Pharmasset Completes Enrollment of Phase 1 Study of R7128 for HCV

- Anticipate Preliminary 14-day Multiple Ascending Dose Efficacy Data in September 2007 -

PRINCETON, N.J., Aug 02, 2007 /PRNewswire-FirstCall via COMTEX News Network/ --

Pharmasset, Inc. (Nasdaq: VRUS) has completed patient enrollment of the ongoing multiple ascending dose study of R7128 for the treatment of hepatitis C virus (HCV). R7128, a nucleoside polymerase inhibitor of HCV, is currently being evaluated in a Phase 1 clinical trial as part of Pharmasset's collaboration with Roche. The primary objective of the multiple ascending dose study is to assess the safety, tolerability and pharmacokinetics of R7128 after once-daily or twice- daily dosing for 14 days in up to 40 patients chronically infected with HCV genotype 1 who have previously failed interferon therapy. The secondary objective is to assess antiviral efficacy by measuring the change in HCV RNA in these patients.

Pharmasset expects to release preliminary 14-day safety and efficacy treatment data from the multiple ascending dose study in September 2007. Results for the entire Phase 1 single ascending and multiple ascending dose study are expected to be presented at various scientific conferences throughout the remainder of 2007. As recently announced, Roche has initiated long-term chronic toxicology studies in support of the potential advancement of R7128 into Phase 2 clinical trials.

About R7128

R7128 is a polymerase inhibitor being developed for the treatment of chronic hepatitis C. R7128 is a prodrug of PSI-6130, which demonstrated potency in preclinical studies. PSI-6130 is a pyrimidine nucleoside analog inhibitor of HCV RNA polymerase, an enzyme that is necessary for hepatitis C viral replication. Results from an oral single ascending dose study in 24 healthy male volunteers showed that PSI-6130 was generally well tolerated with no serious adverse events in doses up to 3000 mg.

R7128 Phase 1 Study Overview

The Phase 1 clinical trial is a multiple center, observer-blinded, randomized and placebo-controlled study to investigate the pharmacokinetics, pharmacodynamics, safety, tolerability and food effect of R7128 in healthy volunteers and in patients chronically infected with HCV genotype 1. This Phase 1 study is comprised of two parts:

* Part 1 is a single ascending dose study conducted in 38 healthy volunteers. The primary objective of Part 1 is to assess the safety, tolerability and pharmacokinetics of R7128 following single ascending doses under fasting conditions. The secondary objective of Part 1 is to explore the effect of food on the pharmacokinetics of R7128.

* Preliminary data from the single ascending dose portion of the study indicate:
  -- All doses of R7128 studied were generally well-tolerated.
  -- All patients completed the study with no gastrointestinal adverse events or serious adverse events reported during the study.
  -- No hematological or laboratory abnormalities of clinical significance were noted.

* Part 2 is a multiple ascending dose study being conducted in up to 40 patients chronically infected with HCV genotype 1 who have previously failed interferon therapy. The primary objective of Part 2 is to assess the safety, tolerability and pharmacokinetics of R7128 after once-daily or twice-daily dosing for 14 days. The secondary objective is to assess antiviral efficacy by measuring the change in HCV RNA.

About Pharmasset

Pharmasset is a clinical-stage pharmaceutical company committed to discovering, developing and commercializing novel drugs to treat viral infections. Pharmasset's primary focus is on the development of oral therapeutics for the treatment of hepatitis B virus (HBV), hepatitis C virus (HCV) and human immunodeficiency virus (HIV).

Pharmasset is currently developing three product candidates: Clevudine for the treatment of chronic HBV infection, which is expected to enter US, European and South American Phase 3 registration clinical trials and is already approved for HBV in South Korea and marketed by Bukwang Pharmaceuticals under the brand name Levovir; R7128, an oral treatment for HCV, in a Phase 1 clinical trial through a strategic collaboration with Roche; and Racivir for the treatment of HIV in combination with other approved HIV drugs, which has completed a Phase 2 clinical trial.

Contact
Alan Roemer, Vice President
Investor Relations & Corporate Communications

alan.roemer@pharmasset.com
Office: (609) 613-4125

Forward-Looking Statements

Pharmasset "Safe Harbor" Statement under the Private Securities Litigation Reform Act of 1995: Statements in this press release regarding our business that are not historical facts are "forward-looking statements" that involve risks and uncertainties, including without limitation the risk that there will be a delay in the release of the preliminary 14-day safety and efficacy treatment data from the multiple ascending dose study or in the results from the entire Phase 1 single ascending and multiple ascending dose study, the risk that our collaboration with Roche will not continue or will not be successful, the risk that the on-going clinical trial or the toxicology studies of R7128 will not be successful or that R7128 will not be successfully developed and commercialized. For a discussion of these risks and uncertainties, any of which could cause our actual results to differ from those contained in the forward-looking statements, see the section of our Quarterly Report on Form 10-Q for the quarter ended March 31, 2007 filed with the Securities and Exchange Commission entitled "Risk Factors" and discussions of potential risks and uncertainties in our subsequent filings with the Securities and Exchange Commission.

SOURCE Pharmasset, Inc.

Alan Roemer, Vice President, Investor Relations & Corporate Communications, of Pharmasset, Inc., +1-609-613-4125, alan.roemer@pharmasset.com

http://www.pharmasset.com/

Copyright (C) 2007 PR Newswire. All rights reserved

News Provided by COMTEX

Close window | Back to top