



## **Idera Announces Initiation of Lupus Clinical Development Program with Phase 1 Trial of IMO-8400**

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### **Presents IMO-8400 Preclinical Data Supporting Autoimmune Activity at ACR/AHRP 2012**

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Nov. 13, 2012-- Idera Pharmaceuticals, Inc. (NASDAQ: IDRA) today announced the initiation of dosing in a Phase 1 trial of IMO-8400. IMO-8400 is an antagonist of Toll-like receptors (TLRs) 7, 8 and 9, and is the second clinical candidate in Idera's autoimmune disease program. Idera expects to develop IMO-8400 for the treatment of lupus as an initial indication. Idera also announced the presentation of preclinical data on IMO-8400 at the American College of Rheumatology that support its potential to treat autoimmune diseases through inhibition of Th1, Th17, and inflammasome activation.

"We are pleased to have initiated the clinical development of IMO-8400 in our lupus program," said Robert Arbeit, MD, Vice President of Clinical Development at Idera. "IMO-8400 provides a novel approach to the treatment of lupus, by blocking signaling through Toll-like receptors. In preclinical studies, lupus-prone mice treated with IMO-8400 demonstrated suppression of multiple pro-inflammatory cytokines, inhibition of auto-antibody production, and improvement in renal function, all of which are components of SLE pathophysiology. These changes are consistent with the intended mechanism of action of this candidate."

"The next objectives in our autoimmune disease programs are to have top-line data for some of the endpoints from our Phase 2 trial of IMO-3100 in patients with psoriasis by year end 2012 and to complete our Phase 1 trial of IMO-8400," said Dr. Sudhir Agrawal, Chief Executive Officer of Idera. "Our recent raise of \$7 million, in addition to the \$8.5 million that we had on hand at the end of the third quarter, we expect will allow us to meet these near-term objectives."

The goals of the Phase 1 trial in the clinical development of IMO-8400 are to assess the safety and pharmacodynamic activity of IMO-8400 in healthy subjects. A total of 30 healthy subjects are scheduled to receive single or multiple ascending doses of IMO-8400. Data from this study are expected to be available during Q2 2013. Following successful completion of the Phase 1 study and additional funding, the Company expects to initiate a Phase 2 clinical trial of IMO-8400 in lupus patients.

The company also announced the presentation of preclinical data at the American College of Rheumatology/Association of Rheumatology Health Professionals (ACR/ARHP) Annual Meeting being held November 9-14, 2012, in Washington, D.C The presentation (#1068) is entitled "A selective inhibitor of endosomal Toll-like Receptors, IMO-8400, suppresses activation of multiple Th1-type cytokines, Th17 response, and inflammasome activation". In this presentation, data showed that in a mouse model of psoriasis, the expression of multiple cytokines, including Th1-type IL-12 and IL-6; Th17-type IL-17 and IL-22; and IL-1 $\beta$ , which is associated with inflammasome activation, was upregulated. In this study, mice treated with IMO-8400 or IMO-3100 showed suppression of Th1, Th17 and inflammasome activation-related cytokines. In addition, treatment led to a decrease in dermal thickness and suppression of keratinocyte peptides, including S100A4, S100A7a, and Defensin  $\beta$ 4, compared to untreated 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 to create 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 for cancer, infectious diseases and Alzheimer's disease. 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; 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 September 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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