Idera Pharmaceuticals Announces Preliminary Data from Phase 1 Clinical Trial of IMO-2125 in Treatment-Naïve Genotype 1 HCV Patients

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-Outlines Phase 2 Clinical Development Plan-

CAMBRIDGE, Mass., Dec 20, 2010 (BUSINESS WIRE) -- Idera Pharmaceuticals, Inc. (Nasdaq: IDRA) announced today preliminary data from a 4-week dose-ranging Phase 1 clinical trial of IMO-2125 in combination with ribavirin in 60 treatment-naïve patients with genotype 1 chronic hepatitis C virus (HCV) infection. In the trial, treatment with IMO-2125 in combination with ribavirin was well tolerated and achieved substantial decline in virus levels at two days after the first dose of IMO-2125 and after four weeks of treatment. IMO-2125 is a Toll-like Receptor 9 (TLR9) agonist which stimulates production of natural interferons and other antiviral cytokines.

"In this study, IMO-2125 plus ribavirin was well tolerated with no treatment-related discontinuations, and demonstrated substantial antiviral activity," said Robert Arbeit, M.D., Vice President of Clinical Development at Idera. "We believe that IMO-2125 may provide an alternative immune modulatory component to pegylated interferons in the anticipated HCV therapy combinations using direct-acting antivirals. In this treatment scenario, effective stimulation of the host immune system through TLR activation could minimize the risk of viral breakthrough."

"Based on the overall data from this trial and our Phase 1 clinical trial of IMO-2125 in null-responder HCV patients, our next step in clinical development will be a 12-week Phase 2 trial of IMO-2125 in combination with ribavirin in treatment-naïve HCV patients," said Sudhir Agrawal, D.Phil., Chairman and Chief Executive Officer at Idera. "We expect that the objectives of the Phase 2 study will be to determine optimal dosing, provide longer-term safety data and generate additional antiviral activity data in support of the future clinical development of IMO-2125."

IMO-2125 Phase 1 Clinical Trial in Treatment-naïve Genotype 1 HCV Patients

Study Design:

In this Phase 1 clinical trial, treatment-naïve genotype 1 HCV patients received IMO-2125 by subcutaneous injection over four weeks in combination with daily oral administration of standard weight-based doses of ribavirin in one of four regimens of 12 patients each. The four regimens of IMO-2125 were 0.08, 0.16, and 0.32 mg/kg once weekly and 0.16 mg/kg twice weekly. In addition, 12 patients received current standard of care treatment (Pegasys***(R)*** plus ribavirin).

Study Results:

Safety

- Treatment with IMO-2125 in combination with ribavirin was well tolerated at all dose levels for four weeks of treatment, with no treatment-related serious adverse events and no treatment discontinuations.
- The most common adverse events observed in the IMO-2125 regimens were flu-like symptoms and injection site reactions.
- Of the 12 patients receiving the standard of care therapy in this trial, neutropenia requiring intervention occurred in two patients and platelet counts dropped below the normal range during the treatment period in seven patients. None of the 48 patients receiving IMO-2125 had neutropenia requiring intervention, and four of the 48 IMO-2125 patients had platelet counts drop below the normal range during the treatment period.

Antiviral Activity

- IMO-2125 induced substantial declines in viral levels at two days after the first dose at all dose levels.
- At the mid-week evaluation in the fourth week of treatment, mean viral load reductions with the three higher-dose IMO-2125 regimens ranged from -2.0 to -3.4 $\log_{10}$. Patients who received Pegasys(R) plus ribavirin achieved a mean viral load reduction of -3.8 $\log_{10}$ at the same timepoint.
- At the end of the fourth week of treatment, mean viral load reductions with the three

higher-dose IMO-2125 regimens ranged from -0.6 to -2.4 log_{10}. The mean viral load reduction for patients treated with Pegasys(R) plus ribavirin at the end of the fourth week of treatment was -3.4 log_{10}.

- The initial dose level in this Phase 1 safety trial, 0.08 mg/kg/week, produced minimal changes in viral load although liver enzyme decreases were observed.
- Liver enzymes (AST/ALT) decreased during the treatment period and were within the normal range by the end of the fourth week of treatment in the majority of IMO-2125-treated patients.
- There was unequal distribution among the treatment groups of patients with poor prognostic factors at baseline, including CT or TT IL28B genotype, IP-10 values >600 pg/mL, and older age.

