Dovato (dolutegravir/lamivudine) – Expanded indication

- On April 8, 2024, ViiV Healthcare announced the FDA approval of Dovato (dolutegravir/lamivudine), as a complete regimen for the treatment of HIV-1 infection in adults and adolescents 12 years of age and older and weighing at least 25 kg with no antiretroviral treatment history or to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies/mL) on a stable antiretroviral regimen with no history of treatment failure and no known substitutions associated with resistance to the individual components of Dovato.
    - Dovato was previously approved for this indication in adults only.
- The approval of Dovato for the expanded indication was based on an open-label study (DANCE) in 30 evaluable treatment-naïve HIV-1–infected adolescents aged 12 to less than 18 years and weighing at least 25 kg.
    - In the study, 87% (26/30) of patients achieved HIV-1 RNA < 50 copies/mL at week 48, and the mean increase from baseline in CD4+ cell count was 234 cells/mm^3.
- Dovato carries a boxed warning for patients co-infected with hepatitis B virus (HBV) and HIV-1 due to emergence of lamivudine-resistant HBV and exacerbations of HBV.
- The recommended dose of Dovato in adults and adolescents 12 years of age and older and weighing at least 25 kg is one tablet (containing 50 mg of dolutegravir and 300 mg of lamivudine) taken orally once daily.