FDA Expands Daklinza/Sovaldi Approval to Include Treatment of Hep C Genotype 1

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The U.S. Food and Drug Administration (FDA) has expanded the approved uses of the combination hepatitis C virus (HCV) regimen of Bristol-Myers Squibb's (BMS) Daklinza (daclatasvir) and Gilead Sciences' Sovaldi (sofosbuvir). Approved to treat genotype 3 of the virus in July 2015, the regimen may now treat genotype 1, as well as individuals with advanced cirrhosis and people whose hep C has returned after a liver transplant.

The regimen has been well-studied in combination with numerous HIV antiretrovirals (ARVs). According to BMS, there is no need to adjust the dose of ARVs when used in combination with Daklinza and Sovaldi. Instead, the Daklinza dose can be adjusted if necessary—a shift that is not possible with fixed-dose combination tablet treatments.

To read the updated drug label, click here.

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