Sustiva® (efavirenz) – New Warning

- On August 31, 2016, the FDA approved a new update to the *Warnings and Precautions* section of the Sustiva (efavirenz) drug label, regarding QTc interval prolongation.
- Sustiva is a non-nucleoside reverse transcriptase inhibitor indicated in combination with other antiretroviral agents for the treatment of human immunodeficiency virus type 1 infection in adults and in pediatric patients at least 3 months old and weighing at least 3.5 kg.
- The effect of Sustiva on the QTc interval was evaluated in an open-label, placebo-controlled study in 58 healthy subjects enriched for CYP2B6 polymorphisms.
    - A positive relationship between Sustiva concentration and QTc prolongation was observed.
- Alternatives to Sustiva should be considered when co-administered with a drug with a known risk of torsade de pointes or when administered to patients at higher risk of torsade de pointes.
- Other warnings and precautions of Sustiva include drug interactions, resistance, co-administration with related products, psychiatric symptoms, nervous system symptoms, embryo-fetal toxicity, rash, hepatotoxicity, convulsions, lipid elevations, immune reconstitution syndrome, and fat redistribution.
- In addition, the Sustiva drug label has been updated with information regarding interactions with QT prolonging drugs and other classes of drugs, and the *Clinical Pharmacology* section has been updated with details about Sustiva's effects on cardiac electrophysiology.