Hep C Therapeutic Vaccine Shows Early Promise

November 4, 2010

The Phase II clinical trial results were presented by Paul J. Pockros, MD, of Scripps Clinic in San Diego. The study is comparing pegylated interferon plus ribavirin—standard-of-care (SOC) treatment for HCV—with subcutaneous injections of multiple doses of GI-5005 in combination with SOC in patients with genotype 1 HCV who are either new to treatment or did not respond adequately to interferon-based therapy in the past. About 133 people living with HCV around the world have been enrolled in the trial; those starting HCV treatment for the first time received 48 weeks of therapy, and those who failed to respond to previous treatment received 72 weeks of therapy.

In a strict (intent-to-treat) analysis of the data conducted by Pockros's team, 58 percent of first-time treatment takers who received the vaccine had an SVR, compared with 48 percent of those receiving SOC alone. As for non-responders—defined as those who did not clear HCV after a minimum of 12 weeks of earlier interferon-based treatment—those receiving GI-5005 plus SOC as a triple therapy had an SVR rate of 17 percent, compared with an SVR rate of only 5 percent in patients receiving SOC alone.

Though the differences in the two study populations between those who received GI-5005 and those who received SOC alone were not statistically significant—they could have occurred by chance—Pockros's group considered the differences to be important enough to warrant further exploration of the therapeutic vaccine.

"Only 4 to 7 percent of patients with genotype 1 HCV who were null, poor or partial responders to their first course of pegylated interferon-based therapy would be expected to achieve a sustained virologic response with a second course of treatment," Pockros said. "In this study, GI-5005 conferred a threefold improvement in SVR, an important treatment effect in this challenging patient population."

The most common adverse events associated with GI-5005 were injection site reactions that were generally mild and transient in nature. Discontinuation rates due to adverse events in the GI-5005 triple therapy arm were comparable to the discontinuation rates in the SOC alone arm.