Clinical Trial for Hepatitis C shows High Cure Rate in 6 to 8 weeks

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At the 2017 Liver Meeting liver specialist's have reported findings from a current clinical trial for Hepatitis C with high cure rates of close to 100% were found in patients being treated in 6 to 8 weeks with a new triple therapy combination.

Dr. Stefan Zeuzem, M.D. of J.W. Goethe University, Franfurt am Main in Germany, and colleagues stated the findings from the new clinical trial for a triple therapy combination called JNJ-4178 that includes the NS5B inhibitor AL-335 (Achillion) at 800mg, and the NS5A inhibitor Odalasvir (Achillion) at 25 mg, and Olysio (simpeprevir from Janssen) at 75 mg in a once daily dose.

Standard Hepatitis C treatment therapy is 12 weeks currently for majority of genotypes (virus strains). This clinical trial was for treatment for 6 to 8 weeks.

"There is evidence that any shortening of treatment for hepatitis C may have potential to improve patient compliance, convenience, and tolerability," Stefan Zeuzem, MD, of J. W. Goethe University, Frankfurt am Main in Germany, said. "The doses were chosen from a prior phase 2a study."

The study included 183 patients treated for 6 weeks and 182 treated for 8 weeks. Patients with Hepatitis C genotypes 1a and 1b comprised approximately 70% of the cohort, with genotypes 2 and 4 comprising about one-quarter and a small proportion having genotype 5 HCV. "We extended the genotypes to the phase 2b study," Zeuzem said. "All genotypes but genotype 6 were enrolled. They were allowed to be enrolled."

For the 8-week arm, 178 of 182 patients reached the primary endpoint, according to Zeuzem. In the 6-week arm, 181 of 183 patients reached SVR12. Zeuzem noted that these findings translated to an overall 98.9% SVR12 rate. "This of course also meets the non-inferiority to historical controls," he said.

SVR12 rates were above 98% in every genotype except genotype 2, Zeuzem added. "Specifically, Hepatitis C patients with genotype 2c (virus strain) experienced relapses most frequently," he said.

There were no grade 4 adverse events reported, no premature discontinuations of the study drug, and no laboratory abnormalities observed, according to Zeuzem. "There were typical adverse

events, fatigue, headache, but nothing special in particular," he said. "Extensive and thorough cardiac evaluation did not reveal any evidence for cardiotoxicity."

There is some debate about the role of resistance variants in patients who failed to reach SVR12, particularly those with genotype 2 disease, according to Zeuzem. Most of the variants were found in patients with genotype 2c.

"Six and 8 weeks of treatment with [JNJ-4178] resulted in SVR rates of 99% and 98%, respectively," Zeuzem concluded.

Researchers followed patients for 24 weeks after the end of this triple therapy treatment for Hepatitis C where most patients received SVR (sustained virologic response-meaning patients show to be Non-detected for the HCV virus 12 and 24 weeks after treatment is completed). Once patients receive SVR12 they are considered cured.

Clinical trials continue for more improved treatment for all Hepatitis C genotypes.

Have you considered becoming part of a Clinical Trial for Hepatitis C or Cirrhosis?

For more information:
Zeuzem S, et al. Abstract 65. Presented at: The Liver Meeting; Oct. 20-24, 2017; Washington, D.C.
Disclosure: Zeuzem reports consulting for AbbVie, Bristol-Myers Squibb, Gilead, Janssen, and Merck/MSD.

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