ViiV Begins Phase III Trial of Two-Drug HIV Regimen

The trial will test a regimen of Tivicay (dolutegravir) plus Epivir (lamivudine) against Tivicay and Truvada (tenofovir/emtricitabine).

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ViiV Healthcare has announced that it will begin a Phase III trial of a two-drug HIV treatment regimen of Tivicay (dolutegravir) and Epivir (lamivudine) for people who have not been treated for the virus before.

A Phase III trial is the last before a pharmaceutical company can apply for approval to the U.S. Food and Drug Administration (FDA) and other regulatory authorities around the world. If approved, the combination of the integrase strand transfer inhibitor (ISTI) Tivicay and the nucleoside reverse transcriptase inhibitor (NRTI, or nuke) Epivir could be the first antiretroviral regimen to hit the market that contains fewer than three drugs.

The randomized, double-blind trial will include two identical studies, called GEMINI 1 and 2, including about 700 men and women in each trial at research centers in Europe, Central America, South America, North America, South Africa and the Asia Pacific region. The purpose of these studies is to compare the safety, efficacy and tolerability of the two-drug regimen of Tivicay and Epivir compared with the three-drug regimen of Tivicay and Truvada (tenofovir disoproxil fumarate, or TDF/emtricitabine).

In each study, participants will be evenly randomly assigned to receive Tivicay with Epivir or Truvada. The purpose of the study is to determine whether the two-drug regimen is non-inferior—in other words, works as well as—the three-drug regimen after 48 weeks of treatment. The researchers will keep monitoring the participants for 148 weeks total to determine the long-term virus-fighting effects of the treatment as well as the safety and tolerability.

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

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http://beta.docker.poz.com/article/viiv-begins-phase-iii-trial-twodrug-hiv-regimen