Juluca® (dolutegravir/rilpivirine) – New drug approval

- On November 21, 2017, the FDA announced the approval of ViiV Healthcare's Juluca (dolutegravir/rilpivirine) as a complete regimen for the maintenance treatment of human immunodeficiency virus (HIV-1) infection in adults who are virologically suppressed (HIV-1 RNA < 50 copies/mL) on a stable antiretroviral (ART) regimen for at least 6 months with no history of treatment failure and no known substitutions associated with resistance to the individual components of Juluca.

- Juluca is the first complete HIV-1 treatment regimen containing only two drugs to treat certain adults with HIV-1 instead of three or more drugs included in standard HIV treatment.

- The efficacy of Juluca was demonstrated in two 148-week, open-label, non-inferiority studies (SWORD-1 and SWORD-2) of 1,024 adult patients with HIV-1 infection. Patients were randomized to continue their current ART regimen or switched to dolutegravir and rilpivirine therapy. The primary efficacy endpoint for the SWORD trials was the proportion of patients with plasma HIV-1 RNA < 50 copies/mL at week 48.

    — Dolutegravir and rilpivirine therapy achieved non-inferior viral suppression at 48 weeks vs. current ART regimens in the pooled analyses (treatment difference = -0.2% [95% CI: -3.0%, 2.5%]).

- Juluca is contraindicated in patients with a previous hypersensitivity reaction to Tivicay® (dolutegravir) or Edurant® (rilpivirine); when co-administered with dofetilide; and when co-administrated with drugs where significant decreases in rilpivirine plasma concentrations may occur, which may result in loss of virologic response.

- Other warnings and precautions of Juluca include skin and hypersensitivity reactions, hepatotoxicity, depressive disorders, and risk of adverse reactions or loss of virologic response due to drug interactions.

- The most common adverse reactions (≥ 2%) with Juluca use were diarrhea and headache.

- The recommended dosage of Juluca is one tablet taken orally once daily with a meal. If Juluca is coadministered with rifabutin, patients should take an additional 25-mg tablet of rilpivirine with Juluca once daily with a meal for the duration of the rifabutin co-administration.

- ViiV Healthcare plans to launch Juluca on December 11, 2017. Juluca will be available as a tablet that contains 50 mg of dolutegravir and 25 mg of rilpivirine.