Atea Pharmaceuticals to present positive clinical data with AT-527 for the treatment of chronic Hepatitis C in patients with cirrhosis at The Liver Meeting® 2018

November 9, 2018

- AT-527 is a novel pan-genotypic purine nucleotide prodrug NS5B polymerase inhibitor
- AT-527 shows profound and equivalent pan-genotypic antiviral activity in cirrhotic and non-cirrhotic (NC) hepatitis C virus (HCV) infected patients
- AT-527 was safe and well tolerated with once-daily (QD) dosing of 550 mg for 7 days
- Data support Phase 2 clinical development of AT-527

BOSTON, Mass., November 9, 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 announced it will present positive data from its recently completed Phase IB/IIA trial of AT-527 in treatment-naïve HCV-infected patients, including HCV-infected patients with Child-Pugh A (CPA) cirrhosis. The data will be presented on November 10, 2018 at The Liver Meeting® 2018 sponsored by the American Association for the Study of Liver Diseases taking place in San Francisco, California.

“Despite the introduction of direct acting antiviral therapies in recent years, hepatitis C continues to represent a serious global health burden, particularly among GT-3 infected, cirrhotic and other difficult-to-treat patient populations,” stated Jean-Pierre Sommadossi, PhD, Atea’s Founder, Chairman and Chief Executive Officer. “We are very excited about the clinical profile of AT-527, which has demonstrated significant antiviral potency in HCV-infected subjects, regardless of genotype or cirrhotic status. Based upon the results from our proof of concept clinical trial, we believe AT-527 may be the backbone of the first drug regimen that allows for 8-week treatment in both cirrhotic and non-cirrhotic patients. We look forward to advancing AT-527 into Phase II development in 2019.”

Poster No. 1002

Title: AT-527, a purine nucleotide prodrug, exhibits potent pan-genotypic antiviral activity in HCV-infected subjects with cirrhosis

Date/Time: Saturday, November 10, 2018; 2:00 pm – 7:30 pm PST

Location: Moscone Center North/South Building, Hall C

A summary of the data to be presented shows rapid and potent pan-genotypic antiviral activity in HCV-infected subjects with cirrhosis, as in non-cirrhotic subjects, with a mean HCV reduction of 2.4 log 10 IU/mL after a single dose and a mean maximum HCV RNA reduction of 4.6 log10 IU/mL after 7 days of dosing with AT-527 550 mg. Previously reported data also show a mean maximum HCV RNA reduction of 4.4 log10 IU/mL after 7 days of dosing of AT-527 550 mg in NC GT-1b HCV-infected subjects, and a mean reduction of 4.5 log10 IU/mL after 7 days of dosing was achieved in NC GT-3 HCV-infected subjects. No serious adverse events, dose-limiting toxicities or premature discontinuations were observed, and pharmacokinetic data (PK) in cirrhotic subjects was similar to non-cirrhotic subjects. Emax modeling demonstrated that a dose of 550 mg QD will result in maximum viral load reduction.

About the Trial

The five-part, Phase IB/IIA trial studied 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). Additional cohorts evaluated 550 mg QD for 7 days in NC GT-3 (Part D) and CPA 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 are expected to exceed $8 billion in 2018.

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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