Adding Sovaldi and Ribavirin to Retreatment With Mavyret Beats Hep C

Those for whom Mavyret did not work the first time had a high cure rate with this intensified retreatment regimen.

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Among those for whom treatment with AbbVie's Mavyret (glecaprevir/pibrentasvir) did not cure their hepatitis C virus (HCV) after the first go-round, intensifying the regimen by retreating with Mavyret plus Sovaldi and ribavirin yields a high cure rate.

Preliminary findings from an ongoing study of individuals who experienced virologic failure after Mavyret treatment were presented at the 2018 Conference on Retroviruses and Opportunistic Infections (CROI) in Boston.

The study includes individuals who participated in AbbVie's Phase IIIb clinical trials of Mavyret experienced virologic failure, including eight people from SURVEYOR-2, eight from ENDURANCE-3, six from MAGELLAN-1 and one from EXPEDITION-1.

Individuals who had genotypes 1, 2, 4, 5 or 6 of hep C, did not have cirrhosis and were not treated with a NS5A inhibitor or protease inhibitor before taking Mavyret the first time were assigned to receive 12 weeks of Mavyret plus Sovaldi and ribavirin. The two people who fell into this category had genotype 2 and had a mutation in their virus associated with resistance to the NS5A inhibitor class of direct-acting antivirals (DAAs) for HCV.

The remaining 21 people were treated for 16 weeks, a treatment length assigned to those with genotype 3, those who had cirrhosis, and those who were previously treated with an NS5A inhibitor or protease inhibitor. Seven of the individuals treated for 16 weeks had genotype 1; 14 of them had genotype 3. Seven had compensated cirrhosis (the milder form of the advanced liver disease) and six had been treated with an NS5A inhibitor prior to their initial Mavyret treatment. Sixteen of these individuals had a viral mutation associated with NS5A inhibitor resistance, five of them also had a mutation linked to resistance to NS3/4A inhibitor DAAs.

The study excluded those coinfected with hepatitis B virus (HBV) and those with decompensated cirrhosis, the more severe stage of the advanced form of liver disease. The trial did not exclude those coinfected with HIV, although such individuals had to be either off antiretroviral treatment for that virus or on ARVs with a fully suppressed viral load.

Both of the participants who were treated for 12 weeks achieved a sustained virologic response 12 weeks after completing therapy (SVR12, considered a cure). Ninety-five percent (20 of 21) of those treated for 16 weeks were cured. The one person in the study who did not achieve an SVR12 experienced virologic failure following the intensified regimen had genotype 1a, compensated cirrhosis and had not been cured by Harvoni (ledipasvir/sofosbuvir) prior to taking Mavyret the first time.

No participant experienced a serious adverse health event judged related to treatment. A total of 82.6 percent experienced any adverse health event, including headache (26.1 percent of participants), itching (21.7 percent), dizziness (17.4 percent), irritability (17.4 percent), fatigue (13 percent), insomnia (13 percent) and upper respiratory-tract infection (13 percent).

One person (4.3 percent of the total group) experienced a lab-based abnormality.

To read the conference abstract, click here.

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