AbbVie’s Glecaprevir/Pibrentasvir Cures Genotype 1 of Hep C at High Rates

The once-daily investigational hepatitis C virus (HCV) combination tablet will likely be approved in 2017.

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AbbVie’s investigational, once-daily, fixed-dose combination tablet glecaprevir/pibrentasvir, known as G/P, cured those with genotype 1 of hepatitis C virus (HCV) at high rates in a recent large trial, aidsmap reports. The pangenotypic treatment (meaning it works on all genotypes of hep C) will likely gain approval from the U.S. Food and Drug Administration (FDA) in 2017.

Researchers from the Phase III ENDURANCE-1 trial of 703 people with genotype 1 of hep C presented findings at the Annual Meeting of the American Association for the Study of Liver Diseases (AASLD) in Boston.

The trial included both those who were being treated for the first time and those who failed a previous treatment with an interferon-based regimen or Sovaldi (sofosbuvir) and ribavirin. The trial excluded those with cirrhosis but included those who also had HIV.

The participants were randomized into two even groups to receive G/P once daily for either eight or 12 weeks.

Ninety-nine percent of those in the eight-week treatment group and 99.7 percent of those in the 12-week treatment group achieved a sustained virologic response 12 weeks after completing therapy (SVR12, considered a cure).

No one stopped treatment because of drug-related adverse health events. The most common adverse health events were headache (19 percent overall) and fatigue (9 percent in the eight-week study arm and 12 percent in the 12-week arm). Two people in the eight-week group and one in the 12-week group experienced a grade 3 elevation of their bilirubin, an indication of liver problems.

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