# First two-drug regimen approved for HIV-1 treatment

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(HealthDay)—The U.S. Food and Drug Administration has announced

the approval of Dovato (dolutegravir and lamivudine), the first approved two-drug, fixed-dose, complete regimen for adults with HIV-1 who have not been previously treated with antiretroviral medication.

Dovato is indicated for patients with no known or suspected substitutions associated with resistance to the drug's individual components. As opposed to the standard-of-care three-drug regimen, Dovato provides patients with the option of a two-drug regimen in a single tablet without the additional toxicity and potential drug interactions carried by a third drug.

Data from two randomized, double-blind, controlled clinical trials demonstrated the efficacy and safety of one daily tablet of Dovato in 1,433 HIV-infected adults who had no history of antiretroviral treatment. Researchers found that a regimen of dolutegravir and lamivudine similarly reduced the amount of HIV in the blood compared with a drug regimen of dolutegravir, emtricitabine, and tenofovir. Treatment was successful if patients maintained less than 50 copies/mL of HIV RNA in their blood for at least 48 weeks. Commonly reported adverse reactions included headache, diarrhea, nausea, insomnia, and fatigue.

Patients should not use Dovato from conception through the first trimester of pregnancy because of a known risk for neural tube defects with dolutegravir. The boxed warning on the Dovato labeling indicates that patients who have both HIV and hepatitis B should add treatment for hepatitis B or consider a different drug regimen. Patients infected with both HIV and hepatitis B who take lamivudine-containing products have developed resistance to lamivudine and may have severe liver problems when they cease taking these drugs. Patients with both HIV and hepatitis B who stop taking Dovato should be closely monitored.

Approval of Dovato was granted to ViiV Healthcare.

**More information:** More Information