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China's NMPA approves Gilead's Vemlidy for HBV

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HBV is highly prevalent in China with an estimated 20 million people meeting current guidelines for therapy – accounting for almost one-third of all patients currently requiring therapy worldwide.

Gilead Sciences, Inc. has announced that the China National Medical Products Administration (NMPA) has approved Vemlidy (tenofovir alafenamide, TAF) 25 mg, a once-daily treatment for chronic hepatitis B in adults and adolescents (aged 12 years and older with body weight at least 35 kg).

Vemlidy is a novel, targeted prodrug of tenofovir that has demonstrated antiviral efficacy similar to Gilead's Viread (tenofovir disoproxil fumarate, TDF) 300 mg but at one-tenth of the dose. Data show that because Vemlidy has greater plasma stability and more efficiently delivers tenofovir to hepatocytes compared to Viread, it can be given at a lower dose, resulting in less tenofovir in the bloodstream. In clinical trials, Vemlidy demonstrated improved renal and bone laboratory safety parameters compared to Viread.

"With the approval of Vemlidy, physicians can now offer their patients a treatment that retains the efficacy of TDF while improving renal and bone safety parameters in clinical trials," said Prof. Jinlin Hou, Nanfang Hospital of Southern Medical University.

HBV is highly prevalent in China with an estimated 20 million people meeting current guidelines for therapy – accounting for almost one-third of all patients currently requiring therapy worldwide. Each year, approximately 300,000 people in China die from cirrhosis of the liver related to HBV.

"Chronic hepatitis B remains an urgent public health issue in China, and many people still need well tolerated and effective treatment options with a high barrier to resistance, especially as therapy can be life-long," said Gregg Alton, Gilead Chief Patient Officer. "Gilead is committed to working with health officials and affected communities to help address the ongoing hepatitis B challenge in China."

Vemlidy's approval is supported by data from two international Phase 3 studies (Studies 108 and 110) among 1,632 treatment-naive and treatment-experienced adult patients with HBeAg-negative and HBeAg-positive HBV disease (including 334 treated in China). In an integrated analysis of both studies, patients receiving Vemlidy demonstrated improvements in certain bone and renal laboratory parameters compared to those treated with Viread. In addition, no patient developed resistance to tenofovir during the studies through 96 weeks of therapy.

The most commonly reported adverse events through 96 weeks in both studies included headache, abdominal pain, fatigue, cough, nausea and back pain and occurred at similar rates in patients receiving either Vemlidy or Viread.

The U.S. Prescribing Information for Vemlidy has a Boxed Warning for the risk of post-treatment severe acute exacerbation of hepatitis B. See below for U.S. Important Safety Information and Indication. In the U.S., Vemlidy is only indicated for adult patients with compensated liver disease.

Vemlidy received marketing approval from the U.S. Food and Drug Administration (FDA) and the Japanese Ministry of Health, Labour and Welfare in 2016, and from the European Commission in 2017.