



Achillion Announces Positive 96-Week Data for Elvucitabine at the 17th Annual Conference on Retroviruses and Opportunistic Infections

NEW HAVEN, Conn., Feb 17, 2010 (GlobeNewswire via COMTEX News Network) -- Achillion Pharmaceuticals, Inc. (Nasdaq:ACHN), a leader in the discovery and development of small molecule drugs to combat the most challenging infectious diseases, today announced the presentation of additional positive safety and efficacy results from its Phase 2 trial studying elvucitabine in patients infected with Human Immunodeficiency Virus (HIV). The new data were presented in a poster entitled, "Elvucitabine vs Lamivudine with Tenofovir and Efavirenz in Antiretroviral-Treatment-Naïve HIV-1 Infected Patients: 96 Week Final Results," at the 17th Annual Conference on Retroviruses and Opportunistic Infections underway in San Francisco.

Elvucitabine is an L-cytosine nucleoside analog reverse transcriptase inhibitor (NRTI) that has previously demonstrated potent in vitro antiviral activity against HIV, including strains resistant to other NRTIs.

96-Week Safety and Efficacy Findings

The objectives of the trial, ACH443-015, included the assessment of safety, tolerability and antiviral activity with a once daily 10 mg dose of elvucitabine, as compared to 3TC (lamivudine), in a standard triple-combination regimen. The results at 96 weeks demonstrated that elvucitabine had a substantial anti-viral effect similar to 3TC, with 95% of patients in the elvucitabine-treated group who reached 96 weeks of treatment achieving undetectable viral load, defined as achieving fewer than (\leq 50 copies/ml), compared with 93% in the 3TC group. The study demonstrated a mean change in HIV-RNA from baseline in the elvucitabine treatment group of $-3.0 \log_{10}$ (+0.6) vs. $-3.2 \log_{10}$ (+ 0.7) in the 3TC treatment group in the as-treated patient analysis. Elvucitabine was well-tolerated and demonstrated a safety profile comparable to 3TC for both incidence and severity of adverse events. Further, no resistance to elvucitabine was documented at 96 weeks of therapy.

"Elvucitabine continues to demonstrate substantial and sustained viral suppression with a generally safe and tolerable side effect profile. Importantly, these data show that treatment with elvucitabine is durable," said Elizabeth A. Olek, D.O., Vice President and Chief Medical Officer. "We are encouraged that as these data mature, elvucitabine continues to demonstrate excellent safety and efficacy, while offering an important potential treatment option for HIV patients."

"These 96-week data confirm our belief that elvucitabine offers a very promising treatment for use in combination therapy, and we are pleased to see that the response to elvucitabine in patients with HIV is sustained over time," commented Michael D. Kishbauch, President and CEO of Achillion. "We recently announced a license agreement for the development and commercialization of elvucitabine in China, and with these data we will continue to seek additional partnerships in other geographies so that this important treatment can continue to advance."

Study Design

ACH443-015 is a randomized, double-blind study in patients infected with wild-type HIV-1 virus. The trial included a 12-week blinded treatment period after which responders (patients with viral loads below 400 copies/mL, or $<2 \log_{10}$ decrease) continued to an 84-week open-label extension period. The trial enrolled 78 subjects who were randomized 1:1 into two treatment groups: 10 mg/day elvucitabine with 600 mg/day efavirenz and 300 mg/day tenofovir; or 300 mg/day 3TC with 600 mg/day efavirenz and 300 mg/day tenofovir.

About Elvucitabine

Elvucitabine, Achillion's HIV product candidate, is an L-cytosine nucleoside analog reverse transcriptase inhibitor (NRTI) that has demonstrated potent antiviral activity against HIV, including strains resistant to other NRTIs, in vitro. NRTIs are the predominant class of drugs for use in HIV combination therapy and are frequently prescribed given their established potency, favorable short- and long-term safety profile and fewer and less severe adverse side effects. Clinical and pre-clinical data collected to date indicate that elvucitabine can be dosed as a 10 mg pill once daily and may be used in combination therapy. In addition, the L-nucleoside configuration of the compound may provide protection against mitochondrial toxicity, a serious side effect often seen with D-nucleosides. Finally, elvucitabine has been demonstrated to have a longer half-life than other approved NRTIs, providing a potential barrier to the emergence of drug resistance in patients who are less than perfectly compliant.

About Achillion

Achillion is an innovative pharmaceutical company dedicated to bringing important new treatments to patients with infectious

disease. Achillion's proven discovery and development teams have advanced multiple product candidates with novel mechanisms of action. Achillion is focused on solutions for the most challenging problems in infectious disease -- hepatitis C, resistant bacterial infections and HIV. For more information on Achillion Pharmaceuticals, please visit www.achillion.com or call 1-203-624-7000.

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that are subject to risks, uncertainties and other factors, including statements with respect to the potency, safety and other characteristics of elvucitabine and Achillion's expectations regarding timing and duration of other clinical trials. Among the factors that could cause actual results to differ materially from those indicated by such forward-looking statements are: uncertainties relating to results of clinical trials, unexpected regulatory actions or delays, and Achillion's ability to secure additional license arrangements for the further development and commercialization of elvucitabine. These and other risks are described in the reports filed by Achillion with the U.S. Securities and Exchange Commission, including its Annual Report on Form 10-K for the fiscal year ended December 31, 2008.

All forward-looking statements reflect Achillion's expectations only as of the date of this release and should not be relied upon as reflecting Achillion's views, expectations or beliefs at any date subsequent to the date of this release. Achillion anticipates that subsequent events and developments may cause these views, expectations and beliefs to change. However, while Achillion 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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