Daklinza Approved for Genotype 3

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The U.S. Food and Drug Administration (FDA) has approved the combination of Bristol-Myers Squibb's (BMS) NS5A inhibitor Daklinza (daclatasvir) with Gilead Sciences' Sovaldi (sofosbuvir) to treat genotype 3 of hep C. This is the first hep C regimen ever to be specifically approved for this genotype, which makes up an estimated 12 percent of U.S. cases of the virus.

"Daclatasvir is a terrific drug," says Daniel Fierer, an associate professor of medicine and infectious disease specialist at Mount Sinai Hospital in New York City. "I wish we hadn't had to have waited over a year and a half beyond the approval of sofosbuvir, but I'm glad we have it in hand now."

BMS has set the price of Daklinza at $63,000 for the recommended 12-week regimen. So considering Sovaldi's $84,000 list price, the total treatment cost (before potential discounts to insurers) for the combo will be a staggering $147,000.

The approval is based on a Phase III trial of the two drugs among 152 people with genotype 3. Ninety percent of those new to treatment and 86 percent of those who'd failed a previous attempt were cured. Ninety-six percent of those without cirrhosis beat hep C. The cure rate for study participants with cirrhosis, however, was only 63 percent.
