FDA Approves Delstrigo and Pifeltro as Switch Options for People With HIV

These medications can now be used by people on stable antiretroviral treatment with undetectable viral load.

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The Food and Drug Administration (FDA) has approved expanded indications for Merck's Delstrigo and Pifeltro as switch options for people with HIV who currently have full viral suppression on their current regimen. The new approvals come a year after the medications were initially approved as first-line treatment for people newly diagnosed with the virus.

Pifeltro is a stand-alone tablet containing the next-generation non-nucleoside reverse transcriptase inhibitor (NNRTI) doravirine. It must be taken with other antiretrovirals. Delstrigo is a single-tablet regimen that contains doravirine plus tenofovir disoproxil fumarate (TDF) and lamivudine, offering a complete regimen in a single once-daily pill.

The new approval is for adults currently on stable antiretroviral therapy with an undetectable viral load (below 50 copies), no prior history of treatment failure and no known resistance to doravirine or the other drugs in Delstrigo.

The approval was based on results from the Phase III DRIVE-SHIFT trial, which enrolled 670 people on stable antiretroviral therapy containing a boosted protease inhibitor, a NNRTI or the boosted integrase inhibitor elvitegravir who had full viral suppression for at least six months.

Study participants were randomly assigned to switch to Delstrigo immediately or after a six-month delay. The immediate group had 48 weeks of follow-up and the delayed group had 24 weeks of follow-up.

At 24 weeks, 93.7% of people in the immediate Delstrigo group had undetectable viral load, compared with 94.6% of those who stayed on their current regimen. Among those who took Delstrigo for the full 48 weeks, 90.8% maintained viral suppression. Rates of virologic treatment failure were low (below 2%) in both groups, and no one who took Delstrigo developed drug resistance.

Treatment with Delstrigo was safe and well tolerated, and just 1.6% of people stopping the medication because of side effects. Blood lipid levels were more favorable among those taking

Delstrigo. LDL cholesterol and triglyceride levels decreased when people switched, while remaining stable among those who stayed on their existing regimen.

The TDF and lamivudine in Delstrigo are also active against hepatitis B virus (HBV), and stopping them may lead to worsening hepatitis. People with HIV and HBV coinfection should be closely monitored when they discontinue Delstrigo. Delstrigo contains the older TDF version of tenofovir; people at risk for kidney or bone problems may instead use Pifeltro with Descovy, which contains the safer updated tenofovir alafenamide (TAF).

“Thanks to developments in HIV science, more treatment options are becoming available to address the medical needs of people living with HIV,” DRIVE-SHIFT researcher Princy Kumar, MD, of Georgetown University School of Medicine in Washington, D.C., said in a Merck press release. “The expanded indications offer certain people with HIV-1 infection, and their doctors, the choice to switch their current antiretroviral therapy to Delstrigo or Pifeltro in combination with other antiretroviral agents.”

Click here for full prescribing information for Delstrigo.

Click here for full prescribing information for Pifeltro.

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