Vemlidy® (tenofovir alafenamide) – New Drug Approval

- On November 10, 2016, Gilead announced the FDA approval of Vemlidy (tenofovir alafenamide) for the treatment of chronic hepatitis B virus (HBV) infection in adults with compensated liver disease.

- According to the Centers for Disease Control and Prevention, an estimated 850,000 – 2.2 million persons have chronic HBV infection in the U.S. People with chronic HBV infection might be asymptomatic, have no evidence of liver disease, or have a spectrum of disease ranging from chronic hepatitis to cirrhosis or liver cancer.

- Vemlidy is a targeted prodrug of tenofovir. Data show that Vemlidy has a greater plasma stability and ability to deliver tenofovir to the liver, hence a lower dose can be given than Viread® (tenofovir disoproxil fumarate).

- The safety and efficacy of Vemlidy were based on two 48-week clinical studies of patients with chronic HBV infection with compensated liver disease who received either Vemlidy or Viread. The first study enrolled 425 patients who were HBeAg-negative and the second study enrolled 873 patients who were HBeAg-positive. The efficacy endpoint in both trials was the proportion of patients with plasma HBV DNA levels < 29 IU/mL at week 48.

    - In the first study, 94% of patients taking Vemlidy and 93% of patients taking Viread achieved HBV DNA < 29 IU/mL (treatment difference: 1.8%; 95% CI: -3.6%, 7.2%).
    - In the second study, HBV DNA < 29 IU/mL was achieved by 64% of Vemlidy patients and 67% of Viread patients (treatment difference: -3.6%; 95% CI: -9.8%, 2.6%)

- Similar to Viread, Vemlidy carries a boxed warning regarding lactic acidosis/severe hepatomegaly with steatosis and post treatment severe acute exacerbation of hepatitis B.

- Other warnings and precautions of Vemlidy include risk of development of human immunodeficiency virus (HIV)-1 resistance in patients coinfected with HBV and HIV-1, and new onset or worsening renal impairment.

- The most common adverse events (≥ 5%) with Vemlidy use were headache, abdominal pain, fatigue, cough, nausea and back pain.

- The recommended dose of Vemlidy is 25 mg orally once daily with food.

    - Prior to initiation of Vemlidy, patients should be tested for HIV-1 infection. Vemlidy alone should not be used in patients with HIV infection.
    - Vemlidy is not recommended in patients with CrCl < 15 mL/min or decompensated (Child-Pugh B or C) hepatic impairment.

- Gilead launched Vemlidy immediately. Vemlidy is available as 25 mg tablets.

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