

Idera Pharmaceuticals Reports Preclinical Mechanism of Action Data on IMO-8400, a Novel TLR Inhibitor for Autoimmune Diseases

June 21, 2012 12:30 PM EDT

Submission of an Investigational New Drug Application Expected During the Fourth Quarter of 2012

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jun. 21, 2012-- Idera Pharmaceuticals, Inc. (NASDAQ: IDRA) today announced results from preclinical studies evaluating the mechanism of action of IMO-8400, a selective inhibitor of Toll-like Receptors (TLRs) 7, 8, and 9. The data were presented on Wednesday, June 20, during the Federation of Clinical Immunology Societies (FoCIS) meeting being held June 20-23, 2012, in Vancouver, BC, Canada.

In this study, the mechanism of action of IMO-8400 has been studied in non-human primates. The administration of IMO-8400 led to inhibition of immune responses mediated through targeted Toll-like receptors. Multiple cytokines were suppressed, including TNF- α , IL-12, IL-6, IFN- α , IL-1 β . Similar results of IMO-8400 suppression of TLR7, 8 and 9-mediated immune responses were observed in human blood cells. IMO-8400 is a lead candidate in development for the treatment of lupus.

"These studies confirm that in a preclinical primate model and in human blood cells treatment with IMO-8400 specifically blocked cytokine induction mediated through targeted TLRs," said Tim Sullivan, VP of Development Programs and Alliance Management. "The selective inhibition of these TLRs is consistent with the preclinical efficacy we have seen in commonly used mouse models of lupus and holds promise for potential use of IMO-8400 in humans with lupus and other autoimmune diseases. The activity demonstrated with IMO-8400 in various models forms the basis for the Investigational New Drug Application we anticipate submitting to the FDA in the fourth quarter of this year."

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 has developed novel drug candidates which modulate immune response through activation or inhibition of specific TLRs to treat a broad range of diseases, including autoimmune diseases and cancer, and to enhance the effectiveness of vaccines.

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 submit 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 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 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.

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 such as the studies referred to in this release will be indicative of results obtained in clinical trials; whether Idera will submit its anticipated IND for IMO-8400 on a timely basis or at all; 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 sill 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 Quarterly Report on Form 10-Q for the three months ended March 31, 2012 which important factors are incorporated herein by reference. Idera disclaims any intention or obligation to update any forward-looking statements.

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.

Source: Idera Pharmaceuticals, Inc.

Idera Pharmaceuticals, Inc. Lou Arcudi, 617-679-5517 Iarcudi@iderapharma.com