First Two-Drug Regimen

September 25, 2017 By Benjamin Ryan

ViiV Healthcare has applied to the Food and Drug Administration (FDA) for approval of the first two-drug antiretroviral (ARV) regimen to treat HIV. In advanced clinical trials, the dual combination of ViiV's integrase strand transfer inhibitor Tivicay (dolutegravir) and Janssen's non-nucleoside reverse transcriptase inhibitor (NNRTI) Edurant (rilpivirine) has proved as effective as three- and four-drug ARV regimens.

The FDA application is for the use of a daily combination tablet of Tivicay and Edurant among people who already have a fully suppressed viral load thanks to effective HIV treatment. The federal agency is expected to issue a decision by January 2018.

ViiV's submission to the FDA is based on findings from a pair of matching Phase III trials that included more than 1,000 participants who had already achieved an undetectable viral load on a three- or four-drug ARV regimen based on an integrase inhibitor, NNRTI or boosted protease inhibitor. The participants were randomized to remain on their original regimen or to switch to Tivicay and Edurant, given as individual tablets.

At the 48-week point, participants in either arm of each study had similar rates of fully suppressed HIV.

"I like the fact that we are looking at using fewer drugs as alternative treatments for HIV," says Antonio E. Urbina, MD, an associate professor of medicine at the Icahn School of Medicine at Mount Sinai Hospital in New York. He notes the new regimen's benefits for older individuals and those looking to avoid nucleoside reverse transcriptase inhibitors, including people with cardiovascular or kidney problems.

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