Sofosbuvir, Daclatasvir Combo Cures 100% in Hep C Trial

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Gilead Sciences' sofosbuvir and Bristol-Myers Squibb's daclatasvir, taken with or without ribavirin, cured 100 percent of previously treated participants of hepatitis C virus (HCV) in a recent trial, echoing previous studies of this highly potent combination therapy, Bloomberg Businessweek reports. However, because of the fact that Gilead has opted not to work jointly with BMS on advanced studies of the two drugs in combination, preferring instead to set its sights on a single combination pill of sofosbuvir with the company's own ledipasvir, it appears unlikely there will ever be a U.S. Food and Drug Administration approval of sofosbuvir and daclatasvir in combination.

The results of the study, which included 41 people with genotype 1 of hep C who had failed an interferon-based therapy including either Victrelis (boceprevir) or Incivek (telaprevir), were presented at the International Liver Congress, the 48th annual meeting of the European Association for the Study of the Liver (EASL) in Amsterdam.

The study did not include those with cirrhosis of the liver, although more than four in five of the participants had moderate fibrosis or higher.

The participants were randomly assigned to receive the NS5A replication complex inhibitor daclatasvir and the nucleotide analog HCV polymerase inhibitor sofosbuvir either with or without ribavirin for 24 weeks.

All 41 of the participants achieved a sustained virologic response (SVR, considered a cure) 24 weeks after completing the therapy. The treatment was generally safe and well tolerated in both arms of the study. Those taking ribavirin reported greater fatigue and gastrointestinal symptoms.

If both drugs are approved as independent agents, physicians will have the option to prescribe them "off-label."

To read the Bloomberg story, click here.

To read the abstract and see study slides, click here.

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