Hep C Inhibitor PSI-7977 Goes Interferon-Free in Phase III Studies

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Princeton, New Jersey–based Pharmasset is putting its lead experimental hepatitis C nucleotide inhibitor to the test in three late-stage clinical trials exploring the drug's safety and efficacy as a component of a regimen that only needs to be taken for three months and that doesn't include pegylated interferon, according to a November 1 announcement by the company. If all goes well in the studies, the company will petition the U.S. Food and Drug Administration (FDA) to begin the process of reviewing PSI-7977 for approval sometime in the second half of 2013.

The development of hepatitis C virus (HCV) curative drug regimens that don't contain pegylated interferon is a major priority for researchers, hepatitis C-treating clinicians, people living with HCV and pharmaceutical companies. There are several reasons for this, including the fact that pegylated interferon requires weekly intramuscular injections, is associated with debilitating side effects and is only moderately effective against HCV, even when combined with ribavirin.

The first Phase III trial, FISSION, will enroll about 500 people living with genotype 2 or 3 HCV infection and starting therapy for the first time. The study will evaluate the safety and efficacy of a 12-week interferon-free regimen of PSI-7977 and ribavirin, compared with 24 weeks of pegylated interferon and ribavirin—the standard-of-care treatment for people living with genotype 2 or 3 HCV infection.

FISSION plans to begin enrolling volunteers by the end of this year.

Pharmasset plans to initiate a second 12-week interferon-free Phase III trial, dubbed POSITRON, in early 2012. This trial will enroll about 225 patients with HCV genotype 2 or 3 who cannot take interferon.

In mid-2012, Pharmasset intends to start a third 12-week interferon-free Phase III trial. The NEUTRINO study will enroll patients who cannot take interferon, and will include patients with HCV regardless of viral genotype, including those with HCV genotype 1. The final study design will be based on two Phase II studies being conducted by Pharmasset: the recently completed ELECTRON trial and the ongoing QUANTUM study.

"Based on encouraging results to date, we have selected an [interferon]-free regimen of PSI-7977 [plus ribavirin] for our registrational program," said Michelle Berrey, MD, MPH, Pharmasset's chief

medical officer. “We continue to believe that interferon remains the greatest impediment to care for a majority of the millions of individuals living with HCV. PSI-7977 has demonstrated high cure rates, without viral resistance, and across HCV genotypes; we hope to confirm these benefits in these registrational studies.”
