New Treatment For Hepatitis C Offers Individualized Dosing Regimen

(NAPSA)—The U.S. Food and Drug Administration (FDA) has approved combination therapy with Pegasys® (peginteferon alfa-2a), a pegylated interferon, and Copegus™ (ribavirin) for the treatment of adults with chronic hepatitis C who have compensated liver disease and have not previously been treated with interferon alpha. Patients in whom efficacy was demonstrated included patients with compensated liver disease and histological evidence of cirrhosis (Child-Pugh class A).

Pegasys and Copegus combination therapy was granted approval based on the results of two pivotal Phase III clinical trials that demonstrate it is an effective treatment for patients with chronic hepatitis C. In both studies, virus genotype was clearly the strongest predictor of whether or not a patient achieved a sustained virological response.

"Different genotypes of the hepatitis C virus need to be approached differently. Certain genotypes of the hepatitis C virus are easier to treat while others are stubborn and more difficult to treat," said Pegasys investigator David Bernstein, MD, director of hepatology at North Shore University Hospital, Manhasset, N.Y. "With Pegasys combination therapy, we can now tailor the dose and duration of a patient's therapy to the genotype of the virus."

The first study evaluated the effects of the duration (24 weeks compared to 48 weeks) of Pegasys (180mcg once weekly) and Copegus treatment (24 weeks compared to 48 weeks) and the daily dose of Copegus (800mg compared to 1,000 for patients weighing less than 75 kg and 1,200 for patients equal to or more than 75 kg) in patients with chronic hepatitis C. The study showed that patients with strains of the hepatitis C virus known as genotype non-1 (predominantly 2 and 3) achieved similar sustained virological response rates when treated with a 24-week regimen of Pegasys and 800mg Copegus compared to a 48-week regimen of Pegasys and 1,000-1,200 Copegus. Genotype non-1 patients who were treated with the 24-week lower Copegus dose regimen experienced fewer side effects. The sustained virological response rates for these groups treated with Pegasys and Copegus therapy were:

A new combination therapy may offer new hope for patients with chronic hepatitis C.

- Genotype 1: 48-week duration with 1,000-1,200mg Copegus: 51 percent
- Genotype non-1: 24-week duration with 800mg Copegus: 82 percent

"I was very enthusiastic about going into the Pegasys combination therapy trial," said David Freeman, a genotype non-1 Pegasys and Copegus patient. "Six months into the study, I was virus free. The key benchmark is six months after the study is over and I was still virus free."

The other pivotal study was published in the September 26, 2002 *New England Journal of Medicine* and showed that Pegasys and Copegus combination therapy is a more effective treatment for chronic hepatitis C than interferon alfa-2b and ribavirin. The sustained virological response rate in the Pegasys- and Copegus-treated patients was 53 percent compared to 44 percent in the interferon alfa-2b and ribavirin group.

Pegasys, a pre-mixed solution, was approved as monotherapy on October 16, 2002. Pegasys is administered at a fixed dose of 180mcg as a subcutaneous injection once a week. Copegus, available as a 200mg tablet, is administered at 800 to 1,200mg taken twice daily as a split dose. Pegasys is currently available at pharmacies. Copegus will be available in early 2003. The two products will be sold separately.