High Hepatitis C Cure Rates in Trial of Sovaldi and Daclatasvir

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Daclatasvir and Sovaldi (sofosbuvir), given with or without ribavirin, cured between 92 and 100 percent of treatment-naive and treatment-experienced people with genotypes 1, 2 and 3 of hepatitis C virus (HCV), MedPage Today reports. Publishing their findings in The New England Journal of Medicine, investigators designed a Phase II open-label study of Gilead Sciences' recently approved nucleotide analogue NS5B polymerase inhibitor Sovaldi and Bristol-Myers Squibb's NS5A replication complex inhibitor daclatasvir.

In the first arm of the study, which looked at treatment-naive participants, the researchers randomly assigned 44 people with genotype 1 of the virus and another 44 with genotypes 2 or 3 to receive daclatasvir and Sovaldi with or without ribavirin for 24 weeks. Later, the investigators expanded the study to include another arm with 123 people with genotype 1, who were also randomly assigned the same cocktail. Eighty-two of those in this second group were treatment naive and received 12 weeks of therapy, while 41 had had previous virologic failure with Incivek (telaprevir) or Victrelis (boceprevir) plus pegylated interferon-alfa and ribavirin.

A total of 211 people received treatment. Ninety-eight percent of both the 126 treatment-naive and the 41 treatment-experienced people with genotype 1 achieved a sustained virologic response 12 weeks after completing therapy (SVR12, considered a cure). Ninety-two percent of the 26 participants with genotype 2 and 89 percent of the 18 participants with genotype 3 achieved an SVR12. Ninety-eight percent of those with genotype 1a and 100 percent of those with genotype 1b achieved an SVR12. On average, 94 percent of those who took ribavirin achieved an SVR12, compared with 98 percent of those who did not.

Phase III trials of this drug combination are in the works.

To read the MedPage Today story, click here.

To read a release on the study, click here.

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