ViiV's Experimental Two-Drug Regimen Shows Promise

The combo of dolutegravir and lamivudine controlled HIV as well as a triple-drug combo of dolutegravir plus Truvada.

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ViiV Healthcare has announced positive results from its advanced clinical trials comparing the two-antiretroviral combination of dolutegravir and lamivudine with a three-ARV combination of dolutegravir plus Truvada (tenofovir disoproxil fumarate/emtricitabine), Reuters reports.

In November 2017, the Food and Drug Administration approved ViiV and Janssen's joint effort, Juluca (dolutegravir/rilpivirine), which became the first two-drug HIV regimen to make it to market. The combination of dolutegravir and lamivudine, which amounts to Triumeq (dolutegravir/abacavir/lamivudine) without the abacavir component, would give ViiV a two-drug single-tablet regimen in which both drugs' patents are held outright by the company.

Dolutegravir is an integrase inhibitor marketed as a stand-alone tablet under the name Tivicay. Lamivudine, which has the brand name Epivir, is a nucleoside/nucleotide reverse transcriptase inhibitor (NRTI).

The duplicate Phase III randomized, double-blind, multicenter, parallel group noninferiority trials known as GEMINI 1 and GEMINI 2 randomized HIV-positive participants who had not been treated for the virus before and who had a viral load below 500,000 to receive either dolutegravir and rilpivirine or dolutegravir and Truvada (tenofovir disoproxil fumarate/emtricitabine).

The studies achieved their primary target, finding that the proportion of each study arm that had a fully suppressed viral load after 48 weeks of treatment was comparable. Consequently, the regimen of dolutegravir and lamivudine was deemed noninferior to, or as effective as, the regimen of dolutegravir and Truvada.

ViiV will present more detailed findings from this study at a future medical conference, presumably the International AIDS Conference in Amsterdam in late July. In the meantime, the pharmaceutical company reported that the safety results for the two-drug regimen were in line with safety reports established in each of the two drugs' labels. Additionally, no study participants who experienced virologic failure on either regimen developed drug resistance driven by their particular regimen.

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

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