Prezista® (darunavir) – Expanded Indication

- On July 18, 2016, Janssen Therapeutics announced the FDA approval of an expansion to the prescribing information for Prezista (darunavir) to include dosing recommendations for pregnant women with human immunodeficiency virus (HIV-1) and results from a study investigating the use of Prezista during pregnancy and the postpartum period.

- Prezista, co-administered with Norvir® (ritonavir), in combination with other antiretroviral (ARV) agents, is indicated for the treatment of HIV-1 infection in adult and pediatric patients 3 years of age and older.

- Approximately 8,500 women living with HIV give birth annually. Mother-to-child HIV transmission is the most common way young children become infected with HIV.

- The expanded indication for Prezista is based on an analysis of 34 pregnant women and available data from the antiretroviral pregnancy registry (APR).

    - Pharmacokinetic data demonstrate that exposure to darunavir and ritonavir at either 600 mg/100 mg twice daily or 800 mg/100 mg once daily as part of an ARV regimen was lower during pregnancy compared with the postpartum period.
    - Virologic response was preserved throughout the trial in both arms.
    - No mother to child transmission occurred in the infants born to the 29 patients who stayed on the ARV treatment through delivery.
    - Based on reports to the APR, there was no difference in rate of overall birth defects for darunavir compared with the background rate for major birth defects in a U.S. reference population.

- The recommended dose of Prezista in pregnant women is 600 mg taken orally with ritonavir 100 mg twice daily with food.

    - Prezista 800 mg taken with ritonavir 100 mg once daily should only be considered in certain pregnant patients who are already on a stable Prezista 800 mg with ritonavir 100 mg once daily regimen prior to pregnancy, are virologically suppressed (HIV-1 RNA < 50 copies/mL), and in whom a change to twice daily Prezista 600 mg with ritonavir 100 mg may compromise tolerability or compliance.

- The Prezista prescribing information should be consulted for dosage recommendations for treatment-naïve and treatment-experienced adults, and pediatric patients.