Dosing IMO-2125 (mg/kg/wk) n=12/regimen	IL28B CT or TT genotype*	N with age >50 years, IP-10 >600 pg/mL or both	Viral load reduction at two days after 1st dose (Mean log_{10} HCV RNA)	Mean viral load reduction at mid-week evaluation during week 4 (Mean log_{10} HCV RNA)	Decrease in ALT from baseline to end of treatment
0.08	N/A	5	-1.1	-1.5	-46%
0.16	N/A	1	-2.5	-3.4	-57%
0.32	9 of 12	7	-1.3	-2.0	-38%
0.16 twice/wk	9 of 12	5	-1.6	-3.3	-59%
Pegasys(R)	3 of 6	3	-1.4	-3.8	-43%

* IL28B data were not collected for first two IMO-2125 dose levels and for six patients who received Pegasys(R).

The Company plans to present detailed results of this study at a scientific meeting in 2011.

Planned Phase 2 Clinical Trial

In the planned 12-week Phase 2 randomized clinical trial, patients will be stratified for IL28B genotype (CC vs. CT/TT) and will receive either IMO-2125 plus ribavirin or Pegasys(R) plus ribavirin. The Company plans for recruitment of this clinical trial to start in the first quarter of 2011, pending regulatory concurrence. The Company expects that the objective of this clinical trial will be to provide the basis for subsequent clinical development of IMO-2125 as an alternative to pegylated-interferon in triple combination therapy with ribavirin and a direct-acting antiviral.

IMO-2125 Monotherapy Phase 1 Clinical Trial in Null-Responder HCV Patients

IMO-2125 has also been evaluated in a Phase 1 clinical trial in 51 null-responder HCV patients; 41 patients received IMO-2125 monotherapy at one of five dose levels and 10 patients received placebo once per week for four weeks. Interim safety, antiviral activity and mechanism of action data were presented for the once-weekly dosing regimens in April 2010 at the Annual Meeting of the European Association for the Study of the Liver and complete data were presented in October 2010 at the Annual Meeting of the American Association for the Study of Liver Diseases.

Seven patients were enrolled in an additional cohort to evaluate twice-weekly dosing of IMO-2125 at 0.16 mg/kg/dose. Consistent with the patients' null-responder status, 6 of 7 patients had CT or TT IL28B genotype. There were no treatment-related serious adverse events or discontinuations. As previously observed, the most common adverse events were injection site reactions and flu-like symptoms. Three patients in this cohort achieved greater than 1 log_{10} reduction, ranging from -1.9 to -3.5 log_{10}, in viral load at least once during the treatment period. One of the patients with CT genotype achieved HCV viral levels at the lower limit of quantification (100 copies/mL) at Day 29, four days after the last IMO-2125 dose.

"We are pleased that the results of our Phase 1 clinical trials have shown that IMO-2125 stimulates the immune system in a manner consistent with the intended TLR9 agonist mechanism of action, and that this biological activity has led to reductions in HCV viral load," said Tim Sullivan, Vice President of Development Programs and Alliance Management at Idera. "IMO-2125 was designed using our chemistry-based approach to optimize the activity of TLR-targeted drug candidates."

About IMO-2125

IMO-2125, a Toll-like Receptor (TLR) 9 agonist, is a novel immune modulator being developed as a component of treatment for chronic hepatitis C virus (HCV) infection. IMO-2125 is designed to stimulate the immune system, causing the body to generate natural interferons and other antiviral cytokines. IMO-2125 has been evaluated in a Phase 1 clinical trial in null-responder HCV patients, defined as those who did not achieve a 2 log_{10} reduction with prior standard of care treatment, as monotherapy for 4 weeks and in a Phase 1 clinical trial in treatment-naïve HCV patients in combination with ribavirin for 4 weeks.

About Idera Pharmaceuticals, Inc.

Idera Pharmaceuticals is developing drug candidates that act by modulating immune responses through specific Toll-like Receptors (TLRs). TLRs, a family of immune system receptors and the immune system's first line of defense, recognize pathogens and initiate an immune response. Idera's DNA and RNA chemistry expertise has generated a pipeline of compounds designed to interact with specific TLRs for a broad range of diseases. Through its internal pipeline and collaborative alliances, Idera has established a portfolio of TLR-targeted therapeutic candidates for infectious diseases, autoimmune and inflammatory diseases, cancer, and respiratory diseases, and for use as vaccine adjuvants. 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; whether results obtained in preclinical and clinical studies such as the 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's collaborations 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, 2010, which important factors are incorporated herein by reference. Idera disclaims any intention or obligation to update any forward-looking statements.

Pegasys(R) is a registered trademark of F. Hoffmann-La Roche Company.

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