FDA Approves Merck’s Delstrigo and Pifeltro to Treat HIV

Delstrigo (doravirine/lamivudine/tenofovir disoproxil fumarate) includes Pifeltro (doravirine) in a three-drug single-tablet regimen.

August 30, 2018 By Benjamin Ryan

The Food and Drug Administration (FDA) has approved Merck’s Pifeltro (doravirine), a new non-nucleoside reverse transcriptase inhibitor (NNRTI), as well as Delstrigo (doravirine/lamivudine/tenofovir disoproxil fumarate), which includes Pifeltro in a three-drug, single-tablet antiretroviral (ARV) regimen. Both tablets are indicated for the treatment of HIV among those beginning an ARV regimen for the first time. Pifeltro should be taken in combination with other HIV medications.

The approval of both tablets is based upon the randomized, multicenter, double-blind, active-controlled Phase III trials DRIVE-AHEAD and DRIVE-FORWARD.

DRIVE-AHEAD included 728 people not previously treated for HIV who were randomized to receive either Delstrigo or Atripla (efavirenz/tenofovir disoproxil fumarate/emtricitabine). After 48 weeks of treatment, viral suppression rates were comparable between the two study groups, indicating that Delstrigo was noninferior to, or as effective as, Atripla.

Those receiving Delstrigo had superior results compared with those receiving Atripla with regard to LDL cholesterol and non-HDL cholesterol, although the trial did not demonstrate a clinical benefit of this difference. Those taking Delstrigo also had lower rates of neuropsychiatric adverse health events, including dizziness, sleep problems and an altered ability to think clearly and concentrate.

Those receiving Delstrigo had a lower rate of stopping treatment, at 3 percent, compared with those on Atripla, at 6 percent.

Adverse health events reported by at least 5 percent of those receiving Delstrigo included dizziness (7 percent), nausea (5 percent) and abnormal dreams (5 percent).

The DRIVE-FORWARD trial included 766 people with HIV who had not yet been treated with ARVs. They were randomized to receive Pifeltro or Norvir (ritonavir)-boosted Prezista (darunavir) plus Truvada (tenofovir disoproxil fumarate/emtricitabine) or Epzicom (abacavir/lamivudine). Just as

with the DRIVE-AHEAD study, viral suppression rates were comparable after 48 weeks between the two study groups, indicating the Pifeltro-based regimen's noninferiority to the boosted-Prezista regimen.

Similar to the outcomes in DRIVE-AHEAD, both LDL cholesterol and non-HDL cholesterol outcomes were favorable among those who received Pifeltro compared with those on Prezista; DRIVE-FORWARD did not demonstrate a clinical benefit of these differences either.

Two percent of those who received Pifeltro stopped treatment, as did 3 percent of those who received Prezista. Adverse health events reported by at least 5 percent of those receiving Pifeltro included nausea (7 percent), headache (6 percent), fatigue (6 percent), diarrhea (5 percent) and abdominal pain (5 percent).

To read a press release about the FDA approval, click here.

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