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ACH-1625 Receives Fast Track Designation From the FDA for the Treatment of Chronic Hepatitis C

NEW HAVEN, Conn., Jan. 4, 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, announced today the receipt of a Fast Track designation from the U.S. Food and Drug Administration (FDA) for ACH-1625 for the treatment of chronic hepatitis C virus (HCV). ACH-1625 is a once-daily protease inhibitor with broad genotypic coverage against HCV that was discovered by Achillion and is currently being evaluated in a Phase 2 clinical trial.

Fast Track designation was granted to ACH-1625 for its potential to provide:

- Improved safety and tolerability as compared to the current standard of care;

- Convenient once-daily dosing;

- Broader genotypic coverage of HCV;

- An improved drug-drug interaction profile with greater potential to treat HCV patients with comorbidities, co-infected with HIV, or pre- or post-liver transplantation; and

- Development in a once-daily interferon-free oral combination.

"We are very pleased with the granting of a Fast Track designation for ACH-1625, which we believe highlights this protease inhibitor's attributes which include broad genotypic coverage of HCV, once-daily administration and an improved safety, efficacy and tolerability profile over currently approved therapies for HCV," commented Michael Kishbauch, President and Chief Executive Officer of Achillion. "As we work toward achieving our near-term milestones, we remain eager to initiate an interferon-free, all-oral combination clinical study evaluating our protease inhibitor plus NS5A inhibitor for the treatment of HCV during the second half of this year."

Under the FDA Modernization Act of 1997, the Fast Track program facilitates interactions with the FDA before and during the submission of a New Drug Application (NDA) for therapeutics being investigated as a treatment of serious or life-threatening diseases which demonstrate the potential to address an unmet medical need for such a condition. The Fast Track program enables a company to file an NDA on a rolling basis as data becomes available. This permits the FDA to review the filing as it is received, rather than waiting for the entire document prior to commencing the review process. With a Fast Track designation, there is an opportunity for more frequent interactions with the FDA and the possibility of a priority review, which could decrease the typical development time and review period.

About ACH-1625

ACH-1625 is a 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 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.

In the first segment of a Phase 2a clinical study, treatment-naïve genotype 1 HCV patients received doses of 200 mg, 400 mg, or 800 mg of ACH-1625 in combination with pegylated interferon and ribavirin (SOC) and achieved a rapid viral response (RVR) of 75 — 81% compared to an RVR of 20% for patients receiving SOC only. ACH-1625 was well tolerated at all doses with no serious adverse events reported and adverse events which were reported as mild to moderate and transient. The second segment of this Phase 2a, randomized, double-blind trial is evaluating the safety, tolerability and antiviral activity of once daily ACH-1625, at doses of 200 mg, 400 mg or 800 mg, in combination with SOC for 12 weeks of dosing. The primary endpoint for this trial is complete early virological response (cEVR). Following 12 weeks of therapy, patients will continue to receive an additional 12 weeks of pegylated interferon alfa-2a and ribavirin and be eligible to discontinue treatment at week 24 if they achieve extended rapid virologic response (eRVR) at week 12. Patients who do not achieve an eRVR will continue to receive SOC until week 48.

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 an 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 and tolerability over currently-approved therapies, increased effectiveness and other characteristics of ACH-1625, Achillion's expectations regarding timing for the commencement, completion and reporting of results from clinical trials of Achillion's protease inhibitors, and the potential benefits of Fast Track designation for ACH-1625. Among the important 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 and to 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, 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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