Idera Pharmaceuticals Initiates Phase 1 Clinical Trial of IMO-2125, a TLR9 Agonist, in Combination with Ribavirin for Chronic Hepatitis C Virus Infection

October 7, 2009 12:01 PM EDT

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Oct. 7, 2009-- Idera Pharmaceuticals, Inc. (Nasdaq: IDRA) today announced that patient treatment has been initiated in a phase 1 clinical trial evaluating IMO-2125 in combination with ribavirin in treatment-naive patients with chronic hepatitis C virus (HCV) infection. IMO-2125 is a novel agonist of Toll-like Receptor (TLR) 9.

“We expect that the IMO-2125 trial with ribavirin in treatment-naïve HCV patients and our ongoing IMO-2125 monotherapy trial in HCV patients who failed to respond to previous standard of care therapy will provide us with data in two HCV patient populations on safety, immunological activity, and effect on HCV RNA levels,” said Tim Sullivan, Ph.D., Vice President of Development Programs. “We plan to use the data from these ongoing trials to guide us in further clinical development of IMO-2125 in the treatment of chronic HCV infection.”

About the Trial

The phase 1 randomized, placebo-controlled clinical trial evaluating IMO-2125 in combination with ribavirin is being conducted in treatment-naïve patients with genotype 1 chronic HCV infection. IMO-2125 is administered subcutaneously once a week for four weeks in combination with daily oral administration of standard doses of ribavirin. The target enrollment is 15 patients per cohort, with 12 randomized to receive IMO-2125 plus ribavirin treatment and three randomized to receive placebo plus ribavirin treatment. The primary objective of the trial is to assess the safety and tolerability of IMO-2125 over an escalating range of dosages in combination with standard doses of ribavirin. In addition, the effect of treatment on HCV RNA levels will be monitored. The clinical trial is expected to be conducted at five or more sites in France and Russia.

Upcoming Presentations on IMO-2125 at the 60th Annual Meeting of the American Association for the Study of Liver Diseases

The Company’s two abstracts have been published and can be accessed on the AASLD website. The abstracts are:

- Abstract 1593: “IMO-2125, a TLR9 agonist, induces Th-1 type cytokines and interferons with potent anti-HCV activity in human peripheral blood mononuclear cells and plasmacytoid dendritic cells”
- Abstract 1597: “Gene expression profiles induced by IMO-2125, an agonist of Toll-like receptor 9, in human peripheral blood mononuclear cells”

The posters will be presented on Tuesday, November 3, at 8:00AM ET.

About IMO-2125

IMO-2125 is a novel DNA-based TLR9 agonist being evaluated for the treatment of chronic HCV infection. IMO-2125 was designed to induce endogenous interferon-alpha along with other immune response factors to treat hepatitis C. In preclinical studies, the immune response factors induced by IMO-2125 have potent activity alone and in combination with ribavirin in HCV replicon assays. In addition to the announced trial, IMO-2125 is also being evaluated as a monotherapy in an ongoing phase 1 randomized, placebo-controlled clinical trial for the treatment of patients with chronic HCV infection who have failed to respond to previous standard of care combination therapy of ribavirin and pegylated interferon-alpha.

About the IMO-2125 Monotherapy Trial

In this trial, IMO-2125 is administered subcutaneously once a week with four weeks of treatment. The target enrollment is ten patients per cohort, with eight randomized to receive IMO-2125 treatment and two randomized to receive placebo treatment. The trial is designed to assess the safety and tolerability of IMO-2125 over an escalating range of dose levels and to determine the effect of IMO-2125 on HCV RNA levels and parameters of immune system activation. The trial is being conducted at six U.S. sites.

About Idera Pharmaceuticals, Inc.

Idera Pharmaceuticals develops drug candidates to treat infectious diseases, autoimmune and inflammatory diseases, cancer, and respiratory diseases, and for use as vaccine adjuvants. Our proprietary drug candidates are designed to modulate specific Toll-like Receptors (TLRs), which are a family of immune system receptors that direct immune system responses. Our pioneering DNA and RNA chemistry expertise enables us to create drug candidates for our internal development programs and our partnered programs, and generates opportunities for additional collaborative alliances. For more information, visit 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 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 collaborations with Novartis, Merck

& Co., and Merck KGaA 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 Quarterly Report on Form 10-Q for the three months ended June 30, 2009, which important factors are incorporated herein by reference. Idera disclaims any intention or obligation to update any forward-looking statements.

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