Achillion Announces Updated Phase 2 Results Including Early Sustained Virologic Response on ACH-3102 Plus Ribavirin in Genotype 1b Treatment-Naive Hepatitis C Patients

- ACH-3102 deemed safe and well-tolerated following 12 weeks of therapy -
- High barrier to resistance demonstrated with no on-treatment virologic breakthrough observed -
- Novel NS5A inhibitor study supports differentiated profile of ACH-3102 -

NEW HAVEN, Conn., April 23, 2013 (GLOBE NEWSWIRE) -- Achillion Pharmaceuticals, Inc. (Nasdaq:ACHN) today announced updated interim safety and efficacy results, including early sustained virologic response (SVR4) data, from the pilot Phase 2 trial evaluating once-daily ACH-3102 plus ribavirin (RBV) in treatment-naïve patients with genotype 1b, IL28B CC subtype, chronic hepatitis C virus (HCV) infection. All of the 8 patients enrolled in the trial completed 12 weeks of treatment with no virologic breakthrough observed. ACH-3102 also demonstrated continued declines in HCV RNA in the presence of up to six baseline mutations that are known to confer a high level of resistance to 1st generations NS5A inhibitors. ACH-3102 was deemed safe and well-tolerated with no significant adverse events reported. In all, 75% of patients (6 of 8) had HCV RNA < 25 IU/ml at the end of treatment and 63% (5 of 8) achieved early sustained virologic response 4 weeks (SVR4) after the completion of therapy.

Dr. Andrew Muir, Principal Investigator and Assistant Professor of Medicine and Director of Gastroenterology/Hepatology Research at Duke Clinical Research Institute commented, "The preliminary results from this novel study of a single DAA, an NS5A inhibitor, plus ribavirin demonstrates the safety, high barrier to resistance, and preliminary efficacy of ACH-3102. The profound activity of ACH-3102 as a single DAA, along with its safety profile and lack of virologic breakthrough to date makes this a very promising compound to study further in combination with other oral agents, including sovaprevir, for the treatment of HCV."

Overall, ACH-3102 was well-tolerated and demonstrated a safety profile consistent with that seen during Phase 1 trials in both healthy subjects and HCV-infected patients. No patients experienced virologic breakthrough while on treatment and no patients discontinued treatment due to an adverse event. Final study results are expected to be submitted for presentation at a medical conference later this year.

<table>
<thead>
<tr>
<th>Total 8 subjects enrolled</th>
<th>RVR</th>
<th>ETR</th>
<th>SVR4</th>
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<tbody>
<tr>
<td>n = 8</td>
<td></td>
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<tr>
<td># of subjects (%)</td>
<td>6 / 8</td>
<td>6 / 8*</td>
<td>5 / 8 **</td>
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<tr>
<td></td>
<td>(75%)</td>
<td>(75%)</td>
<td>(63%)</td>
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RVR = Rapid Virologic Response, HCV RNA < LLOQ (< 25 IU/mL) at week 4 of treatment
ETR = End of Treatment Response, HCV RNA < LLOQ (< 25 IU/mL) at week 12 of treatment

* The 2 patients who did not achieve ETR were started on pegylated interferon, ribavirin and telaprevir at the end of the 12-week treatment period, and demonstrated undetectable viral levels beginning at week 13.
** 1 patient with virologic relapse at week 15.

"We believe that these interim results further strengthen our position that ACH-3102 is a differentiated NS5A inhibitor possessing attributes that make it a true second-generation compound," commented Michael D. Kishbauch, President and Chief Executive Officer of Achillion. "The safety and efficacy profile support our recently initiated Phase 2-007 trial evaluating 12 weeks of our protease inhibitor, sovaprevir, in combination with ACH-3012 for the treatment of genotype 1 HCV. With that study now underway, we look forward to reporting interim results beginning in the third quarter of this year, and will continue to explore and execute opportunities to combine our agents with other compounds that could further shorten the treatment duration or provide additional flexibility for treatment regimens to broadly cure HCV."

About ACH-3102

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. ACH-3102, Achillion's second generation NS5A inhibitor, has demonstrated potent activity against all HCV genotypes in vitro and in preclinical studies achieved additive to synergistic activity when combined with NS3 protease inhibitors, NS5B polymerase inhibitors, interferon and ribavirin. In preclinical studies, ACH-3102 demonstrated excellent potency, in the pico-molar range, against wild type HCV RNA replication, as well as potency against resistant mutants that have been identified in clinical studies. ACH-3102 was deemed to be safe and well-tolerated in Phase 1 development and achieved mean maximal reductions in HCV RNA of 3.78 log_{10} after a single dose. ACH-3102 has been granted fast track designation by the FDA and is currently being evaluated in Phase 2 for the treatment of 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 more than 5 million people in the United States, making HCV more than twice as widespread as HIV. Three-fourths of the global 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 HCV 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 expected potency, safety, tolerability, effectiveness and other characteristics of sovaprevir and ACH-3102; and Achillion's expectations regarding timing for the commencement, completion and reporting of results of its clinical trials of both ACH-3102 in combination with ribavirin and sovaprevir in combination with ACH-3102. We may use words such as "expect," "anticipate," "project," "intend," "plan," "believe," "seek," "estimate," and "may" and similar expressions to identify such forward-looking statements. 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 sovaprevir, ACH-3102 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; manage expenses; 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, 2012 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 duty to update any forward-looking statement, except as required by applicable law.

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