Pifeltro™ (doravirine), Delstrigo™ (doravirine/lamivudine/tenofovir disoproxil fumarate) – Expanded indications

- On January 27, 2022, the FDA approved Merck's Pifeltro (doravirine) and Delstrigo (doravirine/lamivudine/tenofovir disoproxil fumarate), for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 35 kg:
    - With no prior antiretroviral treatment history; or
    - To replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies/mL) on a stable antiretroviral regimen with no history of treatment failure and no known substitutions associated with resistance to doravirine or to the individual components of Delstrigo.
- Pifeltro is approved for use in combination with other antiretroviral agents and Delstrigo is a complete regimen for treatment of HIV-1 infection.
- Pifeltro and Delstrigo were previously approved for this indication in adult patients only.
- The approval of Pifeltro and Delstrigo for the expanded indications were based on data from an open-label, single-arm, two-cohort study in HIV-1-infected pediatric patients 12 to less than 18 years of age. In cohort 1, virologically-suppressed patients (n = 9) received a single 100 mg dose of Pifeltro followed by intensive pharmacokinetic sampling. In cohort 2, virologically-suppressed patients (n = 43) were switched to Delstrigo and treatment-naïve subjects (n = 2) were started on Delstrigo.
    - After switching to Delstrigo, 95% (41/43) of virologically-suppressed patients remained suppressed (HIV-1 RNA < 50 copies/mL) at week 24.
    - One of the two treatment-naïve patients achieved HIV-1 RNA < 50 copies/mL at week 24. The other treatment-naïve patient met the protocol-defined virologic failure criteria (defined as 2 consecutive plasma HIV-1 RNA test results ≥ 200 copies/mL at or after week 24) and was evaluated for the development of resistance; no emergence of genotypic or phenotypic resistance to doravirine, lamivudine, or tenofovir was detected.
- Delstrigo carries a boxed warning for posttreatment acute exacerbation of hepatitis B.
- The recommended dosage regimen of Pifeltro in adults and pediatric patients weighing at least 35 kg is one 100 mg tablet taken orally once daily.
- Delstrigo is a fixed-dose combination product containing 100 mg of doravirine, 300 mg of lamivudine, and 300 mg tenofovir disoproxil fumarate. The recommended dosage in adults and pediatric patients weighing at least 35 kg is one tablet taken orally once daily.