



August 16, 2012

## **Idenix Provides Update on IDX184 Clinical Development Program**

**IDX184 has been placed on partial clinical hold by FDA**

**Management to host a conference call webcast today at 8:30 am ET**

CAMBRIDGE, Mass., Aug. 16, 2012 (GLOBE NEWSWIRE) -- Idenix Pharmaceuticals, Inc. (Nasdaq:IDIX), a biopharmaceutical company engaged in the discovery and development of drugs for the treatment of human viral diseases, today announced that the Company received verbal notice from the U.S. Food and Drug Administration (FDA) that a partial clinical hold has been placed on IDX184, the Company's nucleotide polymerase inhibitor under development for the treatment of hepatitis C virus (HCV).

As a result of the recent occurrence of a serious cardiac-related adverse event encountered with a competitor's nucleotide polymerase inhibitor for the treatment of HCV, the FDA has expressed an interest in further reviewing the safety of IDX184 and has placed IDX184 on partial clinical hold. In previous clinical trials as well as the ongoing phase IIb clinical trial of IDX184 in combination with pegylated interferon and ribavirin (PegIFN/RBV), there has been no evidence to date of cardiotoxicity in patients dosed with IDX184 with PegIFN/RBV beyond that seen with PegIFN/RBV alone. There are currently no patients receiving IDX184 worldwide.

The FDA has requested additional data on patients treated with IDX184. Patient safety is our main concern and Idenix will immediately begin work to comply with the FDA request and expects to submit these data to the FDA in the coming weeks. The Company intends to have an ongoing discussion with the FDA following the submission of this data.

### **ABOUT IDX184**

IDX184 is an unpartnered, novel, liver-targeted nucleotide prodrug of 2'-methyl guanosine, which includes Idenix's proprietary liver-targeting technology. This technology enables the delivery of nucleoside monophosphate to the liver, leading to the formation of high levels of nucleoside triphosphate, potentially maximizing drug efficacy and limiting systemic side effects with low, once-daily dosing. The Company reported interim data in June 2012 for the first cohort of 31 patients from an ongoing phase IIb clinical trial of IDX184 in combination with PegIFN/RBV. Of the patients who achieved an extended rapid virologic response (undetectable levels of virus at 4 weeks and 12 weeks) and completed an additional 12 weeks of PegIFN/RBV (n=9), 100% of patients (4/4) in the 100 mg arm and 80% of patients (4/5) in the 50 mg arm achieved a sustained virologic response four weeks after the completion of treatment (SVR4).

In July 2012, an independent data safety monitoring board reviewed the safety data for this study and confirmed that the side effect profile of IDX184 combined with PegIFN/RBV is consistent with that of PegIFN/RBV alone.

### **ABOUT PARTIAL CLINICAL HOLD**

A partial clinical hold is a delay or suspension of only part of the clinical work requested under the investigational new drug (IND) application (e.g., a specific protocol or part of a protocol is not allowed to proceed; however, other protocols or parts of the protocol are allowed to proceed under the IND). Under the partial clinical hold, Idenix cannot enroll patients into additional clinical trials until agreement is reached with the FDA on the next clinical trial design.

### **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 diseases. Idenix's current focus is on the treatment of patients with hepatitis C infection. For further information about Idenix, please refer to [www.idenix.com](http://www.idenix.com).

### **CONFERENCE CALL AND WEBCAST INFORMATION**

Idenix will hold a conference call today at 8:30 a.m. ET. To access the call, please dial (877) 640-9809 (U.S./Canada) or (914) 495-8528 (International) and enter passcode 22005490. A slide presentation will accompany the conference call and can be accessed on the Investor section of the Idenix website at [www.idenix.com](http://www.idenix.com). Please log on approximately 10 minutes prior to the start of the call to ensure adequate time for any downloads that may be necessary.

A replay of the conference call and webcast will be available until August 27, 2012, by dialing (855) 859-2056 (U.S./Canada) or (404) 537-3406 (International) and enter the passcode 22005490.

## **FORWARD-LOOKING STATEMENTS**

This press release contains "forward-looking statements" for purposes of the safe harbor provisions of The Private Securities Litigation Reform Act of 1995, including but not limited to the statements regarding the Company's future business and financial performance. For this purpose, any statements contained herein that are not statements of historical fact may be deemed forward-looking statements. Without limiting the foregoing, the words "expect," "plans," "anticipates," "intends," "will," and similar expressions are also intended to identify forward-looking statements, as are expressed or implied statements with respect to the Company's potential pipeline candidates, including any expressed or implied statements regarding the efficacy and safety of IDX184 or any other drug candidate; the successful development of novel combinations of direct-acting antivirals for the treatment of HCV; and the likelihood and success of any future clinical trials involving IDX184 or our other drug candidates. Actual results may differ materially from those indicated by such forward-looking statements as a result of risks and uncertainties, including but not limited to the following: 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; management's expectations could be affected by unexpected regulatory actions or delays; uncertainties relating to, or unsuccessful results of, clinical trials, including additional data relating to the ongoing clinical trials evaluating its product candidates; changes in the Company's business plan or objectives; 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. 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. These and other risks which may impact management's expectations are described in greater detail under the heading "Risk Factors" in the Company's annual report on Form 10-K for the year ended December 31, 2011 and the quarterly report on Form 10-Q for the quarter ended June 30, 2012, each as filed with the Securities and Exchange Commission (SEC) and in any subsequent periodic or current report that the Company files with the SEC.

All forward-looking statements reflect the Company's estimates only as of the date of this release (unless another date is indicated) 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. While Idenix may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so, even if the Company's estimates change.

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