Janssen's Experimental Symtuza Performs Well in Those New to HIV Meds

A new large study compared the single-tablet regimen with an equivalent containing a different version of tenofovir.

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Janssen's Symtuza (darunavir/cobicistat/emtricitabine/tenofovir alafenamide), which if approved will become the first single-tablet antiretroviral (ARV) regimen including a boosted protease inhibitor, is safe and effective for the treatment of HIV among those new to treatment, Medscape reports. In a study that compared Symtuza with a multitablet regimen that contained the same ARVs but a different version of tenofovir was also associated with better markers of bone and kidney health.

The 48-week, randomized, controlled Phase III AMBER study of 725 people new to ARV treatment was presented at the 16th European AIDS Conference in Milan.

This presentation closely followed the release of similarly positive results from the Phase III EMERALD study of Symtuza among those who were already on ARV treatment before switching to the regimen.

In September, Janssen applied for Food and Drug Administration (FDA) approval of Symtuza, based on the findings from AMBER and EMERALD. A decision is expected by June 2018.

In AMBER, 362 people were randomized to receive Symtuza and 363 were randomized to the control group. Those in the control group received Prezista (darunavir), Tybost (cobicistat) and Truvada (tenofovir disoproxil fumarate/emtricitabine) as three individual tablets.

The tenofovir disoproxil fumarate, or TDF, component of Truvada is an older version of tenofovir compared with the tenofovir alafenamide, or TAF, component of Symtuza. Numerous studies have indicated that TAF is associated with improved markers of bone and kidney health compared with TDF. A major outstanding question, however, is whether TAF, compared with TDF, will actually prevent clinically significant health outcomes on these measures, including fractures and kidney disease.

After 48 weeks of treatment, 91.4 percent of those in the Symtuza group had an undetectable viral load compared with 88.4 percent of those in the control group. Based on preset criteria, this meant that Symtuza was non-inferior to (as effective as) the control regimen. The respective regimens were also associated with a similar rise in average CD4 count: 171 versus 158.

Although one participant developed a viral mutation associated with resistance to emtricitabine, none of the other study members showed signs of resistance to any of the other medications included in the regimens.

The control group had a higher rate of virologic failure, at 4.4 percent, compared with the 3.3 percent rate in the Symtuza group.

Both regimens were well tolerated. No participants died during the study. The respective rates of those who discontinued treatment because of serious adverse health events in the Symtuza and control groups were 4.7 percent and 5.8 percent. The most common adverse health events in both arms were diarrhea, rash and nausea.

Those in the control group developed more adverse measures in markers of bone and kidney health compared with those in the Symtuza group. However, the markers for lipids (fats in the blood, including cholesterol) were better in the control group.

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