Hepatitis C study shows superior viral cure rate

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For patients with the most common form of hepatitis C being treated for the first time, the addition of an investigational hepatitis C–specific protease inhibitor called telaprevir to the current standard therapy markedly improved their sustained viral response (SVR or viral cure) rate.

The lead investigator reporting the results of the ADVANCE trial is Dr. Ira M. Jacobson, chief of the Division of Gastroenterology and Hepatology at NewYork-Presbyterian Hospital/Weill Cornell Medical Center, and the Vincent Astor Distinguished Professor of Medicine at Weill Cornell Medical College. Dr. Jacobson presented these pivotal Phase III results today at the 61st Annual Meeting of the American Association for the Study of Liver Diseases in Boston.

Dr. Jacobson noted that 75 percent of patients treated with a telaprevir-based combination regimen for 12 weeks, followed by 12 or 36 weeks of the standard therapy of pegylated-interferon alfa-2a and ribavirin alone, achieved a viral cure. This compared to 44 percent of people treated with 48 weeks of pegylated-interferon and ribavirin alone. In addition, new data from the study showed that 62 percent of African-Americans achieved a viral cure with the telaprevir-based regimen compared to 25 percent of African-Americans who were treated with pegylated-interferon and ribavirin alone. Additionally, 62 percent of patients with advanced liver fibrosis (cirrhosis or scarring of the liver) achieved a viral cure with the telaprevir regimen compared to 33 percent who were treated with pegylated-interferon and ribavirin alone.

"These groundbreaking data, showing sustained viral response in 75 percent of patients who received 12 weeks of telaprevir combination therapy, highlight telaprevir as a potential new therapy that, if approved by the FDA, could dramatically improve the future treatment of hepatitis C," says Dr. Jacobson, who is also a hepatologist and Medical Director the Center for the Study of Hepatitis C at NewYork-Presbyterian Hospital/Weill Cornell Medical Center. "In contrast to the standard treatment time of 48 weeks, the majority of patients who achieved sustained viral response in the ADVANCE study received only 24 weeks of total therapy."

The results confirm the findings of the U.S. phase 2 PROVE1 study, which was co-authored by Dr. Jacobson, and the European PROVE2 study; both studies were published in the April 30, 2009 *New England Journal of Medicine*. Overall rates of discontinuation for side effects were lower in ADVANCE than in the earlier studies.

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