European Commission Approves New Daklinza Indications

February 3, 2016

The European Commission has approved new indications for Bristol-Myers Squibb's Daklinza (daclatasvir) to treat hepatitis C virus (HCV) in combination with Sovaldi (sofosbuvir), with or without ribavirin. The new approval expands Daklinza's indications to include treating those with decompensated cirrhosis, HIV coinfection, and hep C recurrence following a liver transplant.

Daklinza is already approved in the 28 member states of the European Union for use in combination with other therapies to treat genotypes 1 through 4 of the virus. The drug plus Sovaldi is the only 12-week, all-oral regimen approved in Europe to treat people with genotype 3 without cirrhosis.

The new indications were based on data from the ALLY-1 and ALLY-2 clinical trials, which tested Daklinza and Sovaldi, with or without ribavirin, among people with liver transplants and those with cirrhosis in ALLY-1, and in those coinfected with HIV in ALLY-2.

To read the BMS press release on the approval, click here.