



Presidio Pharmaceuticals Announces Collaboration with Boehringer Ingelheim

The Parties to Initiate a Phase IIa Trial of an All-Oral Combination of Presidio's HCV NS5A inhibitor (PPI-668) with Faldaprevir (BI201335) and BI207127 for the Treatment of Patients with Hepatitis C

San Francisco, CA – March 12, 2013 – Presidio Pharmaceuticals, Inc. announced today a non-exclusive collaboration with Boehringer Ingelheim for a Phase IIa clinical trial of an interferon-free, all-oral, direct-acting antiviral (DAA) combination treatment for patients with chronic hepatitis C virus (HCV) infection. The collaborative trial will evaluate Presidio's pan-genotypic HCV NS5A inhibitor (PPI-668) in combination with Boehringer Ingelheim's HCV protease inhibitor faldaprevir (BI201335) and its non-nucleoside HCV polymerase inhibitor (BI207127), with or without ribavirin.

Both companies have agreed to initiate the Phase II, 12-week treatment study in the second quarter of 2013. The trial will measure on-treatment antiviral responses and sustained virologic response rates (SVR) to the triple DAA combination regimen, with or without ribavirin. Presidio Pharmaceuticals will have primary operational responsibility for the trial, in close collaboration with Boehringer Ingelheim.

"With the potent, complementary antiviral activities of PPI-668, faldaprevir, and BI207127, the present study focuses on patients with HCV genotype-1a infection, which has been harder to treat than HCV genotype-1b in many studies. The study will assess the potential of this three-drug oral regimen to achieve high rates of sustained viral clearance in hepatitis C patients, with good tolerance," said Dr. Nathaniel Brown, Presidio's Chief Medical Officer.

Sustained virologic response results at 4- and 12-weeks post-treatment are expected to be available in the fourth quarter of 2013. Both companies continue to retain all rights to their respective compounds during this collaboration.

About Hepatitis C

Chronic hepatitis C is a progressive inflammatory liver disease caused by chronic infection with the hepatitis C virus (HCV). Approximately 170 to 200 million persons have chronic HCV infection worldwide, resulting in more than 350,000 deaths annually.

The current standard treatment for patients with hepatitis C genotype-1 infection in the United States and several other countries is combined administration of pegylated interferon-alfa, ribavirin, and an HCV protease inhibitor.

Due to the efficacy limitations and tolerance issues for interferon-based therapies and the continuing progression of underlying liver damage in the current large population of hepatitis C patients, there is a continuing need for more effective, better-tolerated, interferon-free combination therapies for HCV infection that can be orally administered with convenient, relatively short dosing schedules.

About PPI-668

PPI-668 is a potent, pan-genotypic, once daily, NS5A inhibitor. In earlier clinical studies in healthy volunteers and HCV-infected patients, PPI-668 has been well-tolerated to date with no serious or severe adverse events and no apparent pattern of treatment-related clinical side effects or laboratory abnormalities. In a clinical study of PPI-668 monotherapy in GT1 HCV-infected patients, viral load reductions of 3.5 to 3.7 log₁₀ HCV were achieved in 1-2 days.

About faldaprevir (BI201335)

Faldaprevir is an oral once-daily protease inhibitor, specifically designed to target and inhibit viral replication in the liver. Interferon-based therapy with faldaprevir is studied in a broad spectrum of genotype-1 patients. The STARTVerso™ trial program, which includes treatment-naïve, treatment-experienced and HIV co-infected patients, is nearly complete.

About BI207127

BI207127 is an investigational, potent twice-daily non-nucleoside inhibitor of the HCV polymerase (NS5B) that inhibits HCV genotype-1 replication. BI207127 in combination with faldaprevir and ribavirin is currently in Phase III clinical trials (HCVerso 1 and 2).

About Presidio

Presidio Pharmaceuticals, Inc. is a San Francisco-based clinical stage specialty pharmaceutical company focused on the discovery and development of novel oral antiviral therapeutics. For more information, please visit our website at:

www.presidiopharma.com

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