Dovato® (dolutegravir/lamivudine) – Expanded indication

- On August 6, 2020, ViiV Healthcare announced the FDA approval of Dovato (dolutegravir/lamivudine), as a complete regimen for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults with 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 with no history of treatment failure and no known substitutions associated with resistance to the individual components of Dovato.
    - Previously, Dovato was approved for the treatment of HIV-1 infection in adults with no ARV treatment history and no known substitutions associated with resistance to the individual components of Dovato.
- Dovato contains an integrase strand transfer inhibitor (dolutegravir) and a nucleoside analogue reverse transcriptase inhibitor (lamivudine).
- The approval of the expanded indication was based on TANGO, a 200-week, open-label, non-inferiority study enrolling 741 adult HIV-1–infected subjects who were on a stable suppressive tenofovir alafenamide-based regimen (TBR). Patients received Dovato or their current TBR. The primary efficacy endpoint was the proportion of subjects with plasma HIV-1 RNA ≥ 50 copies/mL (virologic non-response) at week 48.
    - In the primary analysis, < 1% of subjects in both arms experienced virologic non-response (HIV-1 RNA ≥ 50 copies/mL) at 48 weeks (treatment difference: -0.3%; 95% CI: -1.2%, 0.7%).
    - Based on a 4% non-inferiority margin, Dovato was non-inferior to TBR at week 48.
- Dovato carries a boxed warning for patients co-infected with hepatitis B virus (HBV) and HIV-1: emergence of lamivudine-resistant HBV and exacerbations of HBV.
- The recommended dose of Dovato for both indications is one tablet (dolutegravir 50 mg/ lamivudine 300 mg) taken orally once daily with or without food.