

News Release

Positive Phase I/II Data of IDX899 Confirm Potent Antiviral Activity and Favorable Safety Profile in Treatment-Naive HIV-Infected Patients

CAMBRIDGE, Mass., June 12 /PRNewswire-FirstCall/ -- Idenix Pharmaceuticals, Inc. (Nasdaq: IDIX), a biopharmaceutical company engaged in the discovery and development of drugs for the treatment of human viral and other infectious diseases, today reported phase I/II data for IDX899, a non-nucleoside reverse transcriptase inhibitor (NNRTI) being developed for the treatment of HIV-1. Patients receiving once-daily IDX899 achieved a mean plasma viral load reduction of approximately 1.8 log(10) after seven days of treatment in each of the 800 mg, 400 mg and 200 mg dosing cohorts. Patients receiving placebo had a 0.05 log₁₀ viral load increase over the same treatment period. No treatment-related serious adverse events were reported for any of the patients receiving IDX899 and no patients discontinued the study. Also, there were no discernable patterns in adverse events between treatment groups and there were no laboratory abnormalities during the treatment period. These data demonstrate potent antiviral activity and a favorable safety profile at all tested doses.

"The profound inhibition of HIV-1 virus replication of IDX899 at doses of 400 and 200 mg daily confirm the potent antiviral activity previously reported at higher doses," said Dr. Robert Murphy, John P. Phair Professor of Infectious Diseases, Director, Global Health Research, Feinberg School of Medicine, Northwestern University. "These early clinical data are very encouraging, showing that IDX899 offers potent viral suppression combined with a promising safety profile."

Study Design

The phase I/II clinical trial was designed to evaluate the safety, tolerability, antiviral activity and pharmacokinetics of IDX899. Three cohorts of 800 mg/day, 400 mg/day and 200 mg/day were completed with ten HIV-1- infected treatment-naïve patients randomized 8:2 in each cohort to receive orally once-daily IDX899 or matching placebo, respectively, for seven days. Based on the potent antiviral activity of IDX899 seen to date, the study was recently amended to also evaluate a lower dose of 100 mg/day.

Study Results

Patients receiving daily oral administration of 800 mg, 400 mg and 200 mg IDX899 achieved mean viral load reductions of 1.78, 1.78, and 1.83 log(10), respectively, after seven days of treatment based on results determined by the Roche Amplicor(R) 1.5 assay. Patients (n=6) receiving placebo achieved mean plasma viral load increase of 0.05 log(10).

One key eligibility criterion for enrollment in the study was that patients' CD4+ count (or T-cell count) had to be greater than or equal to 200 cells/mm³. The mean CD4+ count change from baseline increased by at least 60 cells/mm³ for each of the 800 mg, 400 mg and 200 mg dosing cohorts and decreased by about 80 cells/mm³ for patients receiving placebo. No clear pharmacokinetic/pharmacodynamic relationship was demonstrated, likely due to drug trough levels well above the EC(90) of IDX899 against wild-type HIV-1.

"We believe any new HIV treatment must demonstrate potent antiviral activity at low doses to be suitable for combination therapy and possible co-formulation with other antiretroviral drugs. We are very encouraged that the robust antiviral activity observed at 800 mg/day was also achieved by the 400 and 200 mg/day cohorts," said Douglas Mayers, M.D., Idenix's chief medical officer. "We look forward to evaluating a 100 mg once-daily IDX899 dose in the upcoming weeks."

Data for patients enrolled in the study will be presented today at the XVII International HIV Drug Resistance Workshop in Sitges, Spain.

About Idenix

Idenix Pharmaceuticals, Inc., headquartered in Cambridge, Massachusetts, is a biopharmaceutical company engaged in the discovery and development of drugs for the treatment of human viral and other infectious diseases. Idenix's current focus is on the treatment of infections caused by hepatitis C virus and HIV. For further information about Idenix, please refer to www.idenix.com

Forward-looking Statements

This press release contains "forward-looking statements" within the meaning of The Private Securities Litigation Reform Act of 1995. Such forward-looking statements can be identified by the use of forward-looking terminology such as "anticipate," "could," "may," "will," or similar expressions, or by express or implied statements with respect to the company's clinical development programs in HIV, or any potential pipeline candidates for the treatment of HIV, including any expressed or implied statement regarding the efficacy and safety of IDX899 and any future clinical trials involving IDX899. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantees that the company will advance any clinical product candidate or other component of its potential pipeline to the clinic, to the regulatory process or to commercialization. In particular, management's expectations could be affected by unexpected regulatory actions or delays; uncertainties relating to, or unsuccessful results of, pre-clinical studies and/or clinical trials, including additional data relating to the ongoing pre-clinical studies and/or clinical trials evaluating its product candidates, including IDX899; the company's ability to obtain additional funding required to conduct its research, development and commercialization activities; the company's dependence on its collaboration with Novartis Pharma AG; changes in the company's business plan or objectives; the ability of the company to attract and retain qualified personnel; competition in general; and the company's ability to obtain, maintain and enforce patent and other intellectual property protection for its product candidates and its discoveries. These and other risks which may impact management's expectations are described in greater detail under the caption "Risk Factors" in the company's annual report on Form 10-K for the year ended December 31, 2007 and the Quarterly Report on Form 10-Q for the quarter ended March 31, 2008, each as filed with the Securities and Exchange Commission (SEC) and other filings that the company makes with the SEC.

All forward-looking statements reflect the company's expectations only as of the date of this release and should not be relied upon as reflecting the company's views, expectations or beliefs at any date subsequent to the date of this release. Idenix anticipates that subsequent events and developments may cause these views, expectations and beliefs to change. However, while Idenix may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so.

Amplicor(R) is a registered trademark of F. Hoffman-La Roche Ltd.

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