Success Across Hep C Genotypes for Daclatasvir and Sovaldi

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Twelve weeks of Bristol-Myers Squibb's (BMS) daclatasvir and Gilead Sciences' Sovaldi (sofosbuvir) offered a 97 percent hepatitis C virus (HCV) cure rate in a recent Phase III trial among those with HCV genotypes 1 through 4 who were coinfected with HIV. The trial also included people with compensated cirrhosis of the liver.

Out of 151 participants who had not been treated for hep C before, two-thirds were randomly assigned to receive 12 weeks of treatment, while the other third took daclatasvir and Sovaldi for just eight weeks. Another 52 people who had failed a previous hep C cure attempt underwent 12 weeks of treatment. The daclatasvir dose could be adjusted depending on an individual's HIV treatment regimen.

While 97 percent of those treated for 12 weeks were cured, just 76 percent of those treated for eight weeks were so fortunate.

Shortly after the trial results were announced, BMS filed for U.S. Food and Drug Administration (FDA) approval of 12 weeks of the combination treatment, specifically for people with genotype 3 of hep C. A decision is expected by mid-September.

"However," says Susanna Naggie, MD, MHS, director of infectious diseases research at Duke Clinical Research Institute in Durham, North Carolina, "similar to the fate of the [Olysio (simeprevir) and Sovaldi] regimen, the individual costs of two drugs is certain to be more expensive than competing FDA-approved regimens, leaving the future of a daclatasvir plus [Sovaldi] regimen unclear except in extenuating cases."

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