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Achillion Announces Additional Phase 2 Results Including 100% SVR24 for Genotype 1 HCV After 6-Weeks of Once Daily JNJ-4178

Ongoing Janssen global Phase 2 program with JNJ-4178, (odalasvir, AL-335, and simeprevir) focused on treatment durations of six and eight weeks for HCV genotype 1, 2, 4, 5, and 6 patients

AMSTERDAM, the Netherlands, April 22, 2017 (GLOBE NEWSWIRE) -- **Achillion Pharmaceuticals, Inc.** (Nasdaq:ACHN) announced today the presentation of updated results from the ongoing phase 2 '604 Study' being conducted by Alios BioPharma Inc., part of the Janssen Pharmaceutical Companies (Janssen). These results were presented as an oral presentation during the European Association for the Study of the Liver (EASL) 2017 International Liver Congress in Amsterdam. These results demonstrate that the triple combination of simeprevir, odalasvir and AL-335 has the ability to shorten treatment duration, offer high efficacy and be generally well tolerated in those whose disease is caused by hepatitis C virus (HCV) genotype 1 (GT1), one of the most prevalent causes of hepatitis C globally.

"The goal of the Janssen HCV development program is to optimize treatment outcomes by providing a novel, simplified therapeutic option with high efficacy, safety, and a shorter treatment duration to address a broad range of patients living with HCV. Importantly, in this study 100% SVR12 was achieved despite the presence of NS5A polymorphisms, which can reduce the efficacy of other HCV regimens, that were observed at baseline," commented David Apelian, M.D., Ph.D., chief medical officer at Achillion. "The clinical community has expressed the need for more simplified treatment options, and these data with JNJ-4178 highlight the potential of this once daily regimen to achieve SVR24 for genotype 1 patients after only six weeks of therapy."

Study results, presented by principal investigator Dr. Edward Gane, professor of medicine at the University of Auckland and chief hepatologist at Auckland City Hospital, included expanded safety and efficacy data and were made in a presentation entitled "Short duration treatment with AL-335 and odalasvir, with or without simeprevir, in treatment-naïve patients with hepatitis C virus (HCV) genotype 1 infection." It reports that 100% of patients receiving treatment for six or eight weeks with a triple combination of once-daily AL-335 800 mg and simeprevir 75 mg with odalasvir 50 mg every other day achieved a sustained viral response 24 weeks after the completion of treatment (SVR24).

Summary of Phase 2 '604 Study' Design and Interim Results

The oral presentation features clinical trial data examining the safety, pharmacokinetics and efficacy of six and eight weeks of treatment with AL-335 and odalasvir with or without simeprevir to treat HCV in treatment naïve subjects across a range of HCV genotypes and stages of liver disease.

Data from this study demonstrate that JNJ-4178, the three-drug combination of simeprevir, odalasvir and AL-335, was highly effective in treatment naïve patients with HCV genotype 1 infection without cirrhosis, achieving 100% SVR24 for treatment durations of both 6 and 8 weeks. The two-drug regimen of odalasvir and AL-335, a combination regimen not anticipated to move forward, achieved 84% SVR24 for treatment duration of 8 weeks in patients with HCV genotype 1 without cirrhosis. The three-drug regimen of simeprevir, odalasvir and AL-335 in HCV genotype 3 patients without cirrhosis achieved an SVR12 of 77% following 12 weeks of therapy, and is also not anticipated to move forward. Genomic sequencing results indicate that despite the presence of multiple NS5A mutations observed at baseline there was no apparent impact on SVR rates.

The all-oral combination regimens containing odalasvir and AL-335, with or without simeprevir, were generally safe and well tolerated. Treatment results from the '604 Study' are summarized in the table below. Based on these data, JNJ-4178 is being further investigated for the treatment of HCV genotypes 1, 2, 4, 5, and 6.

Dose			HCV Genotype	Dosing Duration (weeks)	Number (%) with undetectable HCV RNA at SVR24*
AL-335 (mg QD)	ODV (mg)	SMV (mg QD)			
400	50 QD	100	1	8	20/20 (100%)
800	50 QOD	75	1	8	20/20 (100%)
800	50 QOD	75	1	6	20/20 (100%)
800	50 QOD	--	1	8	21/25 (84%)

800	50 QOD	--	1	12	7/8 (88%)
800	50 QOD	75	3	8	0/5 (0%)
800	50 QOD	75	3	12	10/13 (77%)**

QD: every day; QOD: every other day; RNA: ribonucleic acid; SVR: sustained virologic response. *All results SVR24, with the exception of genotype 3 which is SVR12 **One patient did not attend SVR12 follow-up.

Ongoing Phase 2b Triple Combination Development Program

Janssen has initiated a multi-center, randomized, open-label Phase 2b study of JNJ-4178, the triple combination of once-daily odalasvir 25mg, AL-335 800mg, and simeprevir 75mg for treatment durations of six and eight weeks. Designated OMEGA-1, this trial has now completed enrollment of more than 365 treatment-naïve and treatment-experienced, non-cirrhotic patients chronically infected with HCV genotype 1,2,4,5 and 6. Results from this trial are anticipated during the second half of 2017. In addition, the '604 Study' is ongoing and will assess the triple combination JNJ-4178 in patients with compensated cirrhosis.

Additional Studies Supporting Global Development Program

In addition to the OMEGA-1 and '604 Study,' a number of supplemental clinical trials are being conducted by Janssen including those assessing special populations, certain drug-drug interactions, the bioavailability of a fixed dose combination, and providing for long-term follow-up of patients, all supporting the global development of JNJ-4178.

Further information on clinical studies being conducted with JNJ-4178 can be found at http://www.clinicaltrials.gov.

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 JNJ-4178; 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, including the expected timing of results from the OMEGA-1 trial and the planned continuation of the 604 Study; 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 2b combination trials that include Achillion's licensed drug candidates. Moreover, Janssen may not demonstrate in any current and future clinical trials the requisite safety, efficacy and combinability of drug candidates that incorporate Achillion's HCV assets, or obtain and maintain necessary regulatory approvals for such programs. 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, 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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