AbbVie Applies for FDA OK of Hep C Treatment Glecaprevir/Pibrentasvir

The single-pill regimen would provide an eight-week ribavirin-free option for those with all viral genotypes who do not have cirrhosis.

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AbbVie has applied for approval from the U.S. Food and Drug Administration (FDA) for its fixed-dose combination tablet glecaprevir/pibrentasvir (G/P) to treat all genotypes of hepatitis C virus (HCV).

The new-drug application is backed up by data from eight Phase III studies of G/P, as the tablet is known for short, that included more than 2,300 participants in 27 nations who had all genotypes of the virus, 1 through 6. The studies included those with compensated cirrhosis, without cirrhosis, with severe chronic kidney disease and those who failed a previous cure attempt with direct-acting antivirals.

The results of multiple advanced trials of G/P were presented in November at the Annual Meeting of the American Association for the Study of Liver Diseases (AASLD) in Boston.

In the clinical trial program, eight weeks of G/P cured 97.5 percent (693 of 711) of those with all genotypes of hep C who did not have cirrhosis and who were treated for the virus for the first time. Twelve weeks of treatment cured 98 percent (102 of 104) of those with severe chronic kidney disease. The same length of treatment cured high rates of those with compensated cirrhosis.

The most commonly reported adverse health events among those with severe chronic kidney disease were itching, fatigue and nausea, while among those with all genotypes who did not have cirrhosis, headache and fatigue topped the list.

AbbVie received Breakthrough Therapy Designation from the FDA for G/P in September, specifically for the treatment of those with genotype 1 who had failed a previous direct-acting antiviral treatment for hep C. Such a designation is meant to expedite the development and FDA review of treatments for serious or life-threatening conditions.

For more details about the recent trials of G/P, review the newsfeed devoted to AASLD 2016 here.

To read a press release about the FDA application, click here.