



Achillion Announces Preliminary Phase 1b Proof-of-Concept Data With ACH-2928 NS5A Inhibitor for the Treatment of Hepatitis C

Achieves 3.68 Log₁₀ Reduction in HCV RNA After Three Days of Treatment

NEW HAVEN, Conn., Dec. 5, 2011 (GLOBE NEWSWIRE) -- **Achillion Pharmaceuticals, Inc.** (Nasdaq:ACHN), a leader in the discovery and development of small molecule drugs to combat the most challenging infectious diseases, today reported proof-of-concept data from its Phase 1b clinical trial of ACH-2928, a first-generation NS5A inhibitor, demonstrating that patients treated with ACH-2928 achieved a mean maximum 3.68 log₁₀ reduction in HCV RNA after three-day monotherapy of 60 mg once daily. The compound also demonstrated good safety and tolerability both in healthy volunteers and in patients with chronic hepatitis C (HCV).

ACH-2928, Achillion's first generation inhibitor of the NS5A protein, was discovered through the Company's NS5A inhibitor program. Achillion also recently nominated a second-generation NS5A inhibitor, ACH-3102, which is currently undergoing IND-enabling studies and is expected to be advanced into clinical trials during the first half of 2012.

"We believe NS5A inhibitors have emerged as an important component for an all-oral, direct acting antiviral (DAA) regimen," commented Michael D. Kishbauch, President and Chief Executive Officer of Achillion. "Furthermore, NS5A inhibitors, when combined with a protease inhibitor, have achieved sustained viral responses in clinical trials in tough to treat genotype 1 HCV populations. We believe this highlights the potential to form a proprietary interferon-free DAA combination regimen for the treatment of HCV within Achillion's pipeline."

ACH-2928 Phase 1 Program

In July 2011, Achillion initiated dosing in a randomized, double-blind, placebo-controlled phase 1a/1b clinical trial to investigate the safety, tolerability, pharmacokinetic profile and antiviral activity of ACH-2928. The trial consists of three segments: assessment of single ascending oral doses (SAD) in healthy volunteers, evaluation of 3 days of oral repeat doses in subjects with genotype 1a or 1b HCV, and a 5-day multiple ascending doses segment in healthy volunteers.

During the oral repeat doses segment in subjects infected with HCV, a total of 10 patients were enrolled with 2 patients (genotype 1a) receiving placebo and 8 patients (7 genotype 1a and 1 genotype 1b) treated with 3 doses of 60 mg ACH-2928 administered once daily. No serious adverse events (SAE) were reported and there were no patient discontinuations during treatment. The mean maximum HCV RNA decline during therapy was 3.68 log₁₀ compared to a 0.54 log₁₀ decline for patients receiving placebo. There were no viral breakthroughs observed during ACH-2928 monotherapy.

Preliminary data from the SAD trial segment demonstrated ACH-2928 was well tolerated at all doses evaluated up to and including the maximum dose of 500 mg. There were no serious adverse events, no clinically significant changes in vital signs, electrocardiograms (ECGs), or laboratory evaluations. All reported adverse events were classified as mild or moderate, and were transient in nature.

Based upon these preliminary results, the ongoing Phase 1 study will continue to evaluate the pharmacokinetic, pharmacodynamic, and antiviral profile of ACH-2928. These Phase 1 results have been submitted for presentation at a medical meeting being held during the second quarter of 2012. In parallel, Achillion is advancing its second generation NS5A inhibitor ACH-3102 through IND-enabling studies and the Company expects to initiate clinical development during the first half of 2012.

"As we continue to evaluate ACH-2928 in this Phase 1 study, we are also working rapidly to advance ACH-3102, which has shown in preclinical studies to possess the same potent activity against genotype 1a HCV as ACH-2928, as well as enhanced activity against resistant HCV mutants that have been observed in this patient population," stated Milind Deshpande, PhD, President of Research and Development and Chief Scientific Officer. "We believe these results validate our NS5A development program, and look forward to developing an all-oral combination for clinical evaluation that includes one of our protease inhibitors and an NS5A inhibitor next year."

About NS5A Inhibitors

The NS5A protein is a clinically validated target that serves multiple functions at various stages of the HCV life cycle including involvement in virion production, interaction with host proteins and association with interferon-resistance. Achillion's NS5A inhibitors, including ACH-2928 and ACH-3102, possess potent *in vitro* activity against all HCV genotypes and demonstrate, in preclinical studies, additive to synergistic activity when combined with NS3 protease inhibitors, NS5B polymerase inhibitors, and

ribavirin. In preclinical studies, ACH-2928 and ACH-3102 have demonstrated excellent potency, in the pico-molar range, against HCV RNA replication, including potent activity against genotype 1a while ACH-3102 has been shown to possess enhanced activity against recognized genotype 1 resistant variants.

About HCV

The hepatitis C virus infects the liver and is the most common cause of viral hepatitis, which is an inflammation of the liver. It is currently estimated that more than 170 million people are infected with HCV worldwide and The American Association of Liver Disease estimates that up to 80 percent of individuals become chronically infected following exposure to the virus. If left untreated, chronic hepatitis can lead to permanent liver damage, which can result in the development of liver cancer, liver failure or death. Few therapeutic options currently exist for the treatment of HCV infection. The current standard of care is limited by its specificity for certain types of HCV, significant side-effect profile, and injectable route of administration.

About Achillion Pharmaceuticals

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 including hepatitis C and resistant bacterial infections. For more information on Achillion Pharmaceuticals, please visit www.achillion.com or call 1-203-624-7000.

Forward-Looking Statements

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 important factors, including statements with respect to the potency, safety and other characteristics of Achillion's NS5A inhibitors, which may not be duplicated in clinical studies, and Achillion's expectations regarding results, timing and duration of clinical trials and reporting of results from clinical trials of Achillion's NS5A inhibitors. Among the important factors that could cause actual results to differ materially from those indicated by such forward-looking statements are risks relating to: Achillion's ability to advance the development of its drug candidates under the timelines it anticipates in current and future clinical trials; to obtain patent protection for its drug candidates, and the freedom to operate under third party intellectual property; to establish commercial manufacturing arrangements and to identify, enter into and maintain collaboration agreements with appropriate third-parties; and to raise the substantial additional capital needed to achieve its business objectives. 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, 2010 and its subsequent SEC filings.

In addition, any forward-looking statement in this press release represents Achillion's views only as of the date of this press release and should not be relied upon as representing its views as of any subsequent date. Achillion disclaims any obligation to update any forward-looking statement, except as required by applicable law.

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