Merck’s Doravirine Treats HIV as Well as Norvir-Boosted Prezista

Used as a part of a multidrug HIV regimen, the investigational doravirine is also better for cholesterol levels than Norvir/Prezista.

February 14, 2017

When used as a part of a combination antiretroviral (ARV) regimen, Merck’s investigational doravirine suppresses HIV as effectively as Norvir (ritonavir)-boosted Prezista. The non-nucleoside reverse transcriptase inhibitor doravirine is also better for cholesterol levels than the booster Norvir plus the protease inhibitor Prezista.

Researchers in the ongoing multicenter, double-blind, non-inferiority Phase III DRIVE-FORWARD trial presented interim findings about the 48-week data on 766 HIV-positive individuals (out of 769 who began the study) who were new to treatment and had a viral load of at least 1,000. The participants were randomized evenly to receive either doravirine or boosted Prezista along with the investigators’ choice of either Truvada (tenofovir disoproxil fumarate/emtricitabine) or Epzicom (abacavir/lamivudine) for up to 96 weeks.

Kathleen Squires, MD, a professor of medicine and director of the division of infectious diseases at Thomas Jefferson University, presented findings from the study at the 2017 Conference on Retroviruses and Opportunistic Infections (CROI) in Seattle.

A previous Phase IIb study found that doravirine had similar efficacy to Sustiva (efavirenz) and a considerably more favorable side-effect profile.

The participants included in the 48-week analysis of the DRIVE-FORWARD had an average age of 35.2 and were 84 percent male and 73 percent white. Eighty-seven percent of them took Truvada and the remaining 13 percent took Epzicom.

At the 48-week point, 83.8 percent (321 of 383) of those who took doravirine and 79.9 percent (306 of 383) of those who took boosted Prezista had an undetectable viral load. Consequently, the investigators judged doravirine non-inferior to boosted Prezista, which essentially means the two have comparable efficacy.

Among the approximately 20 percent of the participants who started the trial with a viral load greater than 100,000, 81 percent (64 of 79) of those who took doravirine and 76.4 percent (55 of

72) of those who took boosted Prezista had an undetectable viral load at week 48.

The rates of adverse health events were similar between the two study arms. The most common adverse side effects for those who took doravirine or boosted Prezista were diarrhea (5.5 percent versus 12.8 percent), nausea (6.5 percent versus 7.6 percent) and headache (6 percent versus 2.6 percent).

The levels of fasting LDL and non-HDL cholesterol dropped a respective 4.5 and 5.3 points among those on doravirine while rising a respective 9.9 and 13.8 points among those on boosted Prezista, a respective 14.6- and 19.3-point difference.

A respective 19 (5 percent) and 24 (6) percent of those in the doravirine and boosted Prezista arms developed treatment-emergent drug resistance.

A respective 117 (31 percent) and 123 (32 percent) of participants in the doravirine and boosted Prezista arms experienced a drug-related adverse health event, including a respective 19 (5 percent) and 23 (6 percent) who experienced a serious adverse event. A respective six (2 percent) and 12 (3 percent) dropped out of the study because of adverse events.

The most common adverse events for those taking doravirine and boosted Prezista, occurring in at least 10 percent of participants, were: diarrhea (a respective 14 percent and 22 percent); headache (14 percent versus 11 percent); nausea (11 percent versus 12 percent) and common-cold symptoms (8 percent versus 10 percent).

Doravirine is currently being studied in multiple Phase II and III trials as part of a single-tablet regimen including components of Descovy (emtricitabine/tenofovir alafenamide).

To read a press release about the study, click here.
