Tybost® (cobicistat) – Expanded indication

- On August 22, 2019, the FDA approved Gilead's Tybost (cobicistat), to increase systemic exposure of atazanavir in combination with other antiretroviral agents in the treatment of human immunodeficiency virus (HIV)-1 infection in pediatric patients weighing at least 35 kg.
    - Tybost was previously approved for this indication in adults only.
    - Tybost is also approved to increase systemic exposure of Prezista® (darunavir) (once daily dosing regimen) in combination with other antiretroviral agents in the treatment of HIV-1 infection in adults.
- The approval of Tybost for the expanded indication was based on an open-label study evaluating the pharmacokinetics, safety, and efficacy of Tybost coadministered with atazanavir in 14 pediatric patients ages 12 years and older with virologically suppressed HIV-1 infection.
    - Overall, 93% (13/14) of patients remained suppressed (HIV-1 RNA < 50 copies/mL), and 1 subject experienced virologic failure at week 48.
- The recommended dose of Tybost for the treatment of HIV-infection in pediatric patients is 150 mg orally once daily. Tybost should be used in combination with atazanavir 300 mg orally once daily.
- Refer to the Tybost drug label for adult and additional dosing recommendations.