Delstrigo® (doravirine/lamivudine/tenofovir disoproxil fumarate) – Expanded indication

- On September 19, 2019, the FDA approved Merck's Delstrigo (doravirine/lamivudine/tenofovir disoproxil fumarate [TDF]), as a complete regimen for the treatment of human immunodeficiency virus (HIV)-1 infection in adult patients 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 history of treatment failure and no known substitutions associated with resistance to the individual components of Delstrigo.

- Delstrigo is also approved as a complete regimen for the treatment of HIV-1 infection in adult patients with no antiretroviral treatment history.

- The expanded indication for Delstrigo was approved based on the open-label DRIVE-SHIFT study enrolling 670 adult patients with virologically-suppressed HIV-1. Patients were randomized to either switch to Delstrigo at baseline (Immediate Switch Group [ISG]), or stay on their baseline regimen until week 24, at which point they switched to Delstrigo (Delayed Switch Group [DSG]).

    — Based on HIV-1 RNA $\geq$ 50 copies/mL, the ISG group was shown to be non-inferior to the DSG group (2% vs. 1%, difference = 0.7%; 95% CI: -1.3, 2.6).

- Delstrigo carries a boxed warning for post-treatment acute exacerbation of hepatitis B.

- The recommended dose of Delstrigo for either indication in adults is one tablet of the fixed-dose combination product containing 100 mg of doravirine, 300 mg of lamivudine, and 300 mg of TDF, orally once daily with or without food.