Biktarvy® (bictegravir/emtricitabine/tenofovir alafenamide) – New drug approval

- On February 7, 2018, Gilead announced the FDA approval of Biktarvy (bictegravir [BIC]/emtricitabine [FTC]/tenofovir alafenamide [TAF]), as a complete regimen for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults who have no antiretroviral treatment history or to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA < 50 copies/mL) on a stable antiretroviral regimen for at least 3 months with no history of treatment failure and no known substitutions associated with resistance to the individual components of Biktarvy.

- BIC is an integrase strand transfer inhibitor. FTC and TAF are nucleoside analog reverse transcriptase inhibitor and nucleotide analog reverse transcriptase inhibitor, respectively.

    — FTC and TAF are also available as components in other fixed-dose combination products for the treatment of HIV-1 infection, including Descovy®, Genvoya®, and Odefsey®.

- The efficacy and safety of Biktarvy were demonstrated in four studies enrolling 2,415 adults with HIV-1 infection who were treatment-naive or virologically suppressed. Subjects were given Biktarvy or a suitable combination regimen for HIV-1 infection. Virologic outcome was accessed at 48 weeks in all studies.

    — Biktarvy met the primary objective of non-inferiority at 48 weeks across all four trials.
    — Through 48 weeks, no patient failed Biktarvy with treatment-emergent virologic resistance. In addition, no patient discontinued Biktarvy due to renal adverse events, and there were no cases of proximal renal tubulopathy or Fanconi syndrome.

- Biktarvy carries a boxed warning for post-treatment acute exacerbation of hepatitis B.

- Biktarvy is contraindicated to be co-administered with dofetilide and rifampin.

- Other warnings and precautions of Biktarvy include risk of adverse reactions or loss of virologic response due to drug interactions, immune reconstitution syndrome, new onset or worsening renal impairment, and lactic acidosis/severe hepatomegaly with steatosis.

- The most common adverse reactions (≥ 5%, all grades) with Biktarvy use were diarrhea, nausea, and headache.

- The recommended dosage of Biktarvy is one tablet taken orally once daily with or without food.

    — Prior to or when initiating Biktarvy, patients should be tested for hepatitis B virus infection.
    — Prior to or when initiating Biktarvy, and during treatment with Biktarvy, serum creatinine, estimated creatinine clearance, urine glucose and urine protein levels should be assessed in all patients as clinically appropriate. Serum phosphorus should also be assessed in patients with chronic kidney disease.

- Gilead's launch plans for Biktarvy are pending. Biktarvy will be available as a single tablet containing BIC 50 mg, FTC 200 mg, and TAF 25 mg.