BMS Pulls the Plug on Hep C Drug Asunaprevir in the U.S.

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Bristol-Myers Squibb has decided to end its pursuit of an approval for the hepatitis C virus (HCV) therapy asunaprevir in the United States, The Wall Street Journal reports. In a press release, the company announced that it has withdrawn its application to the U.S. Food and Drug Administration for approval of the dual regimen of pan-genotypic NS5A complex inhibitor daclatasvir and NS3/4A protease inhibitor asunaprevir to treat genotype 1b of the virus.

BMS will still seek FDA approval of daclatasvir. The company plans to submit additional study findings of an ongoing clinical trial program examining the drug's use in difficult-to-treat people with hep C. This includes those with genotype 3 of the virus, those who are pre- and post-liver transplant and those coinfected with HIV.

The asunaprevir-daclatasvir combination offered anemic benefits when compared with offerings from other pharmaceutical companies that are awaiting FDA approval for the next generation of hep C therapies. Gilead Sciences' fixed-dose combination of Sovaldi (sofosbuvir) and ledipasvir, which the FDA is scheduled to decide upon by October 10, boasts cure rates between 94 percent and 99 percent for those with genotype 1 and will likely require just eight or 12 weeks of treatment. In clinical trials, BMS's combination, on the other hand, cured just 82 percent to 90 percent of those with genotype 1b after 24 weeks.

AbbVie, which expects to hear back from the FDA about its "3D" regimen in mid-December, may offer similar cure rates to Gilead's combination pill, but with a higher pill burden. Also, it is likely that 3D will require ribavirin, and the Sovaldi-ledipasvir combination will not.

Over the summer, BMS received approval for daclatasvir and asunaprevir, under the brand names Daklinza and Sunvepra, to treat genotype 1 in Japan. The European Commission also approved Daklinza to be used in combination with other medications to treat genotypes 1 through 4.

To read the press release, click here.

To read the Wall Street Journal report, click here.

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