ViiV Seeks FDA Approval for Two-Drug HIV Treatment

In clinical trials, the single-tablet regimen of Tivicay (dolutegravir) and Epivir (lamivudine) was as effective as a three-drug treatment.

October 18, 2018 By Benjamin Ryan

ViiV Healthcare has applied to the Food and Drug Administration (FDA) for approval of the two-antiretroviral single-tablet regimen of Tivicay (dolutegravir) plus Epivir (lamivudine) for the treatment of HIV.

The application is based on the results of the GEMINI 1 and 2 studies, which included more than 1,400 people with HIV who had viral loads up to 500,000 before starting treatment. Forty-eight-week results from the studies were presented at the International AIDS Conference in Amsterdam (AIDS 2018). By that decisive point in the studies, the two-drug combo was as effective as a three-drug regimen of Tivicay plus Truvada (tenofovir disoproxil fumarate/emtricitabine).

The GEMINI trials are duplicate Phase III randomized, double-blind, multicenter, parallel group noninferiority studies. The trials, which are ongoing and will continue through 148 weeks, are meant to study the efficacy, safety and tolerability of the Tivicay plus Epivir regimen with Tivicay plus Truvada among those new to HIV treatment.

ViiV has submitted along with its application a priority review voucher, which will likely mean that the FDA will issue a decision about the two-drug regimen in six months, or mid-April 2019.

In September, ViiV submitted a marketing authorization for the regimen to the European Medicines Agency.

To read a press release on the new drug application, click here.
