Idera Pharmaceuticals Announces Initiation of a Phase 2 Trial of IMO-8400 in Patients with Moderate to Severe Plaque Psoriasis

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CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jun. 5, 2013-- Idera Pharmaceuticals (NASDAQ: IDRA) today announced that it has initiated dosing in a randomized, double-blind, placebo-controlled Phase 2 trial of IMO-8400 in patients with moderate to severe plaque psoriasis. IMO-8400, an antagonist of the Toll-like receptors (TLRs) 7, 8, and 9, is a lead clinical candidate in Idera's autoimmune disease program. In a Phase 1 trial involving single escalating doses and multiple doses, IMO-8400 was well tolerated and inhibited TLRs 7, 8, and 9-mediated immune responses. Data from the Phase 1 study will be presented at a scientific meeting in June 2013.

"This Phase 2 trial of IMO-8400 will enable us to evaluate over a 12-week treatment period the continued trajectory of Psoriasis Area Severity Index (PASI) score improvement that we observed in the previous 4-week study of our TLR 7 and 9 antagonist, IMO-3100," said Robert Arbeit, M.D., Vice President of Clinical Development at Idera. "We anticipate top-line data from the Phase 2 trial of IMO-8400 to be available by the end of 2013."

"In our proof-of-concept study with IMO-3100 in patients with psoriasis, we observed PASI score improvement, which correlated with significant improvement in psoriasis disease-associated gene profile, including downregulation of the IL-17 pathway. We believe the inclusion of TLR8 activity with IMO-8400 would further enhance the clinical activity observed with IMO-3100 in patients with psoriasis," said Sudhir Agrawal, D.Phil., Chairman and Chief Executive Officer of Idera. "We expect that data from the present Phase 2 trial will help inform our decision on further development of IMO-8400 in patients with psoriasis. In addition, during the fourth quarter of 2013, we expect to be in a position to initiate Phase 2 clinical trials in additional autoimmune disease indications, including lupus."

About the 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 12.5 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. The trial is being conducted in the Netherlands.

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 induces 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. In a Phase 1 trial involving single escalating doses and multiple doses, IMO-8400 was well tolerated and inhibited TLRs 7, 8, and 9-mediated immune responses. A proof-of-concept Phase 2 study of TLR antagonism in patients with psoriasis using Idera's antagonist of TLRs 7 and 9, 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 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; whether the patents and patent applications owned or licensed by the Company will protect the Company's technology and prevent others from infringing it; 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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