



Presidio Pharmaceuticals, Inc. Initiates First-in-Human Clinical Trial of PPI-461, an Investigational NS5A Inhibitor for HCV

San Francisco, CA – April 27, 2010 – Presidio Pharmaceuticals, Inc. announced today that the UK Medicines and Healthcare products Regulatory Agency (MHRA) has authorized the initiation of a Phase 1 first-in-human clinical trial of PPI-461, an orally administered NS5A inhibitor for the treatment of hepatitis C virus (HCV). The Phase 1 clinical trial will be conducted in healthy volunteers.

“We are pleased to advance PPI-461 into clinical development to evaluate its safety, tolerability and pharmacokinetic profile in healthy volunteers,” stated Nathaniel Brown, M.D., Chief Medical Officer at Presidio.

At the recent European Association for the Study of the Liver (EASL) conference, Presidio’s Richard Colonno, Ph.D., Chief Scientific Officer, said, “PPI-461 exhibited potent and selective activity against all HCV genotypes in the *in vitro* replicon system, showed good oral bioavailability in multiple animal species and was well tolerated in a variety of animal studies. PPI-461 exhibited elevated liver concentrations relative to plasma levels that may be advantageous for lower dose regimens and a pharmacokinetic profile that indicated the potential for once daily dosing in humans.”

About HCV

Hepatitis C virus (HCV) infection is a major cause of chronic hepatitis, liver cirrhosis and hepatocellular carcinoma. Approximately 170 million people are infected with HCV worldwide (WHO, 2000), and an estimated 12,000 deaths from liver disease occur each year in the USA due to HCV infection (CDC, 2008).

Current therapy with pegylated IFN- α and ribavirin results in sustained virologic response (SVR) in 40-80% of patients, depending on the HCV genotype. However, such therapy is prolonged, associated with significant side effects and not suitable for many patients. Also, clinical studies have shown that infection with genotypes 1a and 1b, the major genotypes found throughout the developed world, is associated with a poor response to IFN- α therapy. Thus, there is an urgent need to develop more effective and well-tolerated therapeutics for HCV infection.

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.

Contact: Omar K. Haffar, PhD
415-655-7561
omar@presidiopharma.com