Idera Pharmaceuticals Opens Enrollment for Phase 1/2 Clinical Trial of IMO-8400 in Waldenström's Macroglobulinemia

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- IMO-8400 Targets An Oncogenic Mutation Present in Most Waldenström's Macroglobulinemia Patients -

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Dec. 4, 2013-- Idera Pharmaceuticals, Inc. (Nasdaq: IDRA), a clinical stage biopharmaceutical company developing a novel therapeutic approach for the treatment of autoimmune diseases and genetically defined forms of B-cell lymphoma, today announced that enrollment is open for a Phase 1/2 clinical trial of IMO-8400 in patients with Waldenström's macroglobulinemia, following acceptance of its Investigational New Drug (IND) application by the U.S. Food and Drug Administration (FDA). The objectives of the trial are to evaluate the compound's safety, tolerability, and potential clinical activity.

"The trial of IMO-8400 in patients with Waldenström's macroglobulinemia advances a highly targeted mutation-specific approach with the potential to address the significant needs of patients and is an important clinical milestone for Idera," said Sudhir Agrawal, D. Phil., Chief Executive Officer of Idera Pharmaceuticals. "We believe that recent independent research and our own pre-clinical studies provide a strong scientific rationale for the clinical evaluation of IMO-8400 in B-cell lymphoma patients who harbor this specific genetic mutation."

Idera's program in genetically defined forms of B-cell lymphoma is based on recent reports from several independent investigators [1] identifying a specific genetic mutation known scientifically as MYD88 L265P. These reports offered evidence that in certain B-cell lymphomas the presence of the MYD88 L265P mutation led to over-activation of TLR7 and TLR9 signaling, and that blocking these TLRs accelerated tumor cell death. The mutation has been identified in approximately 90% of the patients with Waldenström's macroglobulinemia, which is classified as a non-Hodgkin lymphoma of malignant lymphoplasmacytic B-cells. The cells typically produce immunoglobulin M, or IgM, resulting in high serum levels of the protein and, potentially, hyperviscosity syndrome, with thickening of the blood, decrease in circulation and oxygen delivery, and ultimately impaired function of almost any organ in the body.

"The MYD88 L265P mutation is highly characteristic of Waldenström's macroglobulinemia and has been identified as potentially oncogenic. IMO-8400 targets the activation of the TLR signaling pathway and represents a novel approach to the treatment of these patients," said Robert D. Arbeit, M.D., Vice President of Clinical Development at Idera.

The IND application for the Phase 1/2 trial was supported by preclinical research conducted by Idera, which the Company intends to present at one or more scientific meetings in 2014. The IND was further supported by clinical safety data from a Phase 1 trial of IMO-8400, in which dosages up to 0.6 mg/kg were well-tolerated and inhibited immune responses mediated through TLR7, TLR8, and TLR9.

The Phase 1/2 clinical trial will enroll patients with Waldenström's macroglobulinemia who have a history of relapse or failure to respond to one or more prior therapies. The protocol includes three dose-escalation cohorts to evaluate the safety and tolerability of IMO-8400 and a provision to expand enrollment at selected dose levels to allow further evaluation of clinical activity. Idera expects to enroll a total of approximately 30 patients. Patients and their caregivers interested in more detail about the trial can visit http://www.iderapharma.com/clinical-trials.

Idera previously announced that it intends to submit a protocol to the FDA to conduct a Phase 1/2 trial in patients with diffuse large B-cell lymphoma (DLBCL) in the first quarter of 2014. DLBCL is an aggressive lymphoma. Approximately 30% of the patients with the activated B-cell-like, or ABC, sub-type are reported to also have MYD88 L265P mutation.

[1] Lim, K, et al., AACR 2013, Abstract #2332; Treon, S.P., et al., N Engl J Med 2012, 367:826-833; Ngo, V.N., et al., Nature 2011, 470:115-119

About Idera Pharmaceuticals, Inc.

Idera's technology platform involves creating novel synthetic RNA- and DNA-based compounds to modulate immune responses. Idera has applied this platform to develop proprietary Toll-like receptor (TLR) antagonists as immunomodulatory drug candidates. Toll-like receptor antagonists block the over-activation of immune factors which can cause a range of pathological effects. Idera is conducting clinical development of TLR antagonists in autoimmune and inflammatory diseases, and for use in certain genetically defined forms of B-cell lymphoma. More information on Idera is available at www.iderapharma.com.

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 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 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 Quarterly Report on Form 10-Q for the period ended September 30, 2013, 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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