Pifeltro® (doravirine) – Expanded indication

- On September 19, 2019, the FDA approved Merck's Pifeltro (doravirine), in combination with other antiretroviral agents 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 doravirine.

- Pifeltro is also approved in combination with other antiretroviral agents for the treatment of HIV-1 infection in adult patients with no prior antiretroviral treatment history.

- The expanded indication for Pifeltro 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® (doravirine/lamivudine/tenofovir disoproxil fumarate) 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 the percentage of patients with 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).

- The recommended dose of Pifeltro for either indication in adults is one 100 mg tablet orally once daily with or without food