Idera Pharmaceuticals Announces Initiation of Treatment in Phase 2 Clinical Trial of IMO-3100 for Psoriasis

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Mid-stage clinical trials with Company's Toll-like receptor modulators now underway in both oncology and autoimmune diseases

CAMBRIDGE, Mass., Apr 17, 2012 (BUSINESS WIRE) --Idera Pharmaceuticals, Inc. (NASDAQ: IDRA) today announced the treatment of the first patient in a Phase 2 clinical trial of IMO-3100, the Company's lead Toll-like receptor (TLR) inhibitor for the treatment of autoimmune diseases, in patients with moderate to severe plaque psoriasis.

"With the initiation of a Phase 2 trial for IMO-3100 in psoriasis, we have achieved another important milestone by having mid-stage clinical trials underway for proprietary drug candidates targeting TLRs in both oncology and autoimmune diseases, our two key therapeutic areas of focus," said Sudhir Agrawal, D.Phil., Chairman and Chief Executive Officer. "We expect our clinical pipeline in autoimmune diseases will expand further with the advancement of IMO-8400 for the treatment of lupus following the anticipated submission of an investigational new drug (IND) application with the U.S. Food and Drug Administration during the fourth quarter of 2012. We look forward to achieving additional near-term milestones, including the completion of a Phase 2 study for IMO-2055 in head and neck cancer expected during the second quarter of 2012 and completion of the Phase 2 study for IMO-3100 in psoriasis expected during the first half of 2013."

IMO-3100 is an immunomodulator that inhibits the activity of TLR7 and TLR9 and modulates the production of multiple pro-inflammatory mediators, including TNF-a, INF-a, IL1-B, IP-10, IL-17, and IL-23. IMO-3100 has demonstrated potent activity in reducing pathologic and immunologic manifestations in preclinical mouse models of psoriasis. In Phase 1 studies in healthy subjects, IMO-3100 has been well tolerated at the doses administered, and has shown target engagement of TLR7 and TLR9.

The Phase 2 trial is a randomized, double-blind, and placebo-controlled study of IMO-3100 in patients with psoriasis. The trial is designed to evaluate the safety and markers of efficacy of IMO-3100 as a monotherapy. In the study, 45 patients with moderate to severe plaque psoriasis will receive IMO-3100 at 0.16 or 0.32 mg/kg or placebo (saline) by subcutaneous injection once weekly for four weeks. Assessments of safety will be performed throughout the treatment and follow-up periods. Psoriasis intensity will be monitored throughout the study. Skin biopsies of an active psoriasis plaque will be obtained prior to treatment and one week after the last treatment, and will be analyzed by immunohistologic staining for changes in epidermal thickness, 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 TLRs and Idera's Pipeline

Toll-like Receptors (TLRs) represent a class of proteins that play a key role in both inflammation and immunity. Of the 10 human TLRs identified to date, Idera is focusing on compounds targeted to TLRs 3, 7, 8, and 9, which are expressed in different cells and serve unique functions. For example, activation of TLR7 and TLR9 present in certain dendritic cells and lymphocytes may be useful for the treatment of various types of cancer by stimulating immunity. In contrast, inhibition of specific TLRs may be useful in treating autoimmune disorders, such as psoriasis and lupus, by blocking the production of multiple pro-inflammatory mediators. Using its chemistry-based approach, Idera is advancing novel drug candidates to modulate immune response through activation or inhibition of specific TLRs to treat a broad range of diseases, including autoimmune diseases and cancer.

In oncology, Idera's lead product candidate is IMO-2055, which is designed to activate TLR9. IMO-2055 is the subject of several clinical trials including a randomized, controlled Phase 2 trial in combination with Erbitux(R) as a second-line therapy for patients with recurrent or metastatic squamous cell carcinoma of the head and neck that have not been previously treated with Erbitux. This multicenter, international trial is evaluating the effect of adding IMO-2055 to Erbitux alone in 2nd line treatment, with a primary endpoint of progression-free survival and secondary endpoints including RECIST objective response rate. In addition, crossover of the patients who progress on Erbitux alone is permitted to the combination arm of IMO-2055 and Erbitux. The crossover permits assessment of the efficacy (response rate and progression-free survival) of adding IMO-2055 to Erbitux as a third-line therapy in patients whose disease is refractory to Erbitux alone. A Phase 1b trial with IMO-2055 in combination with Tarceva(R) and Avastin(R) for the treatment of non-small cell lung cancer has been completed and top-line results were announced in the first quarter of 2012. A Phase 1b trial has been conducted with IMO-2055 in combination with FOLFIRI and Erbitux in patients with advanced colorectal cancer who have progressed following chemotherapy.

In autoimmune diseases, Idera is developing inhibitors of TLRs 7, 8, and 9 for the potential treatment of psoriasis, lupus, and other diseases. Idera's lead clinical candidate is IMO-3100, an antagonist of TLR7 and TLR9, which is in Phase 2 development for psoriasis. IMO-8400 is an antagonist of TLRs 7, 8, and 9. Idera expects to file an IND application for IMO-8400 during the fourth quarter of 2012. Idera has selected lupus as the initial disease indication for clinical development of IMO-8400.

About Idera Pharmaceuticals, Inc.

Idera Pharmaceuticals applies its proprietary Toll-like receptor (TLR) drug discovery platform to create immunomodulatory drug candidates and has clinical development programs in autoimmune diseases and cancer. 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.

Erbitux(R) is a registered trademark of ImClone LLC, a wholly-owned subsidiary of Eli Lilly and Company. Tarceva(R) is a registered trademark of OSI Pharmaceuticals, LLC, an affiliate of Astellas Pharma US, Inc. Avastin(R) is a registered trademark of Genentech, Inc.

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 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 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 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; 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 Annual Report on Form 10-K for the year ended December 31, 2011 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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