Vemlidy® (tenofovir alafenamide) – Expanded indication

- On October 17, 2022, the FDA approved Gilead's Vemlidy (tenofovir alafenamide), for the treatment of chronic hepatitis B virus (HBV) infection in adults and pediatric patients 12 years of age and older with compensated liver disease.
    - Vemlidy was previously approved for this indication in adults only.
- The approval of Vemlidy for the expanded indication was based on Trial 1092, a randomized, double-blind, placebo-controlled study in 70 treatment-naïve and treatment-experienced chronic HBV-infected patients between the ages of 12 to less than 18 years. Patients were randomized to receive Vemlidy or placebo.
    - Overall, 21% (10/47) of patients treated with Vemlidy achieved HBV DNA < 20 IU/mL at week 24 vs. 0% (0/23) of patients treated with placebo.
    - At week 24, the overall mean change from baseline in HBV DNA for Vemlidy and placebo groups, respectively, was -5.04 $\log_{10}$ IU/mL and -0.13 $\log_{10}$ IU/mL.
- Vemlidy carries a boxed warning for post-treatment severe acute exacerbation of hepatitis B.
- The recommended dosage of Vemlidy in adults and pediatric patients 12 years of age and older is one 25 mg tablet taken orally once daily with food.