Presidio
PHARMACEUTICALS, INC.

Presidio Pharmaceuticals Reports Progress with Hepatitis C Antiviral Programs

San Francisco, CA – January 09, 2012 – Presidio Pharmaceuticals, Inc. announced today the successful completion of a Phase 1a dose-ranging assessment of PPI-668, a potent, pan-genotypic second-generation hepatitis C virus (HCV) NS5A inhibitor, in healthy volunteers and subsequent advancement to a Phase 1b assessment of the dose-related efficacy in hepatitis C patients.

The Phase 1a dose-ranging assessment of PPI-668 was conducted with 32 healthy volunteers in New Zealand. The trial was a randomized, double-blind, placebo-controlled assessment of the safety and pharmacokinetics of three oral doses of PPI-668, initially assessed as single doses and subsequently as a multi-day regimen, in which the highest PPI-668 dose was given once daily for five successive days. The trial results indicated that all dose regimens of PPI-668 were well-tolerated. There were no serious or severe clinical adverse events, no patterns of treatment-related adverse events or laboratory abnormalities, and all subjects completed the trial successfully.

Pharmacokinetic (PK) analyses of subjects' plasma samples in the Phase 1a trial indicated that substantial blood levels of PPI-668 were rapidly and consistently achieved and dose proportional. PPI-668 plasma concentrations were orders of magnitude above those shown to inhibit HCV replication *in vitro* and were maintained at predicted effective concentrations for more than 24 hours. These PK results support once-daily dosing for PPI-668 in future studies. Also important was the observation that in the 5-day multi-dose regimen, steady-state PK was achieved rapidly (by Day 2), with no evidence of subsequent accumulation or changes in the clearance profile of PPI-668.

"These first clinical data for PPI-668 indicate excellent tolerance in healthy subjects for up to five days," said Nathaniel A. Brown, M.D., Presidio's Chief Medical Officer. "Equally important, the pharmacokinetic profile of PPI-668 is very encouraging, suggesting that effective plasma concentrations can be obtained with relatively low, once-daily doses of PPI-668 - which will facilitate co-formulation of PPI-668 with other HCV antivirals in future combination therapies for hepatitis C."

Patient screening for the Phase 1b evaluation of PPI-668 in hepatitis C patients has begun in New Zealand and the United States and will soon include Australia. Dosing of the first cohort of hepatitis C patients will begin this week. Presidio

expects to have results regarding the antiviral efficacy of PPI-668 in HCV patients in the second quarter of 2012.

In a second HCV research program focused on inhibitors of the HCV NS5B polymerase, Presidio has discovered a lead chemical series of non-nucleosidic NS5B inhibitors with potent activity against all major HCV genotypes. Preclinical profiling is ongoing with a goal of nominating a candidate for clinical development in the coming months.

With its novel NS5A and NS5B inhibitors, Presidio's objective is to provide two complementary HCV antivirals that will be appropriate for broad use in optimized future combination therapies for patients with HCV infection. Presidio anticipates that such therapies will have a convenient oral dosing regimen (once or twice daily), will exhibit rapid pan-genotypic efficacy and will be well-tolerated.

ABOUT HEPATITIS C AND NS5A INHIBITORS

Chronic hepatitis C is a persistent, potentially progressive inflammatory liver disease caused by chronic infection with the hepatitis C virus (HCV). Worldwide there are an estimated 130 to 170 million persons with chronic HCV infection. There are 7 major genotypes (strains) of HCV, which have differing geographic distributions. Globally, about 40-60% of patients are infected with HCV genotype-1, with the remaining patients infected with HCV genotypes 2 through 7.

Patients with advanced hepatitis C can develop potentially fatal liver failure or liver cancer, and hepatitis C is estimated to account for over 350,000 deaths per year worldwide (WHO estimate). The current standard-of-care treatment for hepatitis C in the United States, for patients with HCV genotype-1 infection, is combined administration of pegylated-interferon, ribavirin, and first-generation HCV protease inhibitors. This multi-drug treatment is characterized by incomplete efficacy for HCV genotype-1 patients, variations in efficacy according to patients' underlying human genetic factors, no established efficacy for patients infected with other HCV genotypes, substantial tolerance issues, and dosing inconveniences. Thus, there is a continuing need for more consistently effective and better tolerated HCV inhibitors that can be orally administered in future combination therapies for hepatitis C patients worldwide, regardless of HCV genotype, patient genetic factors, or disease stage.

Inhibitors of the HCV NS5A protein represent an exciting, relatively new class of HCV inhibitors that, when optimized, exhibit potent activity across all HCV genotypes, with a mechanism that is distinct from other classes of HCV antivirals, which commonly target the HCV protease or polymerase. PPI-668 is a novel, optimized, second-generation HCV NS5A inhibitor, which exhibits highly potent and selective activity against all HCV genotypes in replicon assays, with favorable toxicology and pharmacology profiles in preclinical assessments.

ABOUT PRESIDIO

Presidio Pharmaceuticals, Inc. is a San Francisco-based clinical stage specialty pharmaceutical company dedicated to the discovery and development of small-molecule antiviral therapeutics for hepatitis C virus (HCV). For more information, please visit our website at: www.presidiopharma.com.

Contact: H. Daniel Perez, M.D.
President & Chief Executive Officer
415-655-7560
dperez@presidiopharma.com