

## VERTEX VX07-950-108 (TELAPREVIR) STUDY SUMMARY

This is a phase 3 study using Telaprevir (oral protease inhibitor) in combination with peginterferon alfa-2a (Pegasys) and ribavirin (Copegus) in treatment-naïve subjects with genotype 1 hepatitis C.

Potential subjects will be  $\geq 18$  and  $\leq 70$  years of age, treatment naïve, HCV genotype 1, and have clinically compensated liver disease.

Subjects will be excluded if they have other forms of liver disease, anemia, hepatocellular carcinoma, hepatitis A or hepatitis B infection, human immunodeficiency virus (HIV), pre-existing severe depression or other psychiatric disease, significant cardiac disease, renal disease, seizure disorders, or retinopathy. Subjects that will not agree to abstain from alcohol throughout the entire course of treatment and follow-up will be excluded.

Additional eligibility criteria apply.

Subjects will be randomized to 1 of 3 treatment groups:

- **Group T8/PR** will receive PEG and RBV and 8 weeks of telaprevir (**T=telaprevir**) (**PR=Peg and RBV**)
- **Group T12/PR** will receive PEG and RBV and 12 weeks of telaprevir
- **Group Pbo/PR** will receive PEG and RBV and 12 weeks of placebo (**Pbo=placebo**)

The treatment period will be either 24 or 48 weeks depending on the treatment group assigned to.

If you would like to refer a patient, please contact the coordinators, Carol Jones RN or Susan Milstein, RN, BSN at 323-224-5555 at the USC Hepatitis Research and Treatment Center.

IRB Approved: 4/24/08