Gilead’s Vosevi Works Well Among Those Treated for Hep C Before

Having hepatitis C with evidence of resistance to medications did not impact the chances of a cure in a recent study.

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Individuals who have been previously treated for hepatitis C virus (HCV) do well on Gilead Sciences’ Vosevi (sofosbuvir/velpatasvir/voxilaprevir), even if they have virus with evidence of resistance to direct-acting antivirals (DAAs).

Researchers from the double-blind, randomized, placebo-controlled Phase III POLARIS-1 study conducted an analysis of Vosevi treatment among those who initially were randomized to receive a placebo and were subsequently offered 12 weeks of the actual study drug on an open-label basis, meaning they knew at that point that they were receiving Vosevi. The participants had all been previously treated with a DAA in the NS5A inhibitor class.

Results from the placebo group’s ultimate treatment with Vosevi were presented at the Annual Meeting of the American Association for the Study of Liver Diseases in Washington, DC.

All told, POLARIS-1 included 263 people who received Vosevi immediately while 152 people received the placebo. Ultimately, 147 people in the placebo group were treated with Vosevi.

Among those in the placebo group who received Vosevi treatment, the average age was 59, 79 percent were male, 82 percent were white, the average body-mass index, or BMI, was 29 (25 or greater is overweight; 30 or greater is obese), 33 percent had cirrhosis and 99 percent had genotype 1 of the virus, including 77 percent who had genotype 1a and 20 percent who had genotype 1b.

Ninety-six percent of those who had been treated previously with an NS5A inhibitor and an NS5B inhibitor achieved a sustained virologic response 12 weeks after completing therapy (SVR12, considered a cure). The cure rate was 98 percent among those who were treated with an NS5A inhibitor plus an NS3/4A inhibitor with or without an NS5B inhibitor. Ninety percent of the participants went into the study with evidence of resistance to DAAs (baseline resistance-associated substitutions), but this factor did not affect their chances of a cure in the end.

The treatment proved well tolerated. No one discontinued treatment because of adverse health

events, and none experienced abnormal laboratory results considered clinically significant.

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