Idera Pharmaceuticals Announces Positive Interim Data from Phase 1 Clinical Trial of IMO-2125 in Chronic Hepatitis C Patients

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CAMBRIDGE, Mass., Dec 21, 2009 (BUSINESS WIRE) -- Idera Pharmaceuticals, Inc. (Nasdaq: IDRA) today announced positive interim results from a Phase 1 clinical trial of IMO-2125 in patients with chronic hepatitis C virus infection (HCV). IMO-2125 is an agonist of Toll-like Receptor 9 that Idera designed to treat HCV by inducing endogenous interferon-alpha and other Th1-type cytokines and chemokines.

In this four-week trial, IMO-2125 was well tolerated and induced dose-dependent increases in endogenous interferon-alpha and other cytokines. IMO-2125 also demonstrated a treatment-related decrease in viral load at escalating dose levels. All patients enrolled in the trial are null responders, which is defined as patients who have failed to achieve a 2 log10 reduction in viral load during previous 12 to 24 weeks of treatment with pegylated recombinant interferon-alpha plus ribavirin, the current standard of care treatment.

"The interim data in the difficult-to-treat null responder HCV patient population through the first four dose levels of IMO-2125 in this four-week trial are very encouraging," said Tim Sullivan, Ph.D., Vice President of Development Programs. "Based on these data, we are extending the trial to a fifth dose level and beginning to recruit patients in this cohort."

"We believe that the mechanism of IMO-2125 which induces endogenous interferon-alpha may provide advantages over the use of recombinant interferon in the null responder HCV patient population," said Sudhir Agrawal, D.Phil., Chief Executive Officer and Chief Scientific Officer. "We plan to use the results from this ongoing clinical trial to guide our strategy for further development of IMO-2125 for the null responder HCV patient population. In addition, we have ongoing a second clinical trial of IMO-2125 in combination with ribavirin in treatment-naïve HCV patients, the results of which will guide our development strategy for IMO-2125 in this patient population."

Interim results through four dose levels of IMO-2125 are as follows:

- All dose levels of IMO-2125 were well tolerated for the four weeks of treatment
- IMO-2125-treated patients showed dose-dependent increases in endogenous interferon-alpha, interferon-inducible protein 10 (IP-10), and 2',5'-oligoadenylate synthetase (2',5'-OAS) concentrations
- At dose levels from 0.08 to 0.32 mg/kg, an increasing percentage of patients ranging from 40 to 75% achieved a maximum reduction in viral load of 1 log10 or more at least once during the treatment period
- None of the patients who received placebo treatment or IMO-2125 at the 0.04 mg/kg dose level showed a maximum reduction in viral load of 1 log10 or greater at any time during the treatment period

Detailed results of this trial will be presented at an upcoming scientific meeting.

About the Trial (2125-001)

In this trial, IMO-2125 was administered subcutaneously once per week for four weeks at four dose levels of 0.04, 0.08, 0.16, and 0.32 mg/kg and was evaluated for safety, immunological activity, and effect on HCV viral load. Cohorts of ten patients were enrolled at each dose level with two patients randomized to receive placebo treatment. All patients enrolled in the trial were null responders, which is defined as patients who failed to achieve a 2 log10 reduction in viral load during previous 12 to 24 weeks of treatment with pegylated recombinant interferon-alpha plus ribavirin.

To date, 41 patients have been enrolled in four dose cohorts. Forty of the 41 patients enrolled were genotype 1a or 1b. Weekly IMO-2125 treatment for four weeks was well tolerated at all dose levels, with no treatment-related discontinuations or serious adverse events. All adverse events were mild to moderate and most were flu-like symptoms or related to injection site reactions, which are consistent with the mechanism of action.

Based on the safety profile, immunological activity, and effect on HCV RNA viral titers through the first four IMO-2125 dose levels, the Company has amended the protocol to continue dose-escalation to 0.48 mg/kg/week.

The trial is being conducted at six U.S. sites with a central laboratory for safety, immunology, and HCV RNA assessments.

About IMO-2125

IMO-2125, a novel agonist of Toll-like Receptor 9 (TLR9), is designed to induce endogenous interferon-alpha along with other Th1-type cytokines and chemokines. IMO-2125 is Idera's lead drug candidate for the treatment of chronic hepatitis C virus (HCV) infection.

In preclinical studies, IMO-2125 induced high levels of endogenous interferon-alpha and Th1-type cytokines and chemokines in human peripheral blood mononuclear cells (PBMCs) and plasmacytoid dendritic cells (pDCs) *(data presented at 47th Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC), 2007, Abstract 2714)*. Subcutaneous administration of IMO-2125 in non-human primates led to dose-dependent induction of endogenous interferon-alpha, IP-10, and other cytokines. Cytokines induced in human PBMCs, pDCs, and *in vivo* in non-human primates demonstrate potent antiviral activity in the HCV replicon assay *(data presented at ICAAC 2007, Abstract 1583 and at 60th Annual Meeting of the American Association for the Study of Liver Diseases (AASLD), 2009, Abstract 1593)*.

IMO-2125 has been shown to mediate immune responses through TLR9 and associated interferon-signaling pathways involving MyD88 and interferon-regulatory factor 7 (IRF-7) as evaluated in gene microarray studies. Additionally, many type 1 interferon-response genes, interferon-inducible proteins, antiviral proteins, TLR9 signaling molecules and transcription factors are up-regulated *(data presented at AASLD 2009, Abstract 1597)*.

About the Trial in HCV-infected Treatment-naïve Patients (2125-201)

IMO-2125 also is being evaluated in a Phase 1 clinical trial in combination with ribavirin in treatment-naïve patients with chronic HCV infection. IMO-2125 is administered subcutaneously once per week for four weeks at escalating dose levels in combination with daily oral administration of standard doses of ribavirin. The primary objective of the trial is to assess the safety and tolerability of IMO-2125 in combination with standard doses of ribavirin. In addition, the effect of treatment on HCV viral load will be monitored. Patients enrolled in this trial have genotype 1 chronic HCV infection and are treatment-naïve. The clinical trial is currently being conducted at sites in France and Russia.

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 statements with respect to the interim results of this trial of IMO-2125 which may not be duplicated in future cohorts at different doses or in future clinical trials; whether results obtained in preclinical studies and early clinical trials such as the studies and trials 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's collaborations with Merck KGaA and an affiliate of 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; 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 September 30, 2009, 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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