Sofosbuvir and Ribavirin Succeed in Hard-to-Treat Hep C Group

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Between half and two-thirds of a group of people with hepatitis C virus (HCV) who had various attributes weighing against their success with treatment, including liver damage, were cured of the virus with a regimen of Gilead's sofosbuvir and ribavirin, HIVandHepatitis.com reports. Publishing their findings in JAMA, The Journal of the American Medical Association, researchers studied 60 treatment-naive participants with hep C who all had the hard-to-treat genotype 1 of the virus.

In the spring, the U.S. Food and Drug Administration (FDA) granted priority review status to sofosbuvir, a nucleotide analog hep C polymerase inhibitor. The agency's decision on the drug's approval is expected in December.

The Phase II, open-label study had two parts. In the first, which was a proof-of-concept study, 10 people who had liver fibrosis that ranged from absent to moderate in severity received sofosbuvir plus weight-based ribavirin. In the second part, 50 participants who had all the various stages of liver disease were randomly and evenly divided into two groups. Both received sofosbuvir, while one received weight-based ribavirin and the other received a lower dose of 600 milligrams per day of ribavirin, irrespective of their weight.

Seventy percent had the hep C genotype subtype 1a, which is more difficult to treat. More than 80 percent were African American, a racial group that tends not to respond well to interferon-based therapy when compared with whites.

Following 24 weeks of treatment for all study participants, nine out of the 10 participants in the first group completed the trial and all of them (90 percent) achieved a sustained virologic response 24 weeks after completing therapy (SVR24, considered a cure). In the second group, 68 percent of those in the weight-based ribavirin subgroup achieved SVR24, while 48 percent were cured in the low-dose ribavirin arm, although this difference was not statistically significant, meaning it could have occurred by chance.

Sofosbuvir proved generally safe and well tolerated. The most common side effects included headache, anemia, fatigue and nausea, primarily mild to moderate in severity. There were seven incidents of severe side effects, including anemia, neutropenia (diminished levels of certain key white blood cells), nausea, elevated blood phosphate, gallstones and pancreatitis.

To read a National Institutes of Health release on the study, click here.

To read the study abstract, click here.

To read the HIVandHepatitis.com story, click here.

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