2-Drug Regimen Is Comparably Effective to 3-Drug Treatment

Updating previous, similar findings, researchers have now reported on 96-week data from a pair of ongoing trials.

August 5, 2019 By Benjamin Ryan

ViiV Healthcare's two-antiretroviral (ARV) HIV regimen of Tivicay (dolutegravir) plus lamivudine—the drugs in the recently approved Dovato combination pill—suppresses HIV at a rate comparable to the three-ARV regimen of Tivicay plus Truvada (tenofovir disoproxil fumarate/emtricitabine) after 96 weeks among people not previously treated for the virus, aidsmap reports.

At the 10th International AIDS Society Conference on HIV Science (IAS 2019) in Mexico City, Pedro Cahn, MD, of Fundación Huésped in Buenos Aires, presented updated findings from the ongoing pair of identical Phase III trials, called GEMINI 1 and 2.

Findings from the Phase III TANGO trial of people switching to Dovato from a previous regimen were also presented at the conference.

Between them, GEMINI 1 and 2 enrolled 1,433 people with HIV in Europe, North and South America, Asia, Australia, Russia and South Africa. The participants were all first-timers to ARV treatment.

About 85% of the participants were men, and two out of three were white. The median age was 32 years old. Upon enrolling in the study, 80% had a viral load no higher than 100,000, and the remainder had a viral load between 100,000 and 500,000. More than 90% had a CD4 count greater than 200.

The participants were randomized to receive Tivicay plus either lamivudine or Truvada and were scheduled to remain in follow-up for 144 weeks.

The studies' pooled 48-week results were presented a year ago at the International AIDS Conference in Amsterdam (AIDS 2018). At that time, 91.5% of those in the Tivicay plus lamivudine group and 93.3% of those in the Tivicay plus Truvada group had a fully suppressed viral load (below 50). This meant that the two-drug regimen was comparably effective, or noninferior, to the three-drug regimen. Less than 1% of the members of each study group experienced virologic

failure.

Viral suppression rates remained comparable between the two study arms regardless of whether participants began the study with a viral load below or above 100,000.

Cahn presented 96-week findings from GEMINI 1 and 2 in Mexico City, reporting that at this point in the study, 86.0% of those in the Tivicay plus lamivudine group and 89.5% of those in the Tivicay plus Truvada group had an undetectable viral load.

When the investigators counted treatment-related discontinuation of an assigned ARV regimen as a treatment failure but did not include in this category discontinuation due to other causes, a respective 96.7% and 96.4% of those receiving the two- and three-drug regimens had a fully suppressed viral load 96 weeks into the studies.

Eleven people in the two-drug group and seven in the three-drug group experienced virologic withdrawal. None of them developed drug resistance related to the regimens studied in these trials.

The regimens proved generally safe and well tolerated. The most common adverse health events included headache, diarrhea, sore throat and upper respiratory tract infections. Among those in the two- and three-drug groups, a respective 20% and 25% experienced drug-related adverse health events—a statistically significant difference, meaning it is unlikely to have been driven by chance. Nine percent of the members of each group experienced serious adverse health events, and 3% in each group withdrew from the studies because of adverse health events.

Two people in the two-drug group and seven of those in the three-drug group discontinued treatment owing to kidney-related health events. The tenofovir disoproxil fumarate (TDF) in Truvada is associated with kidney toxicity.

Those receiving Tivicay plus Truvada tended to have better shifts in blood lipid levels compared with those receiving Tivicay plus lamivudine. That said, both groups experienced improvements in their HDL cholesterol ratio.

Less than 2% of the members of each group reported weight gain as an adverse health event, a growing concern with Tivicay.

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