Idera Pharmaceuticals Announces Completion of Patient Enrollment in Phase 2 Trial of IMO-3100 in Patients with Psoriasis

October 15, 2012 12:01 PM EDT

First Human Trial in Lupus Program Anticipated to Begin in 2012

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Oct. 15, 2012-- Idera Pharmaceuticals today announced that it had completed patient enrollment in its randomized, double-blind, placebo-controlled Phase 2 trial of IMO-3100 in patients with moderate-to-severe plaque psoriasis. IMO-3100 is an antagonist of specific Toll-like Receptors (TLRs) that the Company is developing for the treatment of psoriasis and other autoimmune diseases. Idera anticipates top-line data from this study will be available by year-end 2012. TLRs are a class of proteins that play a key role in both inflammation and immunity. Through the inhibition of specific TLRs, Idera's candidates may represent a novel approach for the treatment of psoriasis, lupus and other autoimmune diseases.

"In this Phase 2 proof-of-concept study, we are evaluating multiple endpoints to assess the clinical activity of IMO-3100, including the impact on Psoriasis Area Severity Index (PASI), mean focal psoriasis severity, and Physician Global Assessment (PGA) scores," said Dr. Robert Arbeit, Vice President of Clinical Development at Idera. "In addition to the clinical assessments, we are evaluating biopsies of psoriasis plaques for treatment-related changes in epidermal thickness and immune cell infiltrates consistent with the intended mechanism of action."

"We have made significant progress in advancing our autoimmune disease program, including the completion of enrollment in the Phase 2 trial of IMO-3100 in patients with psoriasis." said Dr. Sudhir Agrawal, Chief Executive Officer of Idera. "In addition, our investigational new drug (IND) application for IMO-8400, a lead candidate for lupus, is now active. We expect our phase 2 study of IMO-3100 and planned clinical trials of IMO-8400 will help us to establish the benefits of inhibiting Toll-like Receptor-mediated pathways, which include controlling the induction of multiple cytokines, such as TNF-α, IL-12, IL-6, and IL-17, as well as downstream signaling. We look forward to reporting top-line data from the Phase 2 study of IMO-3100 in psoriasis and initiating clinical development of IMO-8400 before the end of 2012."

Idera also announced today that its Investigational New Drug application for IMO-8400 with the US Food and Drug Administration is now active. IMO-8400, an antagonist of TLRs 7, 8, and 9, is Idera's second lead candidate for use in treating autoimmune diseases, with lupus selected as an initial indication for clinical development. Idera anticipates initiating a Phase 1 dose escalation trial during the fourth quarter of 2012 to evaluate the safety and pharmacodynamics of IMO-8400 in healthy subjects. Following successful completion of the Phase 1 study, Idera expects to initiate a Phase 2 clinical trial of IMO-8400 in patients with lupus.

Recent and Upcoming Autoimmune Disease Program Milestones

Fourth Quarter 2012:

- Complete enrollment in Phase 2 trial of IMO-3100 for the treatment of moderate to severe plaque psoriasis (completed)
- Submission of Investigational New Drug (IND) application to the US Food and Drug Administration for IMO-8400 (completed)
- Present preclinical data on IMO-8400 at major scientific meetings
- Initiation of Phase 1 trial of IMO-8400
- Report top-line data from the Phase 2 trial of IMO-3100 for the treatment of moderate-to-severe plaque psoriasis

Year 2013:

- Report final data from the Phase 2 trial of IMO-3100 for the treatment of moderate-to-severe plaque psoriasis
- Report data from Phase 1 trial of IMO-8400
- Initiate Phase 2 trial of IMO-8400 in patients with lupus

About TLRs and Idera's Pipeline

Toll-like Receptors (TLRs) play a key role in inflammation and immunity. Of the 10 human TLRs identified to date, Idera is developing compounds targeted to TLRs 3, 7, 8, and 9, which are expressed in different cells and serve unique functions. Using its chemistry-based approach, Idera has created novel drug candidates that modulate immune responses through either activation or inhibition of specific TLRs. Inhibition of specific TLRs may be useful in treating autoimmune disorders, such as systemic lupus erythematosus (SLE), psoriasis, and rheumatoid arthritis, by blocking the induction

of multiple cytokines and signaling pathways. Idera's lead clinical candidates for application in autoimmune diseases are IMO-3100, an antagonist of TLR7 and TLR9, and IMO-8400, an antagonist of TLRs 7, 8, and 9.

