FDA OK's BMS Daklinza (Daclatasvir) to Treat Hep C Genotype 3

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The U.S. Food and Drug Administration (FDA) has approved Bristol-Myers Squibb's (BMS) NS5A inhibitor Daklinza (daclatasvir) to be used in combination with Gilead Sciences' Sovaldi (sofosbuvir) to treat genotype 3 of hepatitis C. This is the first hep C regimen ever to be specifically approved for genotype 3, and it improves cure rates over other currently available treatments. However, the cure rate anticipated for those with cirrhosis is still quite poor.

Twelve weeks of once-daily regimen is recommended.

An estimated 12 percent of Americans with hep C are infected with genotype 3. It is the second most common genotype in the United States, behind genotype 1, which makes up about 70 percent of the U.S. epidemic.

BMS has set the price of Daklinza at $63,000. A statement from BMS says the company has priced the drug "at a level that reflects its fair value"—a statement sure to invite controversy, considering how the high price of hep C drugs has ignited a firestorm of criticism aimed at the pharmaceutical industry.

With Sovaldi retailing for $84,000 for a twelve-week course, its combination with Daklinza will run just short of $150,000. However, the pairing is the same price as the combination of Sovaldi and Janssen's Olysio (simeprevir), which is approved to treat genotype 1. Public and private insurers have negotiated discounts of Sovaldi already, and according to BMS spokes person Robert Perry, the company is "working with payers to ensure that patients have access to Daklinza. Discussions are ongoing."

The FDA's approval was based on the Phase III ALLY-3 study of 152 people with genotype 3 of hep C, 101 of whom were treatment naive and 51 of whom were treatment experienced. After 12 weeks of Daklinza-Sovaldi treatment, 90 percent of the treatment-naive participants and 86 percent of the treatment-experienced participants achieved a sustained virologic response 12 weeks after completing therapy (SVR12, considered a cure). Ninety-six percent of those without cirrhosis were cured, regardless of whether or not they'd been cured before. The cure rate was only 63 percent for those with cirrhosis.

BMS intends to submit a supplementary new-drug application to the FDA based on the Phase III

ALLY-2 trial, in which 97 percent of people coinfected with HIV and genotypes 1 through 4 (who were treatment naive for hep C therapy) were cured.

Daklinza will be available within a week.

To read a press release about the approval, click here.

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