



Achillion Announces 94 - 100% Complete EVR From Phase 2 Trial With ACH-1625 Based Regimen in Hepatitis C

Posters Detailing ACH-1625, ACH-3102 and ACH-2928 Presented at the International Liver Congress(TM) 2012

NEW HAVEN, Conn., April 21, 2012 (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 announced that in the second segment of its Phase 2a trial of ACH-1625, 94 to 100 percent of patients with treatment naïve genotype 1 chronic hepatitis C virus (HCV) achieved a complete early virologic response (cEVR) after 12 weeks of treatment with ACH-1625 in combination with pegylated interferon alfa-2a and ribavirin (P/R). ACH-1625 in combination with P/R for up to 12 weeks was safe and well tolerated and produced high viral response rates regardless of dose level or IL28B genotype status.

Results from this trial were presented during the 47th Annual Meeting of the European Association for the Study of the Liver (EASL) International Liver Congress 2012 in Barcelona, Spain from April 18 — 22, 2012. Additional posters detailing Achillion's NS5A inhibitor program, including ACH-2928 and ACH-3102, were also presented during EASL

Michael D. Kishbauch, President and Chief Executive Officer of Achillion commented, "We are extremely pleased with the safety and efficacy that ACH-1625 has achieved in this Phase 2 clinical trial as well as the impressive resistance profile this compound has shown to date. As we finalize this Phase 2 trial and report on SVR later this year, we are now focused on initiating our all-oral program for the treatment of HCV. With the recent submission of an IND for ACH-3102, our second-generation NS5A inhibitor, we look forward to initiating its Phase 1 program this quarter and rapidly advancing toward a therapeutic, interferon-free combination trial evaluating ACH-1625 plus ACH-3102 during the fourth quarter of this year."

ACH-1625: Phase 2 protease inhibitor for the treatment of HCV

In Segment 2 of this Phase 2a trial, a total of 58 subjects with HCV were enrolled, randomized and stratified by IL28B genotype, including CT and TT, which is a marker of a patient's responsiveness to interferon, to receive one of three doses of once-daily ACH-1625 (200 mg, 400 mg or 800 mg) in combination with P/R for 12 weeks of therapy.

Of the patients enrolled, the majority had HCV genotype 1a (n=35 (60%)), with remaining patients having HCV genotype 1b (n=20) or genotype 1 (n=3). Approximately 71% of the patients were IL28B genotype CT/TT, the more difficult to treat mutation, 64% were male and 17% were African American. No viral breakthroughs were observed during treatment. Results demonstrated rapid virological response (RVR) at week 4, cEVR and end of treatment (EOT) responses for patients returning for EOT visit to date as follows:

Segment 2: 12-week treatment duration assessments	ACH-1625		
	200 mg n=19	400 mg n=20	800 mg n=19
RVR (HCV RNA < 25 IU/mL week 4), % (n)	79% (15/19)	89% (16/18) **	90% (17/19)
cEVR (undetectable week 12), % (n)	100% (18/18) *	94% (15/16) **	100% (19/19)
EOT Response (undetectable) *** % (n)	86% (6/7)	69% (9/13)	100% (10/10)

Reasons for discontinuation include: *200 mg 1 patient withdrew for unrelated AEs at Week 5. **400 mg 1 patient withdrew consent at Week 9, 1 patient moved at Week 2, each were undetectable at the time of withdrawal; 2 patients withdrew for unrelated AEs, one before Week 4 and one before Week 12. ***EOT denominator includes only patients who returned for their end of treatment visit

Safety results from both segments of the trial were similar to those observed and previously reported during clinical trials of ACH-1625. Most reported adverse events (AEs) in patients receiving ACH-1625 were classified as mild to moderate and were transient. The most common AEs were consistent with pegylated interferon alfa-2a and ribavirin treatment. During 12 weeks of co-administration of ACH-1625 plus P/R, there was one reported serious adverse event (SAE) that was deemed unrelated to ACH-1625. There was no difference noted between dose groups for either the incidence or severity of observed adverse

events.

"We were pleased to note that across the dose groups and regardless of IL28B status, nearly all patients treated through 12 weeks achieved cEVR. The clinical potency, unique pharmacokinetic profile, and barrier to resistance for ACH-1625 appear to provide very effective antiviral coverage for all of these genotype 1 patients," commented Dr. Elizabeth A. Olek, Chief Medical Officer of Achillion. "With the continued on-treatment viral suppression and impressive initial end of treatment response rates, we look forward to reporting out the sustained viral response rates for these patients later in the year."

In a separate poster presentation, the clinical virology of NS3 variants from patients enrolled in Segment 1 of the Phase 2a clinical trial evaluating multiple ascending doses of ACH-1625 in combination with P/R was presented. Sequencing of baseline to post-treatment samples revealed that there were no mutations at loci 155, 156, or 168 of NS3 protease, which represent common mutations that may confer resistance to protease inhibitors. To date, no viral breakthrough has been observed during monotherapy with ACH-1625 or with ACH-1625-based treatment regimens suggesting that the potency of ACH-1625 is sufficient to inhibit the growth of the most frequently observed resistant mutants.

Additional NS5A Inhibitor Posters Presented at EASL

- Preclinical characteristics of ACH-3102: A novel HCV NS5A inhibitor with improved potency against genotype 1a virus and variants resistance to 1st generation of NS5A inhibitors (abstract A845. Y. Zhao, et al.)
- Novel NS5A inhibitor ACH-2928 phase 1 results in HCV GT-1 patients (abstract 1211. B. Vince, et al.)

About ACH-1625

ACH-1625 is a Phase 2 pan-genotypic 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. ACH-1625 has demonstrated rapid and extensive partitioning to the liver, as well as high liver/plasma ratios. 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 of approximately 1nM. ACH-1625 has shown clinical antiviral activity against genotypes 1 and 3. Fast Track status was granted to ACH-1625 in 2012 for the treatment of chronic HCV.

About HCV

The hepatitis C virus 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 including nearly 4 million people in the United States, more than twice as widespread as HIV. Three-fourths of the HCV patient population is undiagnosed; it is a silent epidemic and a major global health threat. Chronic hepatitis, if left untreated, can lead to permanent liver damage that 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 that could cause actual results to differ materially from those indicated by such forward-looking statements, including statements with respect to: the potency, safety, tolerability, effectiveness and other characteristics of ACH-1625; and Achillion's expectations regarding timing for the completion and reporting of additional results of Phase 2 clinical trials of ACH-1625 and the commencement of a Phase 1 clinical trials of ACH-1625 plus ACH-3102. Among the factors that could cause actual results to differ materially from those indicated by such forward-looking statements are risks relating to, among other things Achillion's ability to: replicate in later clinical trials positive results found in earlier stage clinical trials of ACH-1625 and its other product candidates; advance the development of its drug candidates under the timelines it anticipates in current and future clinical trials; obtain necessary regulatory approvals; obtain patent protection for its drug candidates, and the freedom to operate under third party intellectual property; establish

commercial manufacturing arrangements; identify, enter into and maintain collaboration agreements with appropriate third-parties; compete successfully with other companies that are seeking to develop improved therapies for the treatment of HCV; and 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, 2011 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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