Idera Pharmaceuticals Announces Expansion of Pipeline into Two Orphan Autoimmune Diseases

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- Company to initiate clinical development of IMO-8400 in polymyositis and dermatomyositis in first half of 2014 -

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Mar. 13, 2014-- Idera Pharmaceuticals, Inc. (NASDAQ: IDRA), a clinical stage biopharmaceutical company developing a novel therapeutic approach for the treatment of autoimmune disorders and genetically defined forms of B-cell lymphoma, today announced that it plans to initiate clinical development of its lead compound, IMO-8400, for the treatment of patients with polymyositis and patients with dermatomyositis, two orphan autoimmune diseases with high unmet clinical needs. The Company plans to submit a protocol to the U.S. Food and Drug Administration (FDA) in the first half of 2014 for a Phase 1/2 clinical trial to investigate the safety and potential utility of IMO-8400 in these two indications. This represents the execution of a previously announced strategy to expand the clinical development of IMO-8400 in orphan autoimmune disease indications. Based on the results from this study, Idera anticipates that it will pursue separate later-stage clinical trials for each indication.

“Polymyositis and dermatomyositis are very challenging autoimmune diseases to manage, and currently there is a need for physicians to offer new treatments to patients suffering from these conditions,” said Dr. Chester Oddis, Professor of Medicine, Division of Rheumatology and Clinical Immunology, University of Pittsburgh. “I am encouraged by the potential of this novel approach, which is targeted to a key disease driver and could represent a promising area of investigation for these life-impacting conditions.”

"Our team of scientists, clinicians, and advisors has prioritized polymyositis and dermatomyositis among a wide range of orphan autoimmune diseases that may potentially benefit from our TLR antagonist program. We are excited to explore the potential of IMO-8400 for the treatment of patients with these challenging conditions,” remarked Dr. Lou Brenner, Senior Vice President and Chief Medical Officer of Idera Pharmaceuticals.

Idera’s Toll-like receptor (TLR) antagonist platform is designed to inhibit over-activation of TLRs, which are implicated in diverse pathological conditions. IMO-8400, an antagonist of Toll-like receptors 7, 8, and 9, is currently being evaluated in a clinical proof-of-concept study in moderate-to-severe plaque psoriasis. Idera continues to consider additional orphan autoimmune disease indications, including graft versus host disease and Sjögren's syndrome, as potential disease targets for subsequent clinical development of IMO-8400. In addition to its potential utility in autoimmune diseases, IMO-8400 is in clinical development for treatment of certain genetically defined forms of B-cell lymphoma, where the TLR pathway also plays a role in disease progression.

About Polymyositis and Dermatomyositis

Polymyositis and dermatomyositis are autoimmune inflammatory myopathies that cause inflammation and progressive weakness in muscles. Polymyositis and dermatomyositis sufferers can develop serious disabilities, including loss in mobility and difficulty breathing and swallowing, and have an increased risk of certain cancers. Dermatomyositis is also accompanied by a purple or red skin rash. There are an estimated 10,000 polymyositis patients and 67,000 dermatomyositis patients in the U.S. alone. Both polymyositis and dermatomyositis have been designated as orphan diseases by the U.S. Food and Drug Administration (FDA).

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 includes statements concerning Idera Pharmaceuticals, Inc. and its future expectations, plans and prospects that constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995 and 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 programs into the second half of 2016, and whether Idera will be able to obtain additional cash resources sufficient to fund the Company’s operations beyond that time; whether results obtained in early research, preclinical studies and clinical trials will be indicative of the results that will be generated in future preclinical and clinical studies; whether Idera’s preclinical studies and clinical trials will commence and will be completed when expected by Idera; 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 FDA 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 Idera's Annual Report on Form 10-K for the year ended December 31, 2013, which important factors are incorporated herein by reference. Idera disclaims any intention or obligation to update any forward-looking statements.

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