FDA Approves ViiV's Two-Drug Dovato to Treat HIV

Dovato (dolutegravir/lamivudine) is the second approved dual-antiretroviral regimen.

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The Food and Drug Administration (FDA) has approved ViiV Healthcare's fixed-dose, single-tablet regimen Dovato (dolutegravir/lamivudine) to treat HIV among those new to antiretroviral (ARV) therapy whose virus does not have mutations associated with either of the drugs in the combination tablet.

Dovato is the second HIV regimen to be approved that includes just two ARVs rather than three or more, as has been standard. The first two-drug regimen, Juluca (dolutegravir/rilpivirine), got the nod from the FDA in November 2017. Dovato is the first to be approved for people starting HIV treatment for the first time.

Both Dovato and Juluca are based on the integrase inhibitor dolutegravir (sold separately as Tivicay). The lamivudine component of Dovato belongs to the nucleoside/nucleotide reverse transcriptase inhibitor (NRTI) class of ARVs while the rilpivirine component of Juluca is a non-nucleoside reverse transcriptase inhibitor (NNRTI).

Dovato has a black box warning for those with hepatitis B virus (HBV). Consequently, those starting the HIV regimen should receive HBV testing. Because HBV has been shown to develop resistance to the lamivudine component of Dovato, those who are HIV/HBV coinfected and opt to take the HIV regimen are advised to receive additional hep B treatment.

Pregnancy testing is also advised for women of childbearing potential who are considering taking Dovato because the dolutegravir component of the tablet has been associated with a small risk neural tube defects in infants.

The FDA approval of Dovato was based on findings from the randomized, double-blind, controlled Phase III GEMINI-1 and GEMINI-2 trials. Together, the trials included 1,433 first-timers to HIV treatment. They were randomized to receive either the components of Dovato or a three-drug regimen of dolutegravir plus tenofovir disoproxil fumarate/emtricitabine (the drugs in Truvada). The two regimens suppressed HIV at a comparably high rate after 48 weeks.

To read a press release about the FDA approval, click here.