Idera Pharmaceuticals Announces Preliminary Data from Phase 1 Clinical Trial of IMO-3100, a Toll-like Receptor Antagonist Drug Candidate for Autoimmune and Inflammatory Diseases

June 8, 2010 11:31 AM EDT

CAMBRIDGE, Mass., Jun 08, 2010 (BUSINESS WIRE) --Idera Pharmaceuticals, Inc. (Nasdaq: IDRA) today announced preliminary results from a Phase 1 clinical trial of IMO-3100, its lead Toll-like Receptor (TLR) 7 and TLR9 antagonist drug candidate for potential applications in autoimmune and inflammatory diseases. In this trial, healthy subjects in five dosage cohorts received single doses of IMO-3100 from 0.04 to 0.64 mg/kg. IMO-3100 was well tolerated at all dose levels. Subjects who received IMO-3100 showed suppression of tumor necrosis factor-alpha (TNF-a), interleukin-1 beta (IL-1B), interleukin-6 (IL-6), interferon-alpha (IFN-a), and other pro-inflammatory cytokines mediated through TLR7 and TLR9 activation. The Company is planning to present detailed results of the trial at a scientific meeting in the fourth quarter of 2010.

"We are pleased with the safety of IMO-3100 in this trial at dosages up to 0.64 mg/kg. In addition, the observation that IMO-3100 treatment led to suppression of TLR7- and TLR9-mediated immune responses is consistent with the intended pharmacodynamic mechanism of action," said Robert D. Arbeit, M.D., Vice President of Clinical Development. "Our next step in the clinical development of IMO-3100 is to initiate a four-week repeat-dose trial in healthy subjects in the third quarter of 2010. We plan to design the trial to evaluate multiple-dose safety and the duration of the pharmacodynamic effect."

"IMO-3100 is a first-in-class antagonist of TLR7 and TLR9 and provides an innovative approach for the potential treatment of autoimmune and inflammatory diseases. IMO-3100 has shown activity in preclinical models of diseases including lupus, rheumatoid arthritis, psoriasis, and hyperlipidemia," said Sudhir Agrawal, D.Phil., Chief Executive Officer and Chief Scientific Officer. "We expect that safety and pharmacodynamic mechanism of action data from our IMO-3100 clinical trials in healthy subjects will help us move rapidly into clinical evaluation of IMO-3100 in selected autoimmune disease indications."

About IMO-3100

IMO-3100 is a DNA-based antagonist of Toll-like Receptor (TLR) 7 and TLR9 developed by Idera that has been shown in preclinical studies to suppress immune responses mediated through TLR7 and TLR9, including suppressing the induction of IFN-a, TNF-a, IP-10, IL-6, and the 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. Blocking these responses through use of a TLR antagonist represents an innovative approach to the treatment of autoimmune and inflammatory diseases. IMO-3100 has shown potent activity in reducing pathologic and immunologic manifestations in preclinical mouse models of diseases such as lupus, rheumatoid arthritis, psoriasis, and hyperlipidemia.

About the Phase 1 Single-Dose Trial of IMO-3100 in Healthy Subjects

In January 2010, the Company initiated a single-dose, dose-escalation Phase 1 clinical trial of IMO-3100 in healthy subjects. In this trial, IMO-3100 was administered by subcutaneous injection. The primary objective was evaluation of safety and tolerability. Secondary objectives were to characterize the pharmacokinetics of IMO-3100 and to assess the pharmacodynamic mechanism of action in peripheral blood mononuclear cells (PBMCs). The trial was conducted at a single U.S. site.

IMO-3100 was evaluated at five dose levels: 0.04, 0.08, 0.16, 0.32, and 0.64 mg/kg. Six healthy subjects were enrolled at each dose level, with a total of six placebo subjects. Subjects were monitored for safety, pharmacokinetic, and pharmacodynamic evaluations through day eight.

IMO-3100 treatment was well tolerated at all dose levels. PBMCs isolated from subjects who received 0.32 or 0.64 mg/kg of IMO-3100 showed suppression of immune responses mediated through TLR7 and TLR9 agonists *ex vivo*, which was not observed in PBMCs isolated from placebo subjects. The PBMC immune responses monitored included induction of TNF-a, IL-1B, IL-6, IFN-a, and other pro-inflammatory cytokines. Immune responses through TLR7 and TLR9 were induced by a RNA-based TLR7 agonist and a DNA-based TLR9 agonist.

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 statements with respect to the preliminary results of the Phase 1 trial of IMO-3100 described above, which may not be reflected in the final analyses of this trial; whether results obtained in preclinical studies and early clinical trials such as the studies and trials referred to in this release will be indicative of results obtained 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 collaborations with Merck KGaA and Merck Sharp & Dohme Corp., 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 March 31, 2010, which important factors are incorporated herein by reference. Idera disclaims any intention or obligation to update any forward-looking statements.

SOURCE: Idera Pharmaceuticals, Inc.

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