AbbVie’s ‘3D’ Cures 100% of Genotype 1b With No Ribavirin

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AbbVie’s so-called “3D” combination regimen cured all study participants in a recent trial who had genotype 1b of hepatitis C virus (HCV), did not have cirrhosis and had previously failed interferon-based treatment, Internal Medicine News reports. Publishing their findings of the open-label Phase III PEARL-II trial in The New England Journal of Medicine, investigators randomized 186 participants to receive the 3D regimen either with or without ribavirin for 12 weeks.

The 3D regimen includes a fixed-dose combination of the protease inhibitor ABT-450 and ritonavir co-formulated with the NS5A inhibitor ombitasvir (ABT-267), as well as the non-nucleoside polymerase inhibitor dasabuvir (ABT-333). AbbVie filed for approval of the regimen, with or without ribavirin, with the U.S. Food and Drug Administration in April. A decision from the FDA is expected at the end of the year.

All of those who did not take ribavirin achieved a sustained virologic response 12 weeks after completing therapy (SVR12, considered a cure), compared with 96.6 percent of those who did take ribavirin. The researchers concluded that ribavirin made no difference in treatment outcomes, implying that for those with genotype 1b, next year may bring a new, highly effective treatment option that can compete with Gilead Sciences’ fixed-dose combination therapy of Sovaldi (sofosbuvir) and ledipasvir. That combination pill is also pending approval, with an expected October 10 decision date from the FDA.

Genotype 1b is the most common in the world. One third of all hep C cases in the United States are 1b, although genotype 1a is still more common here.

Side effects were significantly diminished among those who did not take ribavirin. The most common side effects in both arms of the study were fatigue, nausea and insomnia, followed by anemia and bilirubin more than three times the upper limit of normal in only the anemia group.

To read the study abstract, click here.