Idera Pharmaceuticals Announces Results of Phase 1 Clinical Trial of IMO-8400, Toll-like Receptor Antagonist Drug Candidate for Autoimmune and Inflammatory Diseases

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IMO-8400 Demonstrates Favorable Safety Profile

Sustained Inhibition of Targeted TLR 7-, 8-, and 9-mediated Cytokine Induction Observed

Phase 2 Trial of IMO-8400 in Patients with Moderate-to-Severe Plaque Psoriasis Ongoing

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jul. 1, 2013-- Idera Pharmaceuticals, Inc. (Nasdaq: IDRA) announced results of a Phase 1 clinical trial of IMO-8400, a first-in-class antagonist of Toll-like Receptors (TLRs) 7, 8, and 9 being developed for potential applications in autoimmune and inflammatory diseases. In this trial, IMO-8400 was administered at single escalating dose levels and multiple dose levels weekly for four weeks in healthy subjects. IMO-8400 was well tolerated at all dose levels. IMO-8400-treated subjects showed inhibition of TLR 7-, 8-, and 9-mediated cytokines, including tumor necrosis factor-alpha (TNF-α), interleukin-1 beta (IL-1β), interleukin-6 (IL-6), interferon-alpha (IFN-α), and other pro-inflammatory cytokines. These results were presented at the 13th Annual Meeting of the Federation of Clinical Immunology Societies (FOCIS), held on June 27-30, 2013, in Boston, MA.

"We are very pleased with the safety and tolerability of IMO-8400 in this trial. Further, IMO-8400 showed strong and sustained inhibition of TLR7-, 8-, and 9- mediated cytokine induction," said Robert D. Arbeit, M.D., Vice President of Clinical Development. "Based on these encouraging results, we have initiated a randomized, double-blind, placebo-controlled Phase 2 trial of IMO-8400 in patients with psoriasis to evaluate PASI score improvement over a 12-week treatment period at three dose levels."

“We anticipate data from the ongoing Phase 2 trial to be available by year-end. Results from this study will inform our decisions regarding later stage clinical development of IMO-8400 in patients with psoriasis and clinical development in other indications,” said Sudhir Agrawal, D.Phil., Chairman and Chief Executive Officer. “IMO-8400 has potential applications in a broad range of autoimmune and inflammatory diseases, in which TLRs 7, 8, and 9 are implicated in exacerbating the disease.”

Phase 1 Clinical Trial Results

- IMO-8400 was well tolerated in single- and multiple-dose regimens at all dosages
- The intended pharmacodynamic mechanism of action was demonstrated in IMO-8400 treated subjects
- Cytokine induction mediated by TLRs 7, 8, and 9 was inhibited in IMO-8400 treated subjects and not in placebo treated subjects
- The induction of multiple cytokines was inhibited, including TNF-α, IL-1β, IL-6 and IFN-α
- Inhibition of cytokine induction was sustained for seven days after dosing with IMO-8400
- Pharmacokinetics showed IMO-8400 was rapidly cleared from plasma with no accumulation
- Pharmacodynamic results support a weekly dose regimen for evaluation of IMO-8400 in clinical development in autoimmune disease indications

About the IMO-8400 Phase 1 Trial in Healthy Subjects

A Phase 1 clinical trial of IMO-8400 was conducted to assess the safety, pharmacokinetic and pharmacodynamic activity in healthy subjects. This randomized, double-blind, placebo controlled trial enrolled 42 healthy subjects. The single-dose portion of the trial involved three escalating dose levels of 0.1, 0.3 and 0.6 mg/kg of IMO-8400 or placebo, with six subjects receiving each treatment. The multiple-dose portion of this trial involved two dose levels of IMO-8400, 0.3 and 0.6 mg/kg, and placebo, with six subjects receiving each treatment for four weekly doses. Safety and tolerability were monitored throughout the study. Pharmacokinetic activity and pharmacodynamic activity were monitored at specific times.

About the Ongoing IMO-8400 Phase 2 Trial in Patients with Moderate to Severe Plaque Psoriasis

The Phase 2 trial is a randomized, double-blind, placebo-controlled trial of IMO-8400 monotherapy in patients with moderate to severe plaque psoriasis. In this trial, 32 patients with PASI scores of 12.0 or greater will be randomized 1:1:1:1 to receive weekly subcutaneous doses of IMO-8400 at 0.075, 0.15, or 0.3 mg/kg/week or placebo for 12 weeks. Safety and improvements in PASI score will be monitored throughout the trial.

About TLRs and Idera's Pipeline

Toll-like Receptors (TLRs) play a key role in immunity and inflammation. Using a chemistry-based approach, Idera has created compounds targeted to endosomal TLRs 3, 7, 8, and 9. In autoimmune diseases, immune complexes containing host DNA/RNA activate TLRs 7, 8, and 9, which induce

multiple cytokines that further exacerbate the disease. Inhibition of these TLRs is a novel approach for the potential treatment of autoimmune diseases. IMO-8400 is an antagonist of TLRs 7, 8, and 9, and has shown therapeutic activity in preclinical models of psoriasis, lupus, and arthritis. Our proof-of-concept Phase 2 trial of TLR antagonism in patients with psoriasis using a TLR7 and 9 antagonist, IMO-3100, showed PASI score improvements which correlated with significant improvement in psoriasis disease associated gene profile, including downregulation of the IL-17 pathway.

About Idera Pharmaceuticals, Inc.

Idera Pharmaceuticals applies its proprietary Toll-like receptor (TLR) drug discovery platform to create immunomodulatory drug candidates and is conducting clinical development in autoimmune and inflammatory diseases. Additionally, Idera has a collaboration with Merck & Co. for the use of TLR-targeted candidates as vaccine adjuvants. For more information, visit http://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 Idera’s cash resources will be sufficient to fund the Company’s continuing operations and the further development of the Company’s autoimmune disease program including the additional clinical trials of IMO-8400 referred to in this release; whether results obtained in preclinical studies and early clinical trials such as the results described 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 will be able to license any of its TLR target candidates on a timely basis or at all; whether the Company's collaboration with Merck & Co, Inc., will be successful; 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 quarter ended March 31, 2013 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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