Vemlidy® (tenofovir alafenamide) – New indication

- On March 28, 2024, Gilead announced the FDA approval of Vemlidy (tenofovir alafenamide), for the treatment of chronic hepatitis B virus (HBV) infection in adults and pediatric patients 6 years of age and older and weighing at least 25 kg with compensated liver disease.
    - Vemlidy was previously approved for this indication in adults and pediatric patients 12 years of age and older.
- The approval of Vemlidy for the expanded indication was based on a randomized, double-blind, placebo-controlled study (Trial 1092; Cohort 2) of 18 treatment naïve and treatment-experienced patients between the ages of 6 to less than 12 years weighing at least 25 kg. Patients were randomized to receive Vemlidy or placebo.
    - At week 96, HBV DNA < 20 IU/mL was achieved in 50% of patients with Vemlidy vs. 33% with placebo.
    - No clinically meaningful differences in pharmacokinetics or safety were observed in comparison to those observed in adults.
- Vemlidy carries a boxed warning for discontinuation of anti-hepatitis B therapy may result in severe acute exacerbations of hepatitis B.
- The recommended dosage of Vemlidy in adults and pediatric patients 6 years of age and older and weighing at least 25 kg is one 25 mg tablet taken orally once daily with food.