FDA Grants Priority Review for New Uses of Hep C Drug Daklinza

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The U.S. Food and Drug Administration (FDA) has granted priority review status to Bristol-Myers Squibb's (BMS) applications for new indication approvals for the company's hepatitis C virus (HCV) therapy Daklinza (daclatasvir) in combination with Gilead Sciences' Sovaldi (sofosbuvir), with or without ribavirin. BMS has filed supplementary new drug applications for the regimen to treat those coinfected with HIV and HCV, for those who have advanced cirrhosis (including decompensated cirrhosis), and for those whose hep C has recurred following a liver transplant.

The FDA grants priority review to new medications, or new indications for drugs, that would offer a significant improvement in the safety or effectiveness of a treatment for a particular condition. In this case, the FDA will review the three new indications for Daklinza and Sovaldi within six months, by early March 2016.

Daklinza was approved in July 2015 for use with Sovaldi to treat genotype 3 of hep C.

The three new applications are based on data from the ALLY-1 and ALLY-2 Phase III clinical trials. ALLY-1 tested 12 weeks of Daklinza and Sovaldi among those who either had advanced cirrhosis or post-transplant recurrence of the virus. The cure rates were mostly high among the different study subgroups, with the notable exception of those with very advanced cirrhosis. ALLY-2 studied 12 weeks of the treatment with those who were coinfected with HIV and HCV; 97 percent were cured.

In May 2015, the FDA granted Daklinza and Sovaldi a breakthrough therapy designation for the treatment of genotype 1 of hep C with advanced cirrhosis (Child-Pugh Class B or C) and those who have had a recurrence of genotype 1 of the virus after a liver transplant. This designation is intended to expedite the development and review of drugs for life-threatening conditions when that treatment may provide substantial improvement over available therapies.

To read a BMS press release about the FDA review, click here.