ViiV's 2-Drug Regimen Is on Par With a 3-Drug Combo

Full 48-week results comparing dolutegravir plus lamivudine with a three-drug combo were presented at the International AIDS Conference.

July 31, 2018 By Benjamin Ryan

ViiV Healthcare's experimental two-drug regimen of dolutegravir (sold separately as Tivicay) plus lamivudine (sold alone as Epivir) suppressed HIV as effectively as a three-drug regimen of Tivicay plus tenofovir disoproxil fumarate/emtricitabine (the drugs in Truvada) in an ongoing advanced trial. None of the participants developed drug resistance after one year of treatment.

ViiV intends to seek Food and Drug Administration approval for a fixed-dose combination tablet of dolutegravir plus lamivudine later this year.

[Editor's note: this combination, known as Dovato, was approved on April 8, 2019]

In June, the pharmaceutical company released top-line results from the first year of the ongoing duplicate Phase III randomized, double-blind, multicenter parallel group noninferiority studies known as GEMINI 1 and GEMINI 2. Full 48-week results were presented at the International AIDS Conference in Amsterdam (AIDS 2018).

The studies include people with HIV who had not previously been treated for the virus and who began their participation in either study with a viral load of up to 500,000. A total of 716 people were randomized to receive Tivicay plus lamivudine while 717 people were randomized to receive Tivicay plus Truvada (the latter tablet contains two antiretrovirals).

After 48 weeks of treatment, 91 percent (655 of 716) of those on the two-drug regimen had a fully suppressed viral load, compared with 93 percent (669 of 717) of those on the three-drug regimen. This difference was not statistically significant, meaning it could have been the result of chance. The study authors concluded that the two-drug regimen was noninferior to, or as effective as, the three-drug regimen when it came to suppressing HIV.

The viral suppression results were broadly consistent regardless of participants' initial viral load, specifically when the study authors stratified their analysis based on whether individuals began the study with a viral load greater than 100,000 or a viral load of 100,000 or less.

All the study arms saw a 1 percent or smaller rate of virologic failure. None of the participants who experienced virologic failure developed drug resistance based on the medications they received in the study.

Two percent of each study arm withdrew from the study because of adverse health events, including seven people who received the two-drug regimen in GEMINI 1 and eight people each in the other three groups (those who received the three-drug regimen in GEMINI 1, those who received the two-drug regimen in GEMINI 2 and those who received the three-drug regimen in GEMINI 2).

Pooled results from all the study groups indicated that the most common side effects, reported by at least 5 percent of participants, were headache, diarrhea and the common cold, which occurred in a respective 10 percent, 9 percent and 8 percent in those on the two-drug regimen and a respective 10 percent, 11 percent and 11 percent in those on the three-drug regimen.

Eighteen percent (126 of 716) of those on the two-drug regimen experienced drug-related adverse health events, a rate significantly lower than the 24 percent (169 of 717) seen among those on the three-drug regimen.

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

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