AbbVie Hep C Combo Boasts 96% Cure Rate

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AbbVie's interferon-free regimen of three direct-acting antivirals, plus ribavirin, cured 96 percent of people with hepatitis C virus (HCV) in a large Phase III trial, MedPage Today reports. The pharmaceutical company's double-blind, placebo-controlled SAPPHIRE-1 study includes 631 people with genotype 1 of the virus, the most common in the United States and the most difficult to treat. The participants did not have cirrhosis.

The trial is among six Phase III studies evaluating AbbVie's combination therapy, which is one of the most promising in the highly competitive race to create interferon-free treatments for hep C. Included in the regimen are the NS3/4A protease inhibitor ABT-450/r (which is co-dosed with ritonavir); the NS5A inhibitor ABT-267; the non-nucleoside polymerase inhibitor ABT-333; and ribavirin. ABT-450 and ABT-267 were administered as a coformulated pill.

The study randomly assigned 473 participants to receive 12 weeks of treatment while 158 people received placebo pills. At the end of the first 12 weeks, those in the placebo arm began receiving open-label treatment for a subsequent 12-week period. The results of that group have not been reported.

A total of 455 of those in the treatment group, or 96 percent, achieved a sustained virologic response 12 weeks after completing therapy (SVR12, considered a cure). Genotype 1a subtypes had a slightly diminished response rate: Of the 151 participants with genotype 1b, 148 (98 percent) achieved SVR12, compared with 307 out of 322 with genotype 1a (95 percent).

The most common side effects were fatigue, headache and nausea. Just 0.6 percent of the participants dropped out of the trial because of adverse side effects. A combined total of 1.7 percent of those in the treatment arm experienced virologic relapse or breakthrough.

To read the MedPage Today story, click here.

To read the AbbVie press release, click here.

Editor's Note: A previous version of this article incorrectly stated the coformulated pill in the

regimen includes ABT-267 and ABT-333; it contains ABT-450 and ABT-267

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