FDA OKs Delstrigo and Pifeltro

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

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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 was based upon a pair of randomized double-blind controlled trials that together included 1,500 newcomers to HIV treatment.

One trial compared Delstrigo with Atripla (efavirenz/tenofovir disoproxil fumarate/emtricitabine), while another trial randomized participants to receive Pifeltro or Norvir (ritonavir)-boosted Prezista (darunavir), each paired with Truvada (tenofovir disoproxil fumarate/emtricitabine) or Epzicom (abacavir/lamivudine). In both trials, Delstrigo and Pifeltro-based regimens proved as effective at suppressing HIV as the comparison regimens.

Delstrigo and Pifeltro, however, bested the other regimens with regard to study participants' LDL cholesterol and non-HDL cholesterol. Compared with those who received Atripla, those taking Delstrigo also had lower rates of adverse neuropsychiatric health events, including dizziness, sleep problems and an altered ability to think clearly and concentrate.

"I consider doravirine (Pifeltro) to be the best in the NNRTI class. Its higher genetic barrier and lack of central nervous system side effects make it a viable treatment option for persons living with HIV," says Antonio Urbina, MD, an HIV specialist at Mount Sinai Hospital in New York City. Delstrigo's arrival, he says, marks the first time the U.S. treatment guidelines "include a regimen that includes generic antivirals, a possible tipping point in the landscape for use of generic [antiretrovirals] in the future."

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