Stribild® (elvitegravir/cobicistat/emtricitabine/tenofovir) – Expanded Indication and Updated Warnings

- On January 27, 2017, the FDA approved Gilead Sciences' Stribild (elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate), as a complete regimen for the treatment of human immunodeficiency virus-1 (HIV-1) infection in adults and pediatric patients 12 years of age and older weighing at least 35 kg who have no antiretroviral (ARV) treatment history or to replace the current ARV regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies/mL) on a stable ARV regimen for at least 6 months with no history of treatment failure and no known substitutions associated with resistance to the individual components of Stribild.
    - Previously, Stribild was approved only in adults for this indication.
- Efficacy for the expanded indication of Stribild was established in a 48-week, open-label study of 50 adolescents (12 to < 18 years of age) who were HIV-1-infected and treatment-naïve.
    - At week 48, 44 of 50 (88%) patients achieved HIV-1 RNA < 50 copies/mL and 4 had HIV-1 RNA ≥ 50 copies/mL; 1 patient discontinued the study drug; and 1 had no virologic data.
    - The mean decrease from baseline in HIV-1 RNA was −3.16 $\log_{10}$ copies/mL.
    - The mean increase from baseline in CD4+ cell count was 229 cells/mm^3.
- In addition, updates to the *Warnings and Precautions* section of the Stribild drug label were added regarding new onset or worsening renal impairment and bone loss and mineralization defects.
    - For the new onset or worsening renal impairment subsection, serum creatinine and serum phosphorus have been added to the renal function testing to be assessed before initiating and during administration of Stribild.
    - For the bone loss and mineralization defects subsection, information about the effects of tenofovir disoproxil fumarate on bone mineral density in pediatric and adolescent patients was added.
- The *Adverse Reactions*, *Use in Specific Populations*, and *Clinical Pharmacology* sections of the drug label were also updated with data from the pediatric studies.
- Stribild carries a boxed warning for lactic acidosis/severe hepatomegaly with steatosis and post-treatment acute exacerbation of hepatitis B.

.

- The recommended starting dose of Stribild is one tablet orally once daily with food in adults and pediatric patients 12 years of age and older with a body weight at least 35 kg (at least 77 lbs) and creatinine clearance ≥ 70 mL/minute.