Excellent Results for Gilead's Experimental Regimen for All Hep C Genotypes

Gilead has tested the addition of the investigational voxilaprevir to its already approved Epclusa (sofosbuvir/velpatasvir).

November 18, 2016

Gilead Sciences' experimental fixed-dose combination tablet sofosbuvir/velpatasvir/voxilaprevir performed very well among those with all six genotypes of hepatitis C virus (HCV) who had failed a previous regimen. The new regimen, given for 12 weeks, has the same components of the approved tablet Epclusa (sofosbuvir/velpatasvir) and adds the experimental voxilaprevir.

The double-blind, placebo-controlled Phase III POLARIS-1 study included 415 people with genotypes 1 through 6 of hep C at 109 sites in seven Western nations. They had all previously been treated with the class of hep C drugs known as NS5A inhibitors.

Results were presented at the Annual Meeting of the American Association for the Study of Liver Diseases (AASLD) in Boston.

The study included 300 people with genotype 1, who were randomized to receive 12 weeks of sofosbuvir/velpatasvir/voxilaprevir or a placebo. Out of the eight participants with genotype 6, six received the active treatment and two the placebo. The remaining participants received active treatment, including five people with genotype 2, 78 with genotype 3, 22 with genotype 4, one with genotype 5 and one with an unknown genotype.

A total of 253 out of the 263 people who received active treatment achieved a sustained virologic response 12 weeks after completing therapy (SVR12, considered a cure), for an overall cure rate of 96 percent. No one who received the placebo was cured.

A total of 113 out of the 121 people with cirrhosis, or 93 percent, were cured, compared with 140 of 142 (99 percent) of those without cirrhosis.

The cure rate was 100 percent for the 45 people with genotype 1b, the five people with genotype 2, the one person with genotype 5 and the six people with genotype 6. The cure rate was 97 percent (146 of 150) for those with genotype 1, 96 percent (97 of 101) for those with genotype 1a,

95 percent (74 of 78) for those with genotype 3 and 91 percent (20 of 22) for those with genotype 4.

The rates of adverse health events were similar between those who received the placebo and those who received active treatment.

To read the conference presentation slides, click here.

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