A Hep C Treatment for All Genotypes

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Gilead Sciences appears poised to continue its dominance of the hepatitis C treatment market in 2016 after achieving excellent results from several large Phase III studies of a new regimen that treats all genotypes of the virus. The four studies looked at a once-daily, single-tablet combination of Sovaldi (sofosbuvir) and the investigational drug velpatasvir for the treatment of genotypes 1 through 6 of hep C. In October, Gilead filed for U.S. Food and Drug Administration approval of the combination regimen.

Three of the studies included a cumulative 1,035 people with genotypes 1 through 6 of hep C, who were all treated with Sovaldi/velpatasvir for 12 weeks, with or without ribavirin. A fifth of the participants had compensated cirrhosis, and just over a quarter had failed a previous cure attempt.

A fourth study included 267 individuals of all genotypes, all of whom had decompensated cirrhosis. Some of them took ribavirin in addition to Sovaldi/velpatasvir.

When breaking down the results according to ribavirin use and genotype, in most cases the regimens cured 94 to 100 percent of the participants.

Participants with decompensated cirrhosis who did not take ribavirin saw cure rates in only the mid-80 percent range. However, among those with such advanced liver damage who added ribavirin, 94 percent were cured.

The most common side effects of Sovaldi/velpat-asvir were headache, fatigue and nausea, as well as anemia among those also taking ribavirin.

Blaire E. Burman, MD, a hepatologist at the Virginia Mason Medical Center in Seattle, touts this treatment as good news for global treatment of hep C. “In areas of the world with limited health care resources, where the majority of HCV-infected persons live, determining the genotype of the hepatitis C virus is often not feasible, and thus the availability of a single pill that is effective for all genotypes is truly a game-changer,” she says.

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