



Pharmasset Announces Submission of Abstracts to AASLD Liver Meeting Including an Interim Analysis of Roche's Phase 2b PROPEL Trial of RG7128

-- Analysis of data by Roche from all 408 patients concluded safety and tolerability profile of RG7128 administered for 8 or 12 weeks with standard of care (SOC) continues to be similar to SOC alone -- RG7128 in combination with SOC demonstrated highly potent antiviral effects greater than SOC alone, patients with either HCV genotype 1 or 4 -- Roche has submitted two RG7128 abstracts to AASLD for the Annual Liver Meeting

PRINCETON, N.J., June 9, 2010 /PRNewswire via COMTEX News Network/ -- Pharmasset, Inc. (Nasdaq: VRUS) announced today that the interim results from the PROPEL study conducted by its partner Roche demonstrate that RG7128 triple combination therapy was safe and well tolerated. In that study, the safety profile of RG7128 (1000mg BID or 500mg BID), when administered for 8 or 12 weeks with Pegasys (peginterferon alfa-2a) and Copegus (ribavirin), the standard of care (SOC), was similar to the safety profile of SOC alone. An interim analysis of the study included all safety data from all 408 patients who had completed the first 12 weeks of the study. The most common adverse events were no different than those frequently noted with SOC alone. There were no findings related to rash, anemia, bone marrow suppression, or nephrotoxicity across any of the arms.

The PROPEL study is evaluating the dose and duration of treatment of RG7128 in combination with SOC in patients with chronic hepatitis C virus (HCV) genotype 1 or genotype 4 who have not been treated previously. The interim analysis also included on-treatment efficacy data demonstrating that >80% of patients had undetectable HCV RNA in all cohorts receiving the 12-week triple regimen compared to <50% for the placebo/SOC cohort. The safety and efficacy results from the interim analysis of the PROPEL Phase 2b study of RG7128 have been submitted by Roche as an abstract to AASLD for the Annual Liver Meeting (October 29 to November 2, 2010). The title of the abstract is:

"High rates of early viral response, promising safety profile and lack of resistance-related breakthrough in HCV GT 1/4 patients treated with RG7128 plus PegIFN alfa-2a (40KD)/RBV: Planned Week 12 interim analysis from the PROPEL study"

"We are encouraged by the reported efficacy, safety, and resistance data from this interim analysis of the PROPEL study," said M. Michelle Berrey, MD, MPH, Pharmasset's Chief Medical Officer. "We believe safety, absence of resistance, as well as antiviral potency will all be important considerations as HCV treatment incorporates direct acting antivirals in combination with interferon, and in potential interferon-free antiviral combination regimens."

No viral rebounds or resistance-related breakthroughs were noted during the first 8 or 12 weeks of triple combination therapy, consistent with the demonstrated high barrier to resistance in earlier RG7128 clinical studies. In clinical reports to date, the S282T mutation associated with RG7128 resistance *in vitro* has not been detected at baseline in HCV-infected patients enrolling in clinical trials. A separate abstract has been submitted by Roche including details of the resistance analyses that have been conducted during this study, including sequencing of the HCV RNA from all patients at baseline. The abstract is entitled:

"No evidence of drug resistance or baseline S282T resistance mutation among GT1 and GT4 HCV infected patients on nucleoside polymerase inhibitor RG7128 and Peg-IFN/RBV combination treatment for up to 12 weeks: interim analysis from the PROPEL study."

About the Phase 2b PROPEL Study

The Phase 2b study enrolled 408 patients with HCV genotypes 1 or 4, cirrhotic and non-cirrhotic, who have not been treated previously. The primary efficacy endpoint of the study is the proportion of patients who achieve an SVR, defined as HCV below the limit of detection (<15 IU/mL as measured by Roche TaqMan assay) 24 weeks after completion of all treatment. The study is being conducted in North America, Europe, and Australia. Patients were enrolled into one of 5 arms:

- 24 weeks of total treatment; RG7128 500mg BID in combination with SOC for 12 weeks, followed by 12 weeks of SOC ("12+12", RVR guided)
- 24 weeks of total treatment; RG7128 1000mg BID in combination with SOC for 12 weeks, followed by 12 weeks of SOC ("12+12", RVR guided)
- 24 weeks of total treatment; RG7128 1000mg BID in combination with SOC for 8 weeks, followed by a further 16 weeks of SOC ("8+16", RVR guided)

- 48 weeks of total treatment; RG7128 1000mg BID in combination with SOC for 12 weeks, followed by a further 36 weeks of SOC ("12+36", non-RVR guided)
- A control arm with SOC for 48 weeks.

Patients in the 24-week arms will discontinue all treatment at week 24 if they have achieved RVR, defined as HCV RNA below the limit of detection (<15 IU/mL) at week 4 and maintain these low levels of HCV RNA until week 22, a strategy known as "RVR-guided" treatment. Patients who do not meet these criteria will continue on the standard of care until week 48.

RG7128 is also currently being evaluated in a Phase 2b study in which RG7128 and SOC are given for a total of 24 weeks each ("24+0", RVR guided). The regimen will be assessed in treatment-naïve HCV-infected patients with genotypes 1 or 4. Enrollment in this study was completed in early May. In addition, Roche anticipates the initiation of another Phase 2 study in HCV-infected patients with genotypes 2 or 3 by the end of 2010.

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(TM) for the treatment of human immunodeficiency virus (HIV). Our research and development efforts focus on nucleoside/tide analogs, a class of compounds which act as alternative substrates for the viral polymerase, thus inhibiting viral replication. We currently have four clinical-stage product candidates. RG7128, a cytosine analog for chronic HCV infection, is in two Phase 2b clinical studies in combination with Pegasys(R) plus Copegus(R) and is also in the INFORM studies, the first series of studies designed to assess the potential of combinations of small molecules without Pegasys(R) and Copegus(R) to treat chronic HCV. These clinical studies are being conducted through a strategic collaboration with Roche. Our other clinical stage HCV candidates include PSI-7977, an unpartnered uracil nucleotide analog that has recently completed a Phase 2a study, and PSI-938 an unpartnered guanine nucleotide analog in Phase 1. We also have in our pipeline an additional purine nucleotide analog, PSI-661, an isomer of PSI-879, in advanced preclinical development. Racivir, for the treatment of HIV, has completed a Phase 2 clinical study.

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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 that are not historical facts are "forward-looking statements," including, without limitation, statements that involve risks, uncertainties, and other important factors, including, without limitation, the risk of 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 risks, uncertainties, and other important factors, any of which could cause our actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" in our Annual Report on Form 10-K for the fiscal year ended September 30, 2009 and our Quarterly Reports on Form 10-Q for the periods ended December 31, 2009 and March 31, 2010 filed with the Securities and Exchange Commission and discussions of potential risks, uncertainties, and other important factors in our subsequent filings with the Securities and Exchange Commission.

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