New Two-Drug Regimen

The Food and Drug Administration has approved a new treatment for people living with HIV.

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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 therapy whose virus does not have mutations associated with either of the drugs in the combination tablet.

Dovato, which includes the integrase inhibitor dolutegravir (sold separately as Tivicay) and the nucleoside/nucleotide reverse transcriptase inhibitor (NRTI) lamivudine, is the second HIV regimen to include just two antiretrovirals rather than three or more, as has long been standard. It is the first two-drug regimen for those who have not previously received treatment for the virus.

"As HIV moves firmly into the category of a chronic disease that is medically managed, it makes sense to treat patients with simpler and safer regimens," says Anthony Mills, MD, chief medical officer of the Men's Health Foundation in Los Angeles. "While three drugs were needed in the past to provide durable viral suppression, the evolution of more potent drugs with a higher genetic barrier to the development of resistance has led scientists and clinicians to question this age-old paradigm."

Dovato's approval was based on findings from a pair of randomized, double-blind, controlled Phase III trials that together included 1,433 first-timers to HIV treatment. The participants were randomized to receive either the components of Dovato or a three-drug regimen of Tivicay plus Truvada (tenofovir disoproxil fumarate/emtricitabine). The two regimens suppressed HIV at a comparably high rate after 48 weeks.

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