Idera Pharmaceuticals Announces Positive Top-line Data in Phase 2 Trial of IMO-8400

March 28, 2014 11:15 AM EDT

Trial meets primary objective of demonstrating safety and tolerability over 12-week treatment period

IMO-8400 also demonstrates clinical proof-of-concept in psoriasis

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Mar. 28, 2014-- Idera Pharmaceuticals, Inc. (NASDAQ: IDRA) today announced positive top-line data from its randomized, double-blind, placebo controlled Phase 2 trial of IMO-8400 in 32 patients with moderate-to-severe plaque psoriasis. The primary objective of the trial was to evaluate the safety and tolerability of IMO-8400 over a 12-week treatment period, with a secondary objective to evaluate the clinical activity of IMO-8400. The trial met its primary objective as all treatments were well tolerated with no treatment related discontinuation, serious adverse events or dose reductions. IMO-8400 treatment met the secondary objective of demonstrating clinical activity in patients with psoriasis, as assessed by Psoriasis Area and Severity Index (PASI). IMO-8400, which is Idera's lead clinical candidate, is an antagonist of Toll-like receptors (TLRs) 7, 8, and 9. Idera's strategy is to develop IMO-8400 for the treatment of genetically defined forms of B-cell lymphoma and orphan autoimmune diseases.

"Successful completion of this trial is an important additional milestone in our TLR antagonist program. We have studied psoriasis as the initial disease indication to demonstrate clinical proof of concept for our TLR antagonists in autoimmune diseases," said Sudhir Agrawal, D. Phil., Chief Executive Officer of Idera Pharmaceuticals. "With these data, we can now pursue our announced business strategy and advance our TLR antagonist drug candidates for the treatment of orphan diseases with high unmet medical need. Towards this goal, our clinical development strategy for IMO-8400 is focused on B-cell lymphomas harboring the MYD88 L265P mutation, and on orphan autoimmune disease indications. Over the remainder of 2014, we anticipate enrolling patients in IMO-8400 trials for Waldenström's macroglobulinemia, diffuse large B-cell lymphoma and polymyositis and dermatomyositis."

"We are very pleased to have met the goals of this trial related to safety and tolerability over three months of dosing, and to have obtained evidence of clinical activity with IMO-8400 in psoriasis patients. This provides further validation of the scientific rationale of blocking over-activation of specific TLRs," commented Lou Brenner, M.D., Senior Vice President and Chief Medical Officer of Idera Pharmaceuticals. "These data also support our clinical development plans for IMO-8400 in genetically defined forms of B-cell lymphoma and orphan autoimmune diseases."

The trial met its primary objective of demonstrating safety and tolerability at all three dose levels. For all subjects, treatment was well tolerated with no treatment related discontinuation, serious adverse events or dose reductions.

The trial also met a secondary objective of demonstrating clinical activity based on PASI scores. Among patients who completed 12 weeks of treatment per protocol, PASI 50 was achieved in nine (45%) of 20 who received IMO-8400 at any dose level, and in one (14%) of seven who received placebo. PASI 75 was achieved in four (20%) of IMO-8400 treated patients at any dose level, and in zero placebo patients. PASI 50 and PASI 75 are defined as 50% and 75% improvement, respectively, compared to baseline PASI.

About the Phase 2 Trial

This Phase 2 trial is a randomized, double-blind, placebo-controlled trial, in which the Company enrolled 32 patients with moderate-to-severe plaque psoriasis, with a minimum PASI score of 12 or above. All patients were withdrawn from prior therapies with an appropriate wash-out period, and were randomized equally to receive subcutaneous IMO-8400 monotherapy at dose levels of 0.075 mg/kg, 0.15 mg/kg and 0.3 mg/kg or placebo, weekly for 12 weeks, with a six-week follow-up period. The primary objective of the trial was to evaluate the safety and tolerability of IMO-8400. A secondary objective of the trial was to evaluate the clinical activity of IMO-8400 as assessed using standard clinical metrics, including Psoriasis Area and Severity Index (PASI) scores.

Additionally, in October 2013, Idera expanded the trial to evaluate a dose of 0.6 mg/kg once weekly and placebo in 12 patients. This trial is being conducted in the Netherlands. Data from this expanded trial are expected to be available by the end of Q2 2014.

Details of the Phase 2 trial of IMO-8400 in psoriasis patients will be submitted for presentation at an upcoming medical meeting.

About Idera's TLR Antagonist Pipeline

Idera's TLR antagonist drug candidates have been created using a proprietary chemistry-based drug discovery platform. IMO-8400 is a first-in-class synthetic oligonucleotide-based antagonist of TLRs 7, 8, and 9. IMO-8400 has shown activity in preclinical models of autoimmune diseases, including psoriasis, lupus, and arthritis. IMO-8400 has been well-tolerated in a Phase 1 trial in 42 healthy subjects at single and multiple escalating doses up to 0.6 mg/kg for four weeks, and has shown inhibition of immune responses mediated by TLRs 7, 8, and 9. Idera is pursuing clinical development of IMO-8400 in genetically defined forms of B-cell lymphoma, including Waldenström's macroglobulinemia and diffuse large B-cell lymphoma, and orphan autoimmune diseases, including polymyositis and dermatomyositis.

The Company has also selected IMO-9200, a second novel antagonist of TLRs 7, 8, and 9, as an additional candidate for potential development in selected autoimmune disease indications. The Company anticipates initiating clinical development of IMO-9200 with the submission of an Investigational New Drug (IND) application in the second half of 2014.

"We are advancing IMO-9200 into clinical development to expand our pipeline of drug candidates with potential use in selected autoimmune disease indications," added Dr. Agrawal.

About Idera Pharmaceuticals, Inc.

Idera's proprietary technology involves creating novel nucleic acid therapeutics designed to inhibit over-activation of Toll-like Receptors (TLRs). Idera is developing these therapeutics for the treatment of genetically defined forms of B-cell lymphoma and for autoimmune diseases with orphan indications. In addition to its TLR programs, Idera is developing gene silencing oligonucleotides that it has created using its proprietary technology to

inhibit the production of disease-associated proteins by targeting RNA.

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 clinical trials such as the results 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 Annual Report on Form 10-K for the year ended December 31, 2013. 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.

Source: Idera Pharmaceuticals, Inc.

Idera Pharmaceuticals, Inc.
Lou Arcudi, 617-679-5517
larcudi@iderapharma.com
or
Stern Investor Relations, Inc.
Sarah McCabe, 212-362-1200
sarah@sternir.com