



Presidio Pharmaceuticals, Inc. Successfully Completes Phase 1a Clinical Trial of PPI-461, a Potent, New Hepatitis C Virus (HCV) Inhibitor

San Francisco, CA – July 14, 2010 – Presidio Pharmaceuticals, Inc. announced today the successful completion of a Phase 1a clinical trial of PPI-461, its lead HCV NS5A inhibitor, in healthy subjects. This first-in-human trial evaluated four single doses of PPI-461, followed by a five-day, once-a-day treatment regimen with PPI-461 at the highest tested dose.

The randomized, double-blind, placebo-controlled trial was completed with 40 healthy subjects in the United Kingdom. The trial results indicated that PPI-461 was well-tolerated in all dose regimens. There were no serious adverse events, and all subjects completed the trial successfully. Among PPI-461 recipients there were only transient adverse events, none of which were attributed to study drug by the investigator, and there were no significant changes in safety-related clinical laboratory assessments.

Pharmacokinetic (PK) analyses showed substantial blood levels of PPI-461 were rapidly and consistently achieved and were dose proportional. PPI-461 plasma concentrations were orders of magnitude above those shown to suppress viral replication *in vitro* and were maintained at predicted effective concentrations for more than 24 hours. In the five-day, multi-dose regimen, steady-state PK was readily achieved, supportive of once-daily dosing.

“These first clinical data of PPI-461 indicate excellent tolerance in healthy subjects with all tested dosing regimens. The PK profile is very encouraging, suggesting that plasma concentrations of PPI-461 can be obtained with a relatively low dose, once-daily (QD) regimen that may provide a continuous antiviral effect,” said Nathaniel Brown, M.D., Chief Medical Officer.

Presidio Pharmaceuticals, Inc. plans to initiate a Phase 1b proof-of-concept trial in patients with HCV in Q4 2010 and expects to have early results regarding the clinical efficacy of PPI-461 near year-end.

ABOUT PPI-461

PPI-461 is a novel, proprietary NS5A inhibitor against hepatitis C virus (HCV), exhibiting highly potent and selective activity against all genotypes in HCV replicon assays.

Inhibitors of the HCV NS5A protein represent an exciting, highly potent class that is distinct from other classes of HCV antivirals that target the viral protease or replicase. With poor response and tolerance issues associated with the current standard of care treatment—pegylated-IFN and ribavirin—there is clear need for more potent and better tolerated inhibitors that can be orally administered in future combination therapies.

ABOUT PRESIDIO

Presidio Pharmaceuticals, Inc. is a San Francisco-based specialty pharmaceutical company dedicated to the discovery and development of small-molecule antiviral therapeutics for novel and validated targets. For more information, please visit our website at: www.presidiopharma.com.

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