FDA OKs Gilead’s Epclusa for All Genotypes

September 5, 2016 By Benjamin Ryan

The U.S. Food and Drug Administration (FDA) has green-lit Gilead Sciences’ new hepatitis C virus (HCV) treatment, the once-daily combination tablet Epclusa (sofosbuvir/velpatasvir). This is the first approved therapy that treats all six major genotypes of the virus.

The FDA approved a 12-week regimen of Epclusa for those with genotypes 1 through 6 who don’t have cirrhosis or who have compensated cirrhosis while indicating that those with the more advanced decompensated cirrhosis should also take ribavirin.

Andrew H. Talal, MD, MPH, a professor of medicine and a hepatologist at University at Buffalo, State University of New York, doesn’t see Epclusa eclipsing Gilead’s blockbuster tablet Harvoni (ledipasvir/sofosbuvir). “I think that [Epclusa] fills two voids,” he says, “one is genotype 2 and 3 as an alternative to [Daklinza (daclatasvir)] and [Sovaldi (sofosbuvir)], as well as in decompensated cirrhotics.”

The tablet is the first single-tablet treatment approved for those with genotypes 2 and 3 and also improves the treatment outlook for those with very advanced liver disease.

Gilead has set the wholesale price of Epclusa at $74,760.

In advanced clinical trials of 12 weeks of Epclusa among people with genotypes 1 through 6 who did not have cirrhosis or who had compensated cirrhosis, Epclusa boasted a cure rate of 98 percent, putting its efficacy on par with Harvoni’s. In a trial of those with all genotypes who had a more advanced liver disease stage of decompensated cirrhosis, 94 percent of those who took Epclusa and ribavirin for 12 weeks were cured.

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