Biktarvy® (bictegravir/emtricitabine/tenofovir alafenamide) – Expanded indication

- On February 26, 2024, Gilead announced the FDA approval of Biktarvy (bictegravir/emtricitabine/tenofovir alafenamide), for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults and pediatric patients weighing at least 14 kg to replace the current antiretroviral regimen in those who are virologically-suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen with *no known or suspected substitutions associated with resistance to bictegravir or tenofovir*.
    - Biktarvy was previously approved for this indication in patients with no history of treatment failure and no known substitutions associated with resistance to the individual components of Biktarvy.
    - This approval expands the indication for Biktarvy to include patients who have suppressed viral loads with known or suspected M184V/I resistance.
- Biktarvy is also approved for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 14 kg who have no antiretroviral treatment history.
- The approval of Biktarvy for the expanded indication was based on Study 4030, a randomized, double-blind study of 565 virologically suppressed HIV-1 infected adults. Patients must have been stably suppressed on their baseline regimen for at least 6 months (if documented or suspected nucleoside analog reverse transcriptase inhibitors [NRTI] resistance), or at least 3 months (if no documented or suspected NRTI resistance) prior to trial entry. Patients were randomized to switch to Biktarvy or to continue their prior treatment regimen, dolutegravir + emtricitabine and tenofovir alafenamide. The primary endpoint was the proportion of subjects with HIV-1 RNA > 50 copies/mL at week 48.
    - At week 48, the proportion of patients with HIV-1 RNA ≥ 50 copies/mL was 0.4% in the Biktarvy group and 1.1% in the comparator group (difference -0.7, 95% CI: -2.8, 1.0).
    - Of the patients receiving Biktarvy, 47 had HIV-1 with pre-existing M184V or I resistance substitutions (M184M/V, M184M/I, M184V/I, M184V). Eighty-nine percent (42/47) of patients with M184V or I remained suppressed and 11% did not have virologic data at the week 48 timepoint due to study drug discontinuation.
- Biktarvy carries a boxed warning for post treatment acute exacerbation of hepatitis B.
- The recommended dose of Biktarvy in adults and pediatric patients weighing at least 25 kg is one tablet containing 50 mg of bictegravir, 200 mg of emtricitabine, and 25 mg of tenofovir alafenamide taken orally once daily.
- The recommended dose of Biktarvy in pediatric patients weighing at least 14 kg to less than 25 kg is one tablet containing 30 mg of bictegravir, 120 mg of emtricitabine, and 15 mg of tenofovir alafenamide taken orally once daily.