



Pharmasset Initiates Phase 1b Multiple Ascending Dose Clinical Trial of PSI-7851 in Chronic Hepatitis C Patients

-- PSI-7851 was generally safe and well tolerated in Phase 1a single ascending dose trial -- Further results from single ascending and multiple ascending dose trials are expected in second half 2009

PRINCETON, N.J., June 9, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- Pharmasset, Inc. (Nasdaq: VRUS) announced today that it had completed the single ascending dose study and begun dosing in a multiple ascending dose trial with PSI-7851, a nucleotide analog polymerase inhibitor for the treatment of chronic hepatitis C virus (HCV) infection. This study is designed to assess the safety, tolerability and antiviral activity of PSI-7851 over 3 days in HCV-infected individuals.

"We are encouraged by the safety and pharmacokinetics of PSI-7851 thus far," stated Michelle Berrey, MD, MPH, Pharmasset's Chief Medical Officer. "We believe PSI-7851, Pharmasset's lead second generation nucleotide, has the potential to be administered once a day at low milligram doses, while also continuing to demonstrate the many benefits nucleos(t)ides have over other classes of HCV direct acting antivirals, including a high barrier to resistance, pan-genotype potency, and ability to combine with other classes of compounds."

PSI-7851 Phase 1 Program Overview

The Phase 1 program is investigating the safety, tolerability and pharmacokinetics of PSI-7851 in healthy subjects following single doses (Phase 1a) and in patients chronically infected with HCV genotype 1 following repeat dosing for 3 days (Phase 1b). The Phase 1b study will additionally investigate hepatitis C viral dynamics and monitor for the development of drug resistance.

Subjects in the phase 1a single ascending dose study received single doses of PSI-7851 ranging from 25mg to 800mg or a matching placebo. Preliminary data from the phase 1a single ascending dose study demonstrated:

- No serious adverse events or discontinuations;
- No dose-related adverse events;
- No grade III / IV lab abnormalities;
- No clinically significant changes in vital signs or ECGs.

A Phase 1b multiple ascending dose trial has now been initiated in patients with chronic HCV genotype 1 infection. Subjects will be enrolled at multiple centers and randomized to PSI-7851 (8 per cohort) or placebo (2 per cohort). Based upon the results from the SAD study, the first dose of PSI-7851 to be tested will be 50mg once daily. The primary objective is to assess the safety, tolerability and pharmacokinetics of PSI-7851 after repeat dosing over 3 days. The secondary objective is to evaluate the decrease in HCV RNA.

Results from both studies are expected in the second half of 2009.

About PSI-7851

PSI-7851 is a uridine nucleotide analog currently in development for the treatment of chronic HCV infection. PSI-7851 has demonstrated potent in vitro anti-HCV activity with EC50 values of 90 +/- 60 nM, which is approximately 15- to 20-fold more potent than Pharmasset's first generation nucleoside polymerase inhibitor, R7128. In vitro studies of PSI-7851 have not shown evidence of any mitochondrial or other cellular toxicities that may be associated with some nucleoside analogs. The half-life of the triphosphate in primary human hepatocytes is approximately 38 hours, which suggests the possibility for once-daily dosing. Like R7128, PSI-7851 has demonstrated in vitro activity against all of the most common HCV genotypes.

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 C virus (HCV) and, secondarily, on the development of Racivir(R) for the treatment of human immunodeficiency virus (HIV). Our research and development efforts focus on nucleos(t)ide analogs, a class of compounds which act to inhibit the enzymes

required for viral replication. We currently have three clinical-stage product candidates: R7128, a nucleoside analog for chronic HCV infections, has initiated a Phase 2b clinical trial in combination with Pegasys plus Copegus through a strategic collaboration with Roche; PSI-7851, an unpartnered, next generation HCV nucleotide analog, which recently began Phase 1 clinical studies and Racivir, for the treatment of HIV that has completed a Phase 2 clinical trial.

Pegasys(R) and Copegus(R) are registered trademarks of Roche.

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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 adverse events could cause the cessation or delay of any of the ongoing or planned clinical trials and/or our development of our product candidates, the risk that the results of previously conducted studies involving our product candidates will not be repeated or observed in ongoing or future studies involving our product candidates, the risk that our collaboration with Roche will not continue or will not be successful and the risk that any one or more of our product candidates 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 Annual Report on Form 10-K for the fiscal year ended September 30, 2008 and our Quarterly Report on Form 10-Q for the period ended March 31, 2009 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.

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