Idera Pharmaceuticals Announces Cancer Immunotherapy Regimen With Intratumoral IMO-2055 Demonstrated Potent and Systemic Anti-Tumor Activity in Preclinical Models

December 2, 2014 9:30 PM EST

Data Highlight Potential Opportunity to Enhance Activity of Emerging Class of Checkpoint Inhibitors With Idera's Proprietary Toll-Like Receptor Agonists

CAMBRIDGE, Mass., Dec. 2, 2014 (GLOBE NEWSWIRE) -- Idera Pharmaceuticals, Inc. (Nasdaq:IDRA), a clinical-stage biopharmaceutical company developing nucleic acid therapeutics for patients with cancer and rare diseases, today announced new preclinical data that showed cancer immunotherapy with intratumoral injections of IMO-2055 and ipilimumab demonstrated potent and systemic anti-tumor activity in multiple preclinical cancer models. IMO-2055 is a synthetic oligonucleotide-based agonist of Toll-like receptor (TLR) 9 discovered and developed by Idera. Ipilimumab is a checkpoint inhibitor targeting cytotoxic T-lymphocyte-associated protein 4 (CTLA-4). The data were presented at the American Association for Cancer Research (AACR) Tumor Immunology and Immunotherapy Meeting in Orlando, Fla., earlier today.

In the presentation at the AACR meeting, Idera scientists summarized the results of several studies of IMO-2055 alone and in combination with ipilimumab in well-established preclinical models of bladder, colon and lung cancer. Results showed that intratumoral injections of IMO-2055 inhibited the growth of treated and distant tumors, as evaluated by tumor volume and histology. Compared to monotherapy with either agent, the combination regimen involving intratumoral injections of both agents demonstrated increased and sustained inhibition of treated and distant tumor growth. In addition, there were statistically significant increases in cytotoxic T cells against two antigens (AH1 and β-gal) expressed in treated and distant tumors, respectively, for the combination therapy versus monotherapy with either agent.

"In these preclinical models, intratumoral administration of a TLR 9 agonist enhanced the activity of a checkpoint inhibitor by inducing significantly greater anti-tumor immune responses against directly treated tumors and distant tumors representing models of metastatic cancer," said Sudhir Agrawal, D.Phil., President of Research at Idera Pharmaceuticals. "Cancer immunotherapy represents an important and emerging area of oncology research, and combination regimens with agents such as IMO-2055 and ipilimumab or other checkpoint inhibitors may increase the ability to harness the body's immune system to fight difficult-to-treat cancers in patients."

"In addition to our ongoing and planned clinical development programs in genetically defined forms of B-cell lymphoma and rare diseases, Idera's immuno-oncology research holds the promise of advancing cancer treatment for patients and driving value for the Company," said Vincent Milano, Chief Executive Officer of Idera Pharmaceuticals. "With these compelling preclinical data, we are now assessing our options to advance a cancer immunotherapy program into clinical development. We look forward to unveiling those plans in 2015."

The presentation, entitled "Intratumoral injection of IMO-2055, a novel Toll-like receptor 9 agonist, with ipilimumab induces a systemic tumor-specific immune response," is available on Idera's website at: http://www.iderapharma.com/our-science/key-presentations-and-publications. Ipilimumab is approved by the U.S. Food and Drug Administration for the treatment of unresectable or metastatic melanoma, and was developed by Bristol-Myers Squibb Company. The preclinical studies presented at the AACR meeting were conducted by scientists from Idera Pharmaceuticals.

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 CTLA-4 or programmed cell death protein 1 (PD1) are designed to enable the immune system to recognize tumor cells. In this setting, a TLR 9 agonist may enhance the anti-tumor immune response by activating TLR signaling.

Based on the company's proprietary chemistry-based discovery platform, Idera has designed and developed two synthetic oligonucleotide-based TLR 9 agonists, IMO-2055 and IMO-2125. In completed clinical trials, systemic administration of IMO-2055 was generally well tolerated as a monotherapy and in combination with other drugs in more than 300 patients with various types of cancers. In addition, systemic administration of IMO-2125 was generally well tolerated in about 80 patients with hepatitis C. Idera is currently conducting further preclinical research to evaluate the potential of IMO-2055 and IMO-2125 to enhance the anti-tumor activity of checkpoint inhibitors in cancer immunotherapy.

About Idera Pharmaceuticals

Idera Pharmaceuticals is a clinical-stage biopharmaceutical company developing a novel therapeutic approach for the treatment of genetically defined forms of B-cell lymphoma and rare autoimmune diseases. Idera's proprietary technology involves creating novel nucleic acid therapeutics designed to inhibit over-activation of Toll-like receptors (TLRs). In addition to its TLR programs, Idera is developing gene silencing oligonucleotides (GSOs) that it has created 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. 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; 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; whether the Company's case resources are sufficient to fund the Company's proposed programs and the Company's operations for the period anticipated; and such other important factors as are set forth under the caption "Risk Factors" in the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2014. 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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