agent given alone.

In the study we evaluated the antitumor activity of i.t. IMO-2125 in combination with an IDO1 inhibitor in a murine syngeneic colon carcinoma CT26 model. There was a statistically significant decrease in the growth of both local and distant tumors which was greater for combination therapy than for either IMO-2125 or IDO-1 alone (for lung metastases: combination vs IMO-2125: P = 0.0393; combination vs IDO-1 inhibitor: P = 0.0128).

These results and previous observations with IMO plus anti-CTLA4 and IMO plus PD-1 demonstrate that combination immunotherapy with IMO-2125 has the potential to improve clinical outcomes over currently available anti-CTLA4 and PD-1 inhibitors, and now IDO-1 inhibitors. These presentations are all currently available on Idera's website at http://www.iderapharma.com/our-science/key-presentations-and-publications.

In partnership with the MD Anderson Cancer Center, the company is currently conducting a Phase 1/2 clinical trial of intra-tumoral IMO-2125 in combination with ipilimumab (CTLA4) for the treatment of pembrolizumab (PD1) treated refractory metastatic melanoma patients. The study has also recently been amended to include an arm studying the combination of IMO-2125 and PD1 in the same patient population.

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

Toll-like receptors (TLRs) are key components of 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) and, more recently, IDO inhibitors work by targeting mechanisms of adaptive immune resistance. It is believed that intra-tumoral administration of IMO-2125 may potentiate the activity of all of these immunotherapies by creating a more favorable tumor microenvironment that includes increased infiltration by TILs.

Idera's TLR9 agonist, IMO-2125 has been created using the company's proprietary chemistry-based discovery platform. IMO-2125 has been shown to activate dendritic cells and induce interferon and other cytokines. Idera selected IMO-2125 to advance into clinical development in combination with checkpoint inhibitors based on this immunological profile. In preclinical studies in cancer models, IMO-2125 has shown dose-dependent anti-tumor activity in the injected tumor as well as in distant tumors. Anti-tumor activity is associated with changes in the tumor microenvironment, increased T-cell infiltration, and induction of durable, tumor specific memory. In combination with anti-CTLA4, anti-PD1, and IDO1 inhibitor, IMO-2125 has shown greater anti-tumor activity than with either agent alone. In previously completed clinical trials, subcutaneous administration of IMO-2125 was generally well tolerated in about 80 patients with hepatitis C.

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 using a TLR-targeting technology, to design synthetic oligonucleotide-based drug candidates to act by modulating the activity of specific TLRs. In addition to its TLR programs, Idera has created a third generation antisense technology platform using its proprietary technology 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 cancer employing combinations of drug therapies including Idera's IMO-2125 with resistance modulators such as CTLA4, PD1 and IDO1. 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 section of Idera's

most recent annual or quarterly or annual report filed with the Securities and Exchange Commission. 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
VP, IR & Corporate Communications
617-679-5515 (office)
484-639-7235 (mobile)
rdoody@iderapharma.com

Idera Pharmaceuticals, Inc.