BMS Resubmits FDA Application for Hepatitis C Drug Daclatasvir

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Bristol-Myers Squibb (BMS) has submitted an amended new drug application (NDA) to the U.S. Food and Drug Administration (FDA) for a 12-week regimen of daclatasvir, this time in combination with Gilead Sciences' Sovaldi (sofosbuvir), to treat genotype 3 of hepatitis C virus (HCV). In October 2014, BMS withdrew its NDA for the NS5A complex inhibitor daclatasvir and NS3/4A protease inhibitor asunaprevir to treat genotype 1b of the virus.

Daclatasvir and asunaprevir, which cured 82 to 90 percent of people with genotype 1b in clinical trials, proved disappointing when compared with Gilead Sciences' Harvoni (ledipasvir/sofosbvuvir) and AbbVie's Viekira Pak (ombitasvir/paritaprevir/ritonavir; dasabuvir), which were approved to treat genotype 1 of hep C in the fall of 2014, each boasting cure rates in the mid-90 percent range.

BMS's amended FDA application is based on results from the Phase III ALLY-3 trial, in which daclatasvir and the nucleotide analog polymerase inhibitor Sovaldi cured 86 percent of treatment-experienced and 90 percent of treatment-naive study participants who had genotype 3 of the virus. Those in the trial who did not have cirrhosis had a 90 percent cure rate, regardless of whether they had been treated before or not.

The American Association for the Study of Liver Diseases (AASLD) recommends 24 weeks of Sovaldi and ribavirin for people with genotype 3. This regimen offers a cure rate of about 92 to 94 percent for people being treated for the first time, in the 80 percent rage for those who have failed a previous treatment, and about 60 percent for people with cirrhosis. Combining Sovaldi with daclatasvir might not provide an edge for treatment-naive people with genotype 3, but could shorten treatment times and improve success rates for treatment-experienced people and those with cirrhosis.

"The daclatasvir-based NDA seeks to address a high unmet-patient need that still exists despite recent hepatitis C treatment advances. Approximately 9 to 12 percent of HCV patients in the U.S. have genotype 3. That's thousands of individuals in the U.S. who historically have had limited treatment options requiring at least 24 weeks of treatment," Douglas Manion, MD, head of specialty development at BMS, said in a press release. "We also are continuing clinical trials to

determine the potential of daclatasvir-based regimens in treating a range of other high unmet-need patients, including those coinfected with HIV, HCV patients with decompensated cirrhosis, and HCV recurrence in post-transplant patients."

In the ALLY-3 trial, the daclatasvir and Sovaldi combination regimen proved well tolerated. There were no deaths or serious side effects, and no one stopped treatment because of side effects. The most common side effects included headache (20 percent), fatigue (19 percent), nausea (12 percent), diarrhea (9 percent), insomnia (6 percent), abdominal pain (5 percent) and joint pain (5 percent).

A decision from the FDA is expected within six months, meaning that the first new hep C drug to hit the market since Harvoni and Viekira Pak could arrive by mid-September.

To read the press release, click here.

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