# Atea Pharmaceuticals reports positive proof of concept clinical data with AT-527 for the treatment of chronic Hepatitis C

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- AT-527 is a novel pan-genotypic purine nucleotide prodrug NS5B polymerase inhibitor which has been safe and well tolerated in this ongoing multiple part trial
- AT-527 exhibits potent antiviral activity in genotype (GT)-1b and GT-3 hepatitis C virus (HCV) infected patients with once-daily (QD) dosing of 550 mg for 7-days
- Preliminary data suggest that AT-527 has potent and equivalent antiviral activity in both cirrhotic and non-cirrhotic (NC) HCV-infected patients

**BOSTON, Mass., April 12, 2018** – Atea Pharmaceuticals, Inc., a biopharmaceutical company engaged in the development of next-generation therapeutics for the treatment of hepatitis C and other single stranded RNA viral infections, today reported positive data from its ongoing clinical trial of AT-527 in patients with GT-1b and GT-3 HCV infection. The company will present the data today at The International Liver Congress™ 2018 sponsored by the European Association for the Study of the Liver taking place in Paris, France.

"Although the introduction of new therapies has improved cure rates in recent years, hepatitis C continues to represent a serious global health burden, particularly within more difficult-to-treat patient populations. Given the limitations of currently available agents, we are very excited about the emerging clinical profile of AT-527, a novel, highly differentiated purine nucleotide prodrug, which has an attractive safety profile and very significant antiviral potency. Most notably, preliminary data indicate that AT-527 exhibits potent antiviral activity, regardless of genotype or cirrhosis status in HCV-infected subjects," stated Jean-Pierre Sommadossi, PhD, Atea's Founder, Chairman and Chief Executive Officer.

**Poster No. THU-341**

**Title:** AT-527, a pan-genotypic purine nucleotide prodrug, exhibits potent antiviral activity in subjects with chronic hepatitis C

**Date/Time:** Thursday, April 12, 2018; 9:00 am – 5:00 pm CET

A summary of the data to be presented shows a mean maximum HCV RNA reduction of 2.3 log10 IU/mL after a single dose, and 4.4 log10 IU/mL after 7 days of dosing, of AT-527 in NC GT-1b HCV-infected subjects. A mean reduction of 2.4 log10 IU/mL after first dose and 4.6 log10 IU/mL after 7 days of dosing was achieved in NC GT-3 HCV-infected subjects, respectively. In ongoing cohorts, antiviral activity in Child Pugh A cirrhotic GT-1b/3 HCV infected subjects was similar to NC GT-1b and NC GT-3 cohorts. Emax modeling confirms the clinical observation that 550 mg AT-527 QD will produce maximum efficacy. No serious adverse events, dose-limiting toxicities or premature discontinuations were observed.

**About the Trial**

The five part study commenced patient enrollment in 2017, and was designed to assess the safety and efficacy of single and multiple doses of AT-527 in healthy and HCV-infected subjects. All HCV-infected subjects were treatment-naïve with HCV RNA ≥ 5 log10 IU/mL. The objectives of the study were to assess safety/tolerability, pharmacokinetics (PK) and antiviral activity.

The trial evaluated single oral doses up to 367 mg (400 mg salt form) in healthy subjects (Part A), single doses up to 550 mg (600 mg salt form) in NC GT-1b HCV-infected subjects (Part B) and multiple doses up to 550 mg once-daily (QD) for 7 days in NC GT-1b HCV-infected subjects (Part C). Ongoing cohorts are evaluating 550 mg QD for 7 days in NC GT-3 (Part D) and Child Pugh A cirrhotic GT-1b/3 (Part E) HCV-infected subjects. Plasma levels of AT-273, the nucleoside metabolite of the active triphosphate, were measured using LC-MS/MS; HCV RNA was quantified using COBAS® AmpliPrep/TaqMan® HCV Test v2.0 with a limit of quantitation (LOQ) of 15 IU/mL.

**About AT-527**

AT-527, a proprietary investigational agent discovered at Atea, is the salt form of a purine nucleotide prodrug NS5B polymerase inhibitor. Unique structural modifications of AT-527 result in differentiated pharmacologic and antiviral properties as compared to other anti-HCV nucleotides. AT-511, the free base of AT-527, showed potent antiviral activity *in vitro* against wild-type clinical isolates with EC95 values less than 80 nM in all HCV genotypes, and demonstrated about 10- to 14-fold more potency than sofosbuvir (SOF) in GT-1 and GT-3 replicons. AT-511 maintained activity against SOF-resistant S282T single and S282T/L159F double variants, with about 50-fold greater potency than SOF.

**About Hepatitis C**

Hepatitis C is a blood-borne infectious disease of the liver and is a leading cause of chronic liver disease and transplants. According to the World Health Organization, over 70 million people suffer from chronic hepatitis C. Direct-acting antiviral agents (DAAs) have markedly improved the prognosis of many patients infected with the hepatitis C virus and allow the achievement of a cure in 8 – 12 weeks in select patient populations. Further shortening of the treatment duration in those patients and extending it to more difficult-to-treat HCV patient populations continues to be a sought-after goal of the biotech and pharma industry. Global sales of DAAs for the treatment of HCV infection were $12.5 billion in 2017.

**About Atea**

Atea Pharmaceuticals is a clinical stage biopharmaceutical company engaged in the discovery and development of proprietary and novel therapeutics for the treatment of hepatitis C and other single stranded RNA viral infections. Atea was founded in 2013 by its Chairman and Chief Executive Officer Jean-Pierre Sommadossi, PhD, and is headquartered in Boston, MA.

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