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Achillion Announces 100% SVR12 in the 6-Week and 8-Week Cohorts in Janssen's Phase 2 Trial Evaluating the Triple Combination Treatment Regimen Including Odalasvir, AL-335, and Simeprevir for Genotype 1 Treatment-Naïve HCV

- ePoster presented today at the EASL / AASLD Special Conference: New Perspectives in Hepatitis C Virus Infection — The Roadmap For Cure -

- Ongoing Phase 2 development focusing on triple combination for treatment durations as short as six weeks for broad HCV population —

PARIS, Sept. 23, 2016 (GLOBE NEWSWIRE) -- **Achillion Pharmaceuticals, Inc.** (Nasdaq:ACHN) announced that updated interim results were presented today in an ePoster describing a phase 2 study being conducted by Alios BioPharma Inc., part of the Janssen Pharmaceutical Companies (Janssen) at the European Association for the Study of the Liver (EASL) Special Conference in Paris, France.

These results, updated to include expanded safety and efficacy data, were presented in the ePoster entitled "Short duration treatment with AL-335 and odalasvir (ODV), with or without simeprevir (SMV), in treatment-naïve patients with hepatitis C virus (HCV) genotype (GT) 1 infection." It reports that 100 percent of patients receiving treatment for as short as six weeks with a triple combination of once-daily (QD) AL-335 800mg and simeprevir (SMV) 75mg with 50mg every other day (QOD) of ODV achieved a sustained viral response 12 weeks after the completion of treatment (SVR12).

"Odalasvir has continued to show that it has the potential to shorten the treatment duration to as little as six weeks in combination with other direct acting antivirals for the treatment of HCV," commented Dr. Milind Deshpande, president and chief executive officer of Achillion. "We now look forward to seeing confirmation of these impressive data in Janssen's global development program."

Summary of Phase 2 Study Design and Interim Results

This study was designed to determine the safety, pharmacokinetics, and efficacy of different dosing regimens containing ODV and AL-335, with or without SMV, in treatment-naïve patients with GT1 HCV infection for treatment durations of eight or six weeks.

Of the GT1 non-cirrhotic patients that received the triple combination of ODV, AL-335, and simeprevir 100 percent remained HCV RNA undetectable at SVR12 and all patients in cohort 1 achieved SVR24 (i.e., cohorts 1, 3, and 4; N=60, 20/cohort). Cohort 1 evaluated the triple combination of ODV (50mg QD), AL-335 (400mg QD) and simeprevir (100mg QD) for eight weeks, while cohorts 3 & 4 assessed ODV (50 mg QOD), AL-335 (800 mg QD), and SMV (75 mg QD) for eight and six weeks, respectively. In cohort 2, which assessed the dual combination of ODV (50mg QOD) and AL-335 (800mg QD) for eight weeks, 90 percent of subjects achieved SVR12 (N=20).

In all of these cohorts, the dosing regimens were generally well-tolerated. The majority of adverse events (AEs) were mild and the most commonly reported events were headache, fatigue, and upper respiratory tract infection. As previously reported in the abstract, there was one serious adverse event (SAE) in cohort 1 that resulted in premature discontinuation of all study drugs. This consisted of a Mobitz Type 1 2nd degree atrioventricular block and was deemed probably related to ODV and possibly related to AL-335 and simeprevir. The event was not associated with clinical or echocardiographic abnormalities, did not require any therapeutic intervention, resolved following treatment discontinuation, and the patient went on to achieve SVR24. No clinically significant laboratory, echocardiography, or ECG abnormalities (except the SAE) were reported.

Ongoing Phase 2 Triple Combination Development Program

The interim results from this phase 2 study confirmed the treatment duration and dose for each component of the triple combination (i.e., once-daily ODV 25mg, AL-335 800mg, and SMV 75mg for treatment durations of six and eight weeks). The development program will include a multi-center, randomized, open-label study that will enroll treatment-naïve and treatment-experienced non-cirrhotic patients chronically infected with hepatitis C virus genotypes 1, 2, 4, 5, and 6. In addition, the ongoing phase 2a study is assessing the triple combination in patients with or without compensated cirrhosis, and with HCV genotype 3 infection.

Further information on clinical studies can be found at www.clinicaltrials.gov. Study identifier: NCT02765490.

About HCV

Globally, HCV infection is a leading cause of liver disease and liver related mortality. It is currently estimated that more than 150 million people are infected with HCV worldwide including approximately 3 million people in the United States. Three-quarters 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. Despite available treatments, there remains a significant unmet need for many patients infected with HCV.

About Achillion Pharmaceuticals

Achillion Pharmaceuticals, Inc. (NASDAQ:ACHN) is a science-driven, patient-focused company seeking to leverage its strengths across the continuum from discovery to commercialization in its goal of providing better treatments for people with serious diseases. The company employs a highly-disciplined discovery and development approach that has allowed it to pursue best-in-class oral antiviral therapy for chronic hepatitis C (HCV) and build a platform of potent and specific complement inhibitors. Achillion is rapidly advancing its efforts to become a fully-integrated pharmaceutical company with a goal of bringing life-saving medicines to patients with rare diseases. More information is available at http://www.achillion.com.

Cautionary Note Regarding 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. Achillion may use words such as "expect," "anticipate," "project," "intend," "plan," "aim," "believe," "seek," " estimate," "can," "focus," "will," "look forward," "goal," and "may" and similar expressions to identify such forward-looking statements. These forward-looking statements also include statements about: the potential therapeutic benefit of odalasvir in combination with other direct acting antivirals for the treatment of HCV; the Company's expected plans, timing, data readouts and results from ongoing and planned clinical trials of HCV development candidates being advanced by Janssen under the Company's collaboration with Janssen; and statements concerning the Company's strategic goals, milestone plans, and prospects. 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: obtain and maintain patent protection for its drug candidates and the freedom to operate under third party intellectual property; demonstrate in any current and future clinical trials the requisite safety, efficacy and combinability of its drug candidates; obtain and maintain necessary regulatory approvals; identify, enter into and maintain collaboration agreements with third-parties, including the current collaboration with Janssen; compete successfully in the markets in which it seeks to develop and commercialize its product candidates and future products; manage expenses; manage litigation; raise the substantial additional capital needed to achieve its business objectives; and successfully execute on its business strategies. Furthermore, because Janssen is solely responsible for the development and commercialization of Achillion's HCV assets under the exclusive worldwide license Achillion granted to it and has the deciding vote on all collaboration matters, Janssen generally has full discretion over all development plans and strategies and may not advance the HCV programs in the time frames Achillion or Janssen projects, or at all, including with regard to the current and planned phase 2a and phase 2b combination trials that include Achillion's licensed drug candidates. These and other risks are described in the reports filed by Achillion with the U.S. Securities and Exchange Commission, including its Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2016, 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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