



## **Achillion Completes Phase 1a Trial of ACH-1625; Begins Dosing in Phase 1b Segment With HCV-Infected Patients**

### **ACH-1625 Safe and Well-Tolerated in Single Ascending and Multiple Ascending Dose Trial Segments**

NEW HAVEN, Conn., Sep 28, 2009 (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 that the Company has completed Phase 1a of its ongoing clinical trial of ACH-1625, a protease inhibitor for the treatment of hepatitis C virus (HCV) infection, and has begun dosing HCV-infected patients in the Phase 1b segment of the trial.

ACH-1625 is a potent small molecule inhibitor of HCV protease, an enzyme necessary for viral replication. The drug candidate was discovered and is being advanced by Achillion, with the objective of developing a best-in-class protease inhibitor for treatment of HCV infection featuring potency, safety, tolerability and convenient once-daily dosing.

"We are pleased that the outstanding safety profile established in preclinical testing continues to be seen in this human clinical trial. ACH-1625 was safe and well-tolerated in both the single and the multiple ascending dose segments," stated Elizabeth A. Olek, D.O., Vice President and Chief Medical Officer of Achillion. "Clinical data gathered thus far support our belief that ACH-1625 has the potential to offer convenient once-daily dosing and an improved safety and tolerability profile compared with other protease inhibitors being studied for the treatment of hepatitis C."

"This first clinical trial of ACH-1625 has proceeded exactly as planned and we are quite pleased and encouraged with the results to date. The HCV-infected cohort of the trial has begun, and we expect it should conclude within the next few months. We are eager to demonstrate ACH-1625's efficacy and anticipate being able to announce those data early next year," added Michael Kishbauch, Achillion's President and Chief Executive Officer.

#### About the Phase 1 Program

The Phase 1a/1b clinical trial is a randomized, double-blind, placebo-controlled trial to investigate the safety, tolerability, pharmacokinetic profile and antiviral activity of ACH-1625 after single and multiple ascending oral doses in healthy volunteers, and oral repeat doses for 5-days in subjects with hepatitis C infection. The trial is taking place in Europe and is designed to enroll at least 54 subjects, including both healthy volunteers and HCV-infected patients. The trial is anticipated to be completed in the first quarter of 2010.

Subjects in the phase 1a single ascending dose (SAD) segment of the study received single doses of ACH-1625 ranging from 50 mg to 2000 mg. Subjects in the phase 1a multiple ascending dose (MAD) segment of the study received 5 days of ACH-1625 up to a maximal dose of 2000 mg per day.

Preliminary data from the SAD and MAD trial segments demonstrate:

- \* No serious adverse events
- \* No clinically significant changes in vital signs, ECGs, or laboratory evaluations
- \* Adverse events were mild and transient

#### About ACH-1625

ACH-1625 is an HCV protease inhibitor designed and synthesized based on crystal structures of enzyme/inhibitor complex. ACH-1625 is an open chain, non-covalent, reversible inhibitor of NS3 protease. In preclinical studies, ACH-1625 demonstrated high potency, unique pharmacokinetic properties and an excellent safety profile at high drug exposures. With its rapid and extensive partitioning to the liver, as well as high liver/plasma ratios demonstrated in preclinical studies, Achillion believes that ACH-1625 has the potential for once daily dosing. ACH-1625 has shown low single-digit nanomolar potency that is specific to HCV. It is equipotent against HCV genotypes 1a and 1b at IC50~1nM.

## About HCV

The hepatitis C virus (HCV) 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% 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

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](http://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 Achillion's expectations regarding the results of ongoing clinical trials, and the timing and duration of 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 obtain additional funding required to conduct its research, development and commercialization activities. 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.

## ACHN-G

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