Gilead’s All-Genotype Hep C Drug

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The U.S. Food and Drug Administration (FDA) has granted priority review status to Gilead’s application for approval of a once-daily combo tablet of Sovaldi (sofosbuvir) and the investigational pangenotypic NS5A inhibitor velpatasvir to treat those with genotypes 1 through 6 of hepatitis C.

The FDA grants priority review status to drugs that would offer a significant improvement over existing treatments. The status shortens the review period from 10 months to six months.

A decision is expected by June 28.

Gilead’s FDA application is backed up by four large clinical trials that tested 12 weeks of Sovaldi/velpatasvir among participants with the same range of genotypes, including those with compensated cirrhosis, while those with decompensated cirrhosis also took ribavirin.For the most part, between 94 and 100 percent of participant groups were cured, which is comparable to the success rates seen in clinical trials of Harvoni. Study results suggest that those with decompensated cirrhosis will likely have to take ribavirin in addition to Sovaldi/velpatasvir to achieve such a high success rate.

The new regimen “has the potential to alter the treatment paradigm in resource-poor countries where [genotype] testing may be limited,” says Nezam H. Afdhal, MD, director of hepatology at Beth Israel Deaconess Medical Center in Boston.

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