AbbVie Cocktail Cures 96% of Those With Hep C Genotype 1

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The AbbVie “3-D” regimen cured 96 percent of both treatment-naive and treatment-experienced people who had genotype 1 of hepatitis C virus (HCV) and did not have cirrhosis. Results from the randomized, double-blind, placebo-controlled Phase III SAPPHIRE-I and SAPPHIRE-II studies were presented at the 49th annual meeting of the European Association for the Study of the Liver (EASL) in London and published in The New England Journal of Medicine.

The 3-D regimen consists of 12 weeks of a daily dose of the fixed-dose combination of the protease inhibitor ABT-450 and ritonavir co-formulated with the NS5A inhibitor ombitasvir (ABT-267), as well as a twice-daily dose of non-nucleoside polymerase inhibitor dasabuvir (ABT-333). In these studies, the regimen was given with a twice-daily dose of ribavirin.

Out of a total of 631 treatment-naive participants in the SAPPHIRE-I study, 473 were randomized to receive the 3-D regimen with ribavirin for 12 weeks, while 158 were randomized to receive a placebo for 12 weeks and then went on to receive open-label treatment with the 3-D regimen with ribavirin.

The SAPPHIRE-II study included 394 participants who had previously failed treatment with pegylated interferon and ribavirin. Out of that total, 297 were randomized to receive the 3-D regimen with ribavirin for 12 weeks, while 97 were randomized to receive a placebo for 12 weeks and then went on to receive open-label treatment with the 3-D regimen with ribavirin.

In the SAPPHIRE-I study, 96.2 percent (455/473) of those in the group randomized to receive the 3-D regimen up front achieved a sustained virologic response 12 weeks after completing therapy (SVR12, considered a cure). A total of 95.3 percent (307/322) of those with genotype 1a were cured, compared with 98 percent (148/151) of those with genotype 1b.

In the SAPPHIRE-II study, 96.3 percent (286/297) of those in the group randomized to receive the 3-D regimen up front achieved an SVR12. A total of 96 percent (116/173) of those with genotype 1a were cured, compared with 96.7 percent (119/123) of those with genotype 1b. A total of 96.2 percent (139/146) of prior null responders were cured, compared with 95.3 percent (82/86) of prior relapsers and 100 percent of prior partial relapsers (65/65).

In SAPHHIRE-1, 1 percent of the participants stopped therapy because of adverse side effects,

while 0.6 percent of those in SAPPHIRE-II did so, compared with none in the placebo groups. The most common side effects in both studies, occurring in more than 10 percent of participants, were fatigue, headache, nausea, weakness, insomnia, itching, diarrhea and body pain. The symptoms that occurred more frequently in the treatment arm than in the placebo arm in SAPPHIRE-I were itching, insomnia, diarrhea and weakness, while just itching was more common in the treatment group in SAPPHIRE-II.

“These data provide further evidence that AbbVie’s regimen can achieve high SVR12 rates across a range of genotype 1 patients with varying prior treatment experience and response,” said Scott Brun, MD, vice president of pharmaceutical development at AbbVie, said in a release.

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