Achillion Announces Clinical Milestone for the Advancement of JNJ-4178 in Phase 2B Development for Chronic HCV

NEW HAVEN, Conn., Dec. 28, 2016 (GLOBE NEWSWIRE) -- Achillion Pharmaceuticals, Inc. (Nasdaq:ACHN) today announced that it has received a $15 million milestone payment from Janssen Research & Development, LLC., part of the Janssen Pharmaceutical Companies of Johnson & Johnson (Janssen), related to enrollment in the OMEGA-1 Phase 2b global, clinical trial of JNJ-4178, a 3DAA combination of odalasvir, simeprevir, and AL-335 in patients with treatment-naive chronic hepatitis C virus infection (HCV) without cirrhosis.

"We are delighted to have reached this milestone following Janssen's recent initiation of the OMEGA-1 global clinical trial evaluating JNJ-4178, a once-daily combination of AL-335, simeprevir, and the Achillion-discovered NS5A inhibitor, odalasvir, and we look forward to JNJ-4178's continued clinical advancement," commented Milind Deshpande, Ph.D., President and Chief Executive Officer of Achillion.

Initiated in November 2016, the objectives of OMEGA-1 are to investigate the efficacy, safety and pharmacokinetics of JNJ-4178 (AL-335 (800mg QD), odalasvir (25mg QD), and simeprevir (75mg QD)) in treatment-naive and treatment-experienced non-cirrhotic subjects with HCV genotype 1, 2, 4, 5, and 6 infection. A total of 300 patients are expected to be enrolled.

Patients in the study will receive the triple combination for either six or eight weeks, and the primary efficacy endpoint will be the percentage of patients with a sustained virological response 12 weeks after the end of treatment (SVR12).

Further information on the trial planning and conduct can be found on www.clinicaltrials.gov with identifier NCT02765490.

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 expected clinical advancement of JNJ-4178, a triple combination drug candidate being advanced by Janssen under the Company's collaboration with Janssen; and statements concerning the Company's strategic goals, 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: advance the preclinical and clinical development of its complement factor D inhibitors under the timelines it projects in current and future preclinical studies and clinical trials; 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; establish commercial manufacturing arrangements; 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 OMEGA-1 trial and any other current and planned 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 September 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.

Investors:
Glenn Schulman, PharmD, MPH
Executive Director, Investor Relations
Achillion Pharmaceuticals, Inc.
Tel. (203) 752-5510
gschulman@achillion.com

Media:
Liz Power
Senior Director, Public Relations
Achillion Pharmaceuticals, Inc.
Tel: (203) 752-5509
lpower@achillion.com