BMS Gets European OK for Hepatitis C Drug Daklinza (Daclatasvir)

August 27, 2014

The European Commission has approved Bristol-Myers Squibb's Daklinza (daclatasvir) to be used in combination with other medications to treat genotypes 1 through 4 of hepatitis C virus (HCV). The approval grants BMS permission to market the pan-genotypic NS5A replication complex inhibitor in all 28 countries in the European Union.

"HCV is a challenging virus to overcome, requiring multiple modes of attack. With the approval of Daklinza, we have a new class of drug that disrupts the virus in two ways—by inhibiting both viral replication and assembly—and when combined with other compounds often results in a cure among even the hardest-to-treat patients," Michael P. Manns, MD, professor and chairman of the department of gastroenterology, hepatology and endocrinology at Hannover Medical School in Hannover, Germany, said in a release.

Daklinza was approved based on findings from various clinical trials, such as a randomized study of the drug with Sovaldi (sofosbuvir) in genotypes 1, 2 and 3 that included participants with fibrosis as well as those who had not responded to a previous treatment attempt with Incivek or Victrelis. In that trial, 99 percent of treatment-naive participants with genotype 1 achieved a sustained virologic response 12 weeks after completing therapy (SVR12, considered a cure). In addition, 100 percent of those with genotype 1 who had failed treatment with Incivek or Victrelis, 96 percent of those with genotype 2 and 89 percent of those with genotype 3 were cured.

Daklinza is recommended for either 12 or 24 weeks in combination with either Sovaldi, Sovaldi and ribavirin, or interferon and ribavirin, depending on genotype, previous treatment experience, liver disease extent, IL28B CC genotype and baseline viral load. For those with genotype 4 who opt to take Daklinza with interferon and ribavirin as opposed to with Sovaldi, 24 weeks of Daklinza is recommended with 24 to 48 weeks of interferon and ribavirin, depending on how effectively the therapy suppresses the virus during the first 12 weeks of treatment.

To read the press release, click here.

© 2026 Smart + Strong All Rights Reserved.
http://beta.docker.hepmag.com/article/Daklinza-EU-approval-26078-2051043758