Daclatasvir, Sofosbuvir Combo Boasts High Hep C Cure Rates Across Genotypes

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An interferon-free combination therapy of Bristol-Myers Squibb's NS5A inhibitor daclatasvir and Gilead Sciences' NS5B polymerase inhibitor sofosbuvir produced cures in more than 93 percent of hepatitis C virus (HCV) patients, with or without the addition of ribavirin, MedPage Today reports. Study author Mark Sulkowski, MD, of Johns Hopkins University, announced the results of the Phase II study at the Annual Meeting of the American Association for the Study of Liver Diseases (AASLD) in Boston.

However, because the two drugs are manufactured by different companies, it appears unlikely they will enter a Phase III study together and in turn receive FDA approval as a combination therapy. But if the new drugs are each approved independently, then physicians will be at liberty to prescribe them together off-label. Nevertheless, the evidence of their success dovetails with other findings also announced at AASLD: that sofosbuvir, taken in combination with another NS5A inhibitor, GS-5885, achieved a 100 percent sustained virologic response (SVR, considered a cure) rate. This underscores that the two drug classes, when taken in combination, are highly potent against the virus.

Researchers divided the trial's participants into three treatments arms: one taking a week of sofosbuvir followed by 23 weeks of that drug along with daclatasvir; another with the two medications for 24 weeks; and a third arm with the combination therapy along with ribavirin for 24 weeks. Among the 44 patients with the easier-to-treat genotype 2 and 3 viruses, 88 percent reached an SVR 12 weeks after completing the first therapy combination, 100 percent were cured in the second, and 86 percent in the third. Another 44 patients with genotype 1, the hardest to treat, were divided among the same treatment arms. All of them were cured 24 weeks after treatment, with the exception of one participant who still showed evidence of hep C, but who was apparently reinfected with the virus. Meanwhile, the researchers also gave the double combination therapy, both with and without ribavirin, to another 82 genotype 1 patients for just 12 weeks. Data is still forthcoming, but thus far 68 of those patients have reached the 12-week post-treatment benchmark, and all of them have been cured.

To read the MedPage story, click here.

To read slides on the study from the AASLD meeting, click here.

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