A characteristic of autoimmune diseases such as SLE and psoriasis is the production of immune complexes with self-nucleic acids. These abnormal immune complexes activate TLRs 7, 8, and 9 and induce multiple cytokines that cause further damage to the body's own tissues and organs, thereby releasing more self-nucleic acids. Thus, a pathologic amplification cycle is established, promoting disease maintenance and progression. In preclinical models of several autoimmune diseases, IMO-3100 and IMO-8400 inhibited TLR-mediated immune responses, broke the cycle of disease maintenance and progression through decreases in Th1, Th17 and inflammasome pathways, and led to improvements in multiple measures of disease.

About the Phase 2 Trial of IMO-3100 in Patients with Moderate to Severe Plaque Psoriasis

The Phase 2 trial is a randomized, double-blind, placebo-controlled study of IMO-3100 in patients with psoriasis. In the study, 44 patients with moderate to severe plaque psoriasis were randomized 1:1:1 to receive IMO-3100 at 0.16 or 0.32 mg/kg or placebo by subcutaneous injection once weekly for four weeks. Assessments of safety will be performed throughout the treatment and four-week follow-up periods. Psoriasis intensity, using Psoriasis Area Severity Index (PASI), mean focal psoriasis severity and Physician Global Assessment (PGA) scores, will be compared at end of treatment to pre-treatment. Skin biopsies of psoriasis lesions will be obtained to determine mean epidermal thickness prior to treatment and at end of treatment. The biopsy analysis also includes immunohistologic staining for changes in immune cell infiltrates and cytokine expression. This trial is being conducted at multiple sites in the United States, and skin biopsies will be analyzed at a central laboratory.

About Psoriasis

Psoriasis is a systemic immune-mediated disorder, characterized by inflammatory skin and joint manifestations. The most common form, plaque psoriasis, appears as raised, red patches covered with a silvery white buildup of dead skin cells. Psoriasis can occur on any part of the body and is associated with other serious health conditions, such as diabetes, heart disease and depression.

Psoriasis is the most prevalent autoimmune disease in the U.S., according to the National Psoriasis Foundation, affecting as many as 7.5 million Americans.

About IMO-3100

IMO-3100, an antagonist of TLR7 and TLR9, is a lead drug candidate in development to treat autoimmune diseases, including psoriasis. In preclinical mouse models of psoriasis, IMO-3100 exerted therapeutic activity by inhibiting disease-associated gene expression and cytokines, such as IL-6, IL-22, IL-17, IL-23, NLRP3, and IL-1β, and proteins in the skin such as S100A7, DEFB4, and LL37. In addition, histological evaluation showed that the psoriatic lesions in IMO-3100 treated animals had reduced epidermal thickness and decreased lymphocyte infiltration compared to control mice.

About IMO-8400

IMO-8400, an antagonist of TLRs 7, 8, and 9, is a lead drug candidate in development to treat autoimmune diseases, with systemic lupus erythematosus (lupus) as the first indication for development. In preclinical mouse models of lupus, treatment with IMO-8400 has led to a reduction in levels of autoimmune antibodies, including anti-DNA, anti-RNA and anti-SM, compared to untreated mice. In addition, improvements in renal function, such as reductions in blood urea nitrogen, proteinuria, and histopathology changes in the kidney, were observed in IMO-8400 treated mice. Treatment of mice with IMO-8400 inhibited multiple disease-associated cytokines and decreased abnormal gene expression patterns compared to untreated mice.

About Systemic Lupus Erythematosus

Lupus is a chronic autoimmune disease where the body's immune system becomes hyperactive and attacks normal healthy tissue. This results in symptoms such as inflammation, swelling, and damage to joints and almost every major organ in the body, including the heart, kidneys, skin, lungs and brain. According to The Lupus Foundation of America, an estimated 1.5 million Americans and at least five million people worldwide have a form of lupus.

About Idera Pharmaceuticals, Inc.

Idera Pharmaceuticals applies its proprietary Toll-like receptor (TLR) drug discovery platform which has created immunomodulatory drug candidates and has a clinical development program in autoimmune diseases. Additionally, Idera has a collaboration with Merck & Co. for the use of TLR-targeted candidates as vaccine adjuvants. The Company is also advancing its gene-silencing oligonucleotide (GSO) technology for the purpose of inhibiting the expression of disease-promoting genes. 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 planned phase 2 clinical trials of IMO-8400 referred to in this release which the Company will not initiate without having raised the necessary funding.; whether results obtained in preclinical studies and early clinical trials, such as the results from the preclinical studies 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 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 June 30, 2012 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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