Janssen’s Prezista-Based Regimen Symtuza Suppresses HIV Well

Results from a Phase III trial showed Symtuza worked as well as a boosted protease inhibitor-–based antiretroviral regimen.

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Results from an advanced trial of Janssen’s Symtuza (darunavir/cobicistat/emtricitabine/tenofovir alafenamide) indicate that the single-tablet combination antiretroviral (ARV) regimen suppresses HIV as well as a boosted protease inhibitor–based regimen.

Janssen filed for Food and Drug Administration (FDA) approval of Symtuza (as the drug is called in Europe, where it is already approved) in September.

Results from the Phase III EMERALD study of Symtuza were published in The Lancet HIV and also presented at the IDWeek 2017 conference in San Diego. The study was a randomized, open-label, international, multicenter, parallel-group, noninferiority 48-week study evaluating the efficacy and safety of switching from Symtuza compared with staying on a boosted protease inhibitor–based regimen.

The boosted protease inhibitor regimens included: Kaletra (lopinavir/ritonavir); or Reyataz (atazanavir) or Prezista (darunavir) boosted by either Norvir (ritonavir) or Tybost (cobicistat). They were combined with Truvada (tenofovir disoproxil fumarate/emtricitabine).

The study enrolled 1,141 people with HIV who were on one of the aforementioned regimens and who had a viral load below 50 for at least two months and had had no more than one viral load between 50 and 199 during the 12 months prior to enrollment. None of the participants had a history of virologic failure on Prezista, and among those for whom such genetic analysis of their virus was available, none had viral mutations associated with resistance to the ARV.

EMERALD’s primary focus was the cumulative proportion of participants in each arm of the study who experienced virologic rebound during the 48-week period, defined as a viral load of 50 or above or stopping treatment prematurely with a last viral load above that threshold. To be considered noninferior, or as good as, the boosted protease inhibitor–based regimens, Symtuza needed to have a cumulative virologic rebound rate no greater than 4 percent higher than the other regimens.

A total of 763 people were randomized to receive Symtuza while 378 were randomized to the control group to stay on their boosted protease inhibitor–based regimens.

Through 48 weeks of treatment, 2.5 percent of those who received Symtuza experienced virologic rebound, compared with 2.1 percent of the control group. This meant that Symtuza did prove noninferior to the other regimens. Twelve of the 19 people who experienced virologic rebound on Symtuza ultimately got back to an undetectable status during the study, as did four out of the eight people with virologic rebound in the control group.

At the 48-week point, 94.9 percent of those in the Symtuza group and 93.7 percent in the control group had an undetectable viral load. A respective 0.8 percent and 0.5 percent of the study arms experienced virologic failure. No one in the study stopped treatment because of virologic failure, and the researchers detected no emerging drug resistance among the participants.

Among those in the Symtuza and control groups, a respective 1.4 percent and 1.3 percent discontinued treatment because of adverse events; a respective 6.8 percent and 8.2 percent experienced grade 3 to 4 adverse health events; and a respective 4.6 percent and 4.8 percent experienced serious adverse health events. No one died during the study. The most common adverse events in both study arms were head cold symptoms, upper respiratory tract infection and diarrhea.

To read the study abstract, click here.

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