Tivicay® (dolutegravir) – Expanded indication, new warnings

- On November 21, 2017, the FDA approved Tivicay for use in combination with rilpivirine as a complete regimen to replace the current antiretroviral (ART) regimen in those who are virologically suppressed (HIV-1 RNA < 50 copies/mL) on a stable ART regimen for at least 6 months with no history of treatment failure or known substitutions associated with resistance to either antiretroviral. This update was made for consistency with the new Juluca drug approval.

- The *Warnings and Precautions* section of the Tivicay drug label was updated to include hepatotoxicity and risk of adverse reactions or loss of virologic response due to drug interactions.