Idera Pharmaceuticals Presents Phase 1 Clinical Data for IMO-3100, Lead Candidate for the Treatment of Autoimmune Diseases, and Provides Program Update

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CAMBRIDGE, Mass., Oct 21, 2010 (BUSINESS WIRE) -- Idera Pharmaceuticals, Inc. (Nasdaq: IDRA) today announced results from its single-dose, dose-escalation Phase 1 clinical trial evaluating the safety and mechanism of action of IMO-3100, its lead Toll-like Receptor (TLR) 7 and TLR9 antagonist drug candidate for the treatment of autoimmune and inflammatory diseases. In the trial, IMO-3100 was well tolerated at all dose levels evaluated in the 30 healthy subjects that received IMO-3100, and target engagement of TLR7 and TLR9 was observed through inhibition of TLR7- and TLR9-mediated immune responses. The presentation entitled "Safety and Pharmacodynamics of IMO-3100, a Novel Toll-like Receptor Antagonist for Autoimmune and Inflammatory Diseases, in a Rising Single-Dose Phase 1 Clinical Trial" was made today at the 6th Annual Meeting of the Oligonucleotide Therapeutic Society being held in Dana Point, California.

The Company also has completed dosing in its multiple-dose Phase 1 clinical trial of IMO-3100. The multiple-dose clinical trial is designed to assess the safety of IMO-3100 and the duration of inhibition of TLR7- and TLR9-mediated immune responses. In this study, IMO-3100 was administered in two dosing schedules to 16 healthy subjects for four weeks. Eight additional subjects received placebo injections. The study remains blinded; however all 24 subjects have completed dosing and scheduled follow-up with no treatment-related discontinuations or serious adverse events.

"We are pleased with the safety profile of IMO-3100 in the 46 healthy subjects treated to date, and with the activity observed in the single-dose, dose-escalation trial that is consistent with the intended mechanism of action," said Robert Arbeit, Vice President of Clinical Development of Idera Pharmaceuticals. "We plan to analyze the data from the multiple-dose study by year end and present the results at a scientific meeting in the first half of 2011."

"The next step in the clinical development of IMO-3100 would be to initiate a Phase 2 clinical trial in a selected autoimmune disease indication," commented Sudhir Agrawal, D.Phil., Chief Executive Officer and Chief Scientific Officer of Idera Pharmaceuticals. "Prior to initiation of the Phase 2 trial, we plan to conduct additional non-clinical studies in light of some reversible immune responses observed in our 13-week non-clinical toxicology studies that are inconsistent with our other non-clinical studies of IMO-3100."

The Company expects to provide in the first quarter of 2011 an update on the non-clinical studies and the anticipated timing for the initiation of a Phase 2 clinical trial of IMO-3100.

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

Study Design

IMO-3100 was administered by subcutaneous injection at five escalating dose levels: 0.04, 0.08, 0.16, 0.32, and 0.64 mg/kg. 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 using peripheral blood mononuclear cells (PBMCs). Six healthy subjects were enrolled at each dose level, plus six placebo subjects. The trial was conducted at a single U.S. site.

Study Results

- IMO-3100 was well tolerated at all dose levels
- There were no serious adverse events reported and all adverse events were grade 1
- Mild injection site reactions were the most frequent adverse event (65%)
- Proof of target engagement was demonstrated by inhibition of TLR7- and TLR9-mediated cytokine induction in PBMCs isolated from study subjects after IMO-3100 treatment at dosages of 0.32 and 0.64 mg/kg
    - The inhibition of cytokine induction was dependent on dose of IMO-3100 administered
    - Cytokines inhibited include TNF-a, IL-1B, IL-6, IL-2R, IL-12, IL-10, IL-8, MIP-1a and B, IFN- a and RANTES
    - Selected cytokines remain suppressed for up to 5 days in IMO-3100-treated subjects
    - There was no evidence of cytokine inhibition in PBMCs isolated from placebo-treated subjects

About IMO-3100

IMO-3100, an antagonist of TLR7 and TLR9, is a lead drug candidate in development to treat autoimmune diseases. Independent research studies suggest that pro-inflammatory cytokines characteristic of autoimmune disease are induced through activation of TLR7 and TLR9. IMO-3100 is designed to block production of multiple pro-inflammatory cytokines induced through TLR7 and TLR9. In contrast, many current autoimmune disease

treatments aim to block the activity of individual cytokines. IMO-3100 has demonstrated potent activity in reducing pathologic and immunologic manifestations in preclinical mouse models of diseases such as lupus, rheumatoid arthritis, psoriasis and hyperlipidemia.

About Idera Pharmaceuticals, Inc.

Idera Pharmaceuticals is developing drug candidates that act by modulating immune responses through specific Toll-like Receptors (TLRs). TLRs, a family of immune system receptors and the immune system's first line of defense, recognize pathogens and initiate an immune response. Idera's DNA and RNA chemistry expertise has generated a pipeline of compounds designed to interact with specific TLRs for a broad range of diseases. Through its internal pipeline and collaborative alliances, Idera has established a portfolio of TLR-targeted therapeutics for infectious diseases, autoimmune and inflammatory diseases, cancer, and respiratory diseases, and for use as vaccine adjuvants.

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; 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 non-clinical studies and 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 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 June 30, 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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