Merck’s Experimental HIV Drug Doravirine Posts Promising 96-Week Results

Compared with a regimen based on Prezista, doravirine was better for blood lipids, including cholesterol and triglycerides.

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Doravirine, the experimental antiretroviral developed by Merck, suppressed HIV at a higher rate compared with Norvir (ritonavir)-boosted Prezista (darunavir) 96 weeks into a clinical trial that pitted the two medications against each another. Additionally, regimens based on doravirine, a non-nucleoside reverse transcriptase inhibitor (NNRTI), were associated with much better blood lipid outcomes, including cholesterol and triglycerides, compared with regimens based on Prezista.

Merck applied in January to the Food and Drug Administration (FDA) for approval of doravirine, based on findings from the DRIVE-AHEAD and DRIVE-FORWARD studies of the medication. Findings from DRIVE-AHEAD were presented at the 9th International AIDS Society Conference on HIV Science in Paris (IAS 2017). Forty-eight-week data from DRIVE-FORWARD were presented at 2018 Conference on Retroviruses and Opportunistic Infections (CROI) in Boston. That phase of the study indicated that doravirine-based regimens were noninferior to, or as effective as, Norvir-boosted-Prezista–based regimens.

Researchers presented 96-week findings from the multicenter double-blind randomized noninferiority Phase III DRIVE-FORWARD study at International AIDS Conference in Amsterdam (AIDS 2018).

The study included 766 people with HIV who had not previously been treated for the virus. They were evenly randomized to receive either doravirine or Norvir-boosted Prezista, each in combination with Truvada (tenofovir disoproxil fumarate/emtricitabine) or Epzicom (abacavir/lamivudine).

At the 96-week mark, 73.1 percent (277 of 379) of those in the doravirine group had a fully suppressed viral load (a viral load below 50) compared with 66 percent (248 of 376) of those in the Prezista group. This difference was statistically significant, meaning it is unlikely to have been driven by chance. That said, because the study was not designed as a superiority trial, doravirine cannot claim official bragging rights over Prezista as more effective at suppressing HIV.

Looking just at the participants who started the trial with a viral load above 100,000, the researchers found that 65.4 percent (51 of 78) of those on doravirine and 65.2 percent (43 of 66) of those on Prezista had a fully suppressed virus after 96 weeks. This difference was not statistically significant.

The average change in CD4 count during the study from its baseline to the 96-week mark was a gain of 224 cells in the doravirine group and 207 cells in the Prezista group, a difference that was not statistically significant.

Two people in the doravirine group developed resistance to the drug by the 96-week point.

The most common side effects, occurring among 10 percent or more of each study group, were, among those on doravirine and Prezista respectively, diarrhea (17 percent and 23.8 percent), nausea (11.7 percent and 13.6 percent), headache (14.9 percent and 12 percent), upper respiratory tract infection (13.3 percent and 7.8 percent) and viral upper respiratory tract infection (11.5 percent and 13.1 percent).

A total of 1.6 percent (6 of 383) of those in the doravirine group and 3.4 percent (13 of 383) of those in the Prezista group discontinued treatment because of adverse health events.

After 96 weeks of treatment, the average changes since the study's outset in fasting serum blood lipids in the doravirine and Prezista groups, respectively, was a 0.4 milligrams per deciliter decline and a 14 mg/dL increase in LDL cholesterol; a 0.5 mg/dL decline and a 17.7 mg/dL increase in non-HDL cholesterol; a 4.1 mg/dL increase and a 21.9 mg/dL increase in total cholesterol; a 4.5 mg/dL increase and 4.2 mg/dL increase in HDL cholesterol; and a 1.1 mg/dL decline and a 22.5 mg/dL increase in triglycerides. All these differences between the two study groups were statistically significant except for that pertaining to HDL cholesterol.

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