FDA Weighs New Uses for Daklinza

March 7, 2016 By Benjamin Ryan

At press time, the U.S. Food and Drug Administration (FDA) was reviewing Bristol-Myers Squibb's (BMS) request for approval of new uses for the company's hepatitis C virus (HCV) therapy Daklinza (daclatasvir) in combination with Gilead Sciences' Sovaldi (sofosbuvir), given with or without ribavirin. BMS is seeking the green light for the regimen to treat those coinfected with HIV and HCV, those who have advanced cirrhosis, including decompensated cirrhosis, and those whose hep C has returned following a liver transplant.

Clinical trials of the regimen among these groups of people boasted mostly 90 percent-plus cure rates, with the notable exception of people with very advanced cirrhosis.

The FDA's decision was expected by late February.

Kris Kowdley, MD, a liver specialist at Swedish Medical Center in Seattle, says a theoretical approval of the regimen "gives our patients yet another option among historically difficult-to-treat populations."

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