

# News Release

## **IDX899 Demonstrates Rapid and Profound Inhibition of HIV Replication in a Phase I/II Clinical Trial in Treatment-Naive HIV-Infected Patients**

CAMBRIDGE, Mass., Feb. 6 /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 data for IDX899, a non-nucleoside reverse transcriptase inhibitor (NNRTI) being developed for the treatment of HIV. In the first dosing cohort of an ongoing phase I/II study, eight HIV-1 infected treatment-naive patients receiving 800 mg of IDX899 once-daily achieved a mean reduction in virus level of 2.01 log(10), or 99 percent, after seven days of treatment. Additionally, two posters detailing the in-vitro resistance and pharmacokinetic profile in man of IDX899 were presented at the 2008 Conference on Retroviruses and Opportunistic Infections (CROI) this week in Boston, MA.

"New once-a-day NNRTIs that offer improved resistance and safety profiles over what is currently available would be a valuable asset to HIV-treating physicians," said Dr. Douglas Richman, Professor of Pathology and Medicine, University of California San Diego, and Director of the UCSD Center for AIDS Research. "The early profile of IDX899 shows promise and warrants continued clinical evaluation as a potential HIV therapy."

### Interim Proof of Concept Data in HIV-infected Patients

An ongoing phase I/II clinical trial is evaluating the safety, tolerability and antiviral activity of IDX899. In the first cohort of the study, ten HIV-1-infected treatment-naive patients were randomized 8:2 to receive once-daily 800 mg IDX899 or matching placebo, respectively, for seven days.

Patients receiving once-daily 800 mg of IDX899 achieved a mean and median plasma viral load reduction of 2.01 and 2.11 log(10), respectively, after seven days of treatment. Six out of eight patients achieved a 2 log(10) or greater reduction in viral load with one patient achieving undetectable virus levels (< 50 copies/mL). No serious adverse events were reported in this cohort and no patients discontinued the study. Given the potent antiviral activity and favorable preliminary safety demonstrated at 800 mg once-daily, we will explore sequential cohorts of 400 mg once-daily followed by 200 mg once-daily.

"We are pleased with the safety profile and potency observed with the 800 mg dose of IDX899 in HIV-infected patients and based on these data we will continue to evaluate lower dosing regimens in order to optimize the role of

IDX899 in HIV combination therapy," said Douglas Mayers, M.D., Idenix's chief medical officer.

#### In-vitro Resistance Data

In a preclinical resistance study, IDX899 and other marketed and investigational NNRTIs were compared to evaluate in-vitro genotypic resistance and phenotypic cross-resistance profiles. IDX899 demonstrated potent antiviral activity against established NNRTI-resistant clinical isolates. Compared to efavirenz (Sustiva(R)), the emergence of IDX899-resistant HIV-1 isolates was slower and required several mutations suggesting a higher barrier to resistance for IDX899. The resistance mutations selected in-vitro with IDX899 were different from those selected with efavirenz. Efavirenz appeared to be active against IDX899 resistant viruses and IDX899 remained active against efavirenz-resistant virus containing as many as four NNRTI-resistance mutations.

#### Safety, Pharmacokinetics and Drug-Drug Interaction Data in Healthy Volunteers

A phase I study was conducted to evaluate the safety and pharmacokinetics of IDX899 following single escalating (n=65) and multiple (n=20) doses in healthy volunteers. In this study, following once-daily oral administration, IDX899 appeared to be well tolerated at single doses up to 1200 mg and multiple doses up to 800 mg over a seven-day period. No serious adverse events or pattern of laboratory abnormalities were observed. Food enhanced the absorption of IDX899. Additionally, in a single-dose drug-drug interaction study assessing the combination of either 100 or 800 mg IDX899 and 100 mg atazanavir (Reyataz(R)), atazanavir plasma levels were not markedly altered by IDX899.

#### 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](http://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 "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. 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; 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, 2006 and the Quarterly Report on Form 10-Q for the quarter ended September 30, 2007, 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.

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