FDA OKs Merck’s Zepatier

June 6, 2016 By Benjamin Ryan

The U.S. Food and Drug Administration (FDA) has approved Merck’s once-daily, fixed-dose combination tablet Zepatier (elbasvir/grazoprevir), with or without ribavirin, to treat people with genotypes 1 and 4 of hepatitis C virus (HCV).

Zepatier (pronounced “ZEP-ah-teer”) includes the NS5A inhibitor elbasvir and the NS3/4A protease inhibitor grazoprevir.

The recommended treatment lengths for Zepatier are 12 or 16 weeks, depending on hep C genotype, whether the person has been treated before and, for those with genotype 1a, certain genetic differences in their virus. According to Merck, the vast majority of individuals eligible for Zepatier treatment would take it for 12 weeks.

Twelve weeks of Zepatier costs $54,600, which is considerably lower than the prices for other hep C treatments, notably those from Gilead Sciences and AbbVie.

In advanced clinical trials of 12 or 16 weeks of Zepatier, the treatment cured between 94 and 97 percent of those with genotype 1 and between 97 and 100 percent of people with genotype 4.

Calling Zepatier “a welcome addition” to the arsenal of available hep C treatments, Daniel Fierer, MD, an associate professor of medicine and infectious disease specialist at Mount Sinai Hospital in New York City, stresses that the tablet is also the first regimen that’s safe for people on dialysis.

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