Idera Pharmaceuticals Initiates Phase 1 Clinical Trial of IMO-3100, a Toll-like Receptor Antagonist Intended for Autoimmune Disease Indications

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CAMBRIDGE, Mass., Jan 28, 2010 (BUSINESS WIRE) -- Idera Pharmaceuticals, Inc. (Nasdaq: IDRA) today announced initiation of a Phase 1 clinical trial of IMO-3100, an antagonist of Toll-like Receptor (TLR) 7 and TLR9.

"As an antagonist of TLR7 and TLR9, IMO-3100 has a novel mechanism of action and presents a potentially innovative approach in the treatment of a number of autoimmune diseases," said Sudhir Agrawal, D.Phil., Chief Executive Officer and Chief Scientific Officer. "IMO-3100 is our fourth compound to advance into clinical development, each for a different therapeutic application."

"Our first step in the clinical evaluation of IMO-3100 is to assess the safety and mechanism of action in healthy subjects," said Tim Sullivan, Ph.D., Vice President of Development Programs. "We have observed exciting results that show IMO-3100 ameliorates the pathologic findings observed in preclinical models of various autoimmune diseases, including lupus, rheumatoid arthritis, and psoriasis. Data from this Phase 1 clinical trial will support our decisions regarding subsequent clinical development of IMO-3100."

About IMO-3100

IMO-3100 is a DNA-based antagonist of Toll-like Receptor (TLR) 7 and TLR9, which has been shown in preclinical assays to suppress immune responses mediated through TLR7 and TLR9, including induction of interferon-alpha, TNF-alpha, IP-10, IL-6, and activation of B cells. Studies from independent researchers have suggested that immune complexes involved in certain autoimmune diseases induce inflammatory responses mediated through TLR7 and TLR9. Use of a TLR antagonist to block responses to such immune complexes may provide a potentially innovative approach for the treatment of autoimmune diseases. In preclinical mouse models of autoimmune diseases including lupus, rheumatoid arthritis, and psoriasis, IMO-3100 has shown potent activity in reducing pathologic and immunologic manifestations of disease. Idera continues to evaluate IMO-3100 and other TLR antagonist drug candidates in additional preclinical models of autoimmune, inflammatory, and hyperlipidemia diseases.

Idera has evaluated IMO-3100 for its pharmacodynamic mechanism of action in non-human primates. In this study, the *ex vivo* response of peripheral blood mononuclear cells (PBMCs) to TLR7 and TLR9 agonists was assessed at various times after subcutaneous administration of IMO-3100 to non-human primates. The Company plans to present data from this preclinical study at a scientific meeting in the first quarter of 2010.

About the Trial (Study 3100-001)

In this Phase 1 trial, IMO-3100 is being administered by subcutaneous injection to healthy subjects in a rising single-dose design. The primary objective is to evaluate safety and tolerability. Secondary objectives are to characterize the pharmacokinetic profile of IMO-3100 and to assess the pharmacodynamic mechanism of action through measurement of the *ex vivo* response of PBMCs to TLR7 and TLR9 agonists. The trial is being conducted at a single U.S. site.

The Company plans to use the results from this rising single-dose trial to select dosages for an anticipated follow-up trial in healthy subjects, the purpose of which would be to characterize safety, pharmacokinetics, and *ex vivo* pharmacodynamic mechanism of action with weekly subcutaneous administration for four weeks. Based on the data from these two planned Phase 1 trials, the Company intends to identify an autoimmune disease indication for further clinical development of IMO-3100 by the end of 2010.

About Idera Pharmaceuticals, Inc.

Idera Pharmaceuticals develops drug candidates to treat infectious diseases, autoimmune and inflammatory diseases, cancer, and respiratory diseases, and for use as vaccine adjuvants. Our proprietary drug candidates are designed to modulate specific Toll-like Receptors, which are a family of immune system receptors that direct immune system responses. Our pioneering DNA and RNA chemistry expertise enables us to create drug candidates for internal development and generates opportunities for multiple collaborative alliances. For more information, visit www.iderapharma.com.

Idera Forward Looking Statements

This press release contains forward-looking statements concerning Idera Pharmaceuticals, Inc. that involve a number of risks and uncertainties. For this purpose, any statements contained herein that are not statements of historical fact may be deemed to be forward-looking statements. Without limiting the foregoing, the words "believes," "anticipates," "plans," "expects," "estimates," "intends," "should," "could," "will," "may," and similar expressions are intended to identify forward-looking statements. There are a number of important factors that could cause Idera's actual results to differ materially from those indicated by such forward-looking statements, including whether results obtained in preclinical studies such as the preclinical studies referred to in this release will be indicative of results obtained in 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 collaborations with Merck KGaA and an affiliate of Merck & Co., Inc. will be successful; whether the patents and patent applications owned or licensed by the Company will protect the Company's technology and prevent others from infringing it; whether Idera's cash resources will be sufficient to fund the Company's operations; and such other important factors as are set forth under the caption "Risk Factors" in Idera's Quarterly Report on Form 10-Q for the three months ended September 30, 2009, which important factors are incorporated herein by reference. Idera disclaims any intention or obligation to update any forward-looking statements.

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