Merck Applies to FDA for Approval of New HIV Med Doravirine

The new drug application is for doravirine as both an individual tablet and part of a combination tablet.

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Merck has filed a pair of new drug applications (NDAs) with the Food and Drug Administration (FDA) for approval of its investigational antiretroviral doravirine as a component of a combination regimen for the treatment of HIV. One application is for the non-nucleoside reverse transcriptase inhibitor doravirine as an individual tablet; the other NDA is for a fixed-dose combination tablet of doravirine, Epivir (lamivudine) and Viread (tenofovir disoproxil fumarate).

The applications are based on the week 48 findings of two ongoing Phase III trials: DRIVE-FORWARD and DRIVE-AHEAD.

DRIVE-FORWARD is a multicenter, double-blind randomized noninferiority trial including 769 adults who had not yet been treated for HIV upon entering the study. They received either doravirine or Norvir (ritonavir)-boosted Prezista (darunavir) plus either Truvada (tenofovir disoproxil fumarate/emtricitabine) or Epzicom (abacavir/lamivudine). The study primarily looked at the rate of participants who had a fully suppressed viral load—less than 50—by week 48. Findings presented at 2017 Conference on Retroviruses and Opportunistic Infections (CROI) in Seattle in February of that year indicated that doravirine was as effective at suppressing HIV as Norvir-boosted Prezista.

DRIVE-AHEAD a Phase III multicenter, double-blind randomized active comparator-controlled clinical trial in which 728 participants starting their first HIV regimen receive a fixed-dose combination tablet of doravirine, Epivir and Viread or Atripla (efavirenz/tenofovir/emtricitabine). The study had the same primary-outcome focus as DRIVE-FORWARD. According to 48-week results presented at the 9th International AIDS Society Conference on HIV Science in Paris (IAS 2017) in July 2017, the tablet containing doravirine was safer and was associated fewer side effects than Atripla.

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

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