Idera Pharmaceuticals Expands Pipeline by Initiating Clinical Development of Proprietary TLR Antagonist Candidate IMO-9200

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- IND application for Phase 1 clinical trial of IMO-9200 in healthy volunteers accepted by FDA; patient dosing on track to begin in fourth quarter

- New IMO-9200 data presented at 10th Annual Meet ing of the Oligonucleotide Therapeutics Society demonstrate inhibition of TLR-mediated immune responses in multiple preclinical models

CAMBRIDGE, Mass., Oct. 14, 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 it has advanced IMO-9200 into Phase 1 clinical development following acceptance of an Investigational New Drug application by the U.S. Food and Drug Administration. In addition, the company announced today the presentation of new data that showed IMO-9200 inhibited Toll-like receptor- (TLR-) mediated immune responses in multiple preclinical models at the 10th Annual Meeting of the Oligonucleotide Therapeutics Society (OTS) in San Diego, California. These data support the development of IMO-9200, a synthetic oligonucleotide-based antagonist of TLRs 7, 8 and 9, as a potential treatment for autoimmune diseases in which TLRs are over-activated. Idera's pipeline of clinical-stage TLR antagonists also includes IMO-8400, the company's lead product candidate currently in development for genetically defined forms of B-cell lymphoma and rare autoimmune diseases.

In two presentations at the OTS meeting, Idera scientists summarized the results of several preclinical studies of IMO-9200. Collectively, the data showed that IMO-9200 dose-dependently inhibited the induction of multiple inflammatory cytokines, including IL-12, IP-10, IFN-α, IL-6, IL-1β and MCP-1, in cell-based assays, mice and non-human primates. In addition, data from a well-characterized preclinical model of lupus showed that IMO-9200 improved disease-associated parameters in MRL/lpr mice, with decreases in blood urea nitrogen levels, proteinuria, autoantibodies and kidney interstitial inflammation. Idera has evaluated IMO-9200 in additional autoimmune disease models, and plans to present data from these studies in the future.

"The findings announced today provide further support for our proprietary TLR antagonism technology by demonstrating the specific and potent inhibitory activity of IMO-9200 against TLRs that have been implicated in multiple autoimmune diseases," said Sudhir Agrawal, D. Phil., Chief Executive Officer of Idera Pharmaceuticals. "While we continue to advance our lead TLR antagonist candidate IMO-8400 in ongoing and planned clinical trials in genetically defined forms of B-cell lymphoma and rare autoimmune diseases, we believe that the expansion of our clinical-stage pipeline with IMO-9200 may allow us to address an even broader range of autoimmune and inflammatory disorders in which TLRs have been shown to be over-activated."

Idera plans to begin dosing of IMO-9200 in a Phase 1 clinical trial in healthy volunteers in the fourth quarter. In addition, the company plans to finalize a strategic assessment of potential indications for further clinical development of IMO-9200 by year end.

The two presentations, entitled "IMO-9200, a Novel Clinical-stage TLR Antagonist for the Treatment of Autoimmune Diseases, Inhibits TLR-mediated Immune Responses and Shows Activity in Animal Models" and "IMO-9200, a Novel Clinical-stage TLR Antagonist for the Treatment of Autoimmune Diseases, Suppresses TLR-mediated Immune Responses in Non-human Primates following Systemic Administration," are available on Idera's website at: http://www.iderapharma.com/our-science/key-presentations-and-publications.

About Toll-Like Receptors (TLRs) and Idera's Proprietary TLR Antagonist Technology Platform

Toll-like receptors (TLRs) play a central role in the innate immune system and in regulating inflammation, and published data have implicated TLR dysfunction across a broad range of autoimmune diseases and genetically defined forms of B-cell lymphoma.

In autoimmune diseases, endogenous nucleic acids released from damaged or dying cells initiate signaling cascades through TLRs, inducing multiple cytokines. Subsequent inflammation causes further damage to the body's own tissues and organs and the release of more self-nucleic acids. Thus, a pathological amplification cycle is established, promoting disease progression.

In B-cell lymphomas characterized by the MYD88 L265P genetic mutation, an oncoprotein is produced that over activates TLR-initiated signaling, thereby activating transcription factors that promote the survival and proliferation of tumor cells.

Based on the company's proprietary chemistry-based discovery platform, Idera designed and developed two synthetic oligonucleotide-based TLR antagonists, IMO-8400 and IMO-9200. These clinical-stage candidates have demonstrated activity in multiple preclinical models of autoimmune disease and cancer, including psoriasis, lupus, arthritis, and MYD88 L265P-positive B-cell lymphoma.

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, 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 Quarterly Report on Form 10-Q for the quarter ended June 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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