

Two-Drug Regimen Works Well for People With Advanced HIV

Additional data show Dovato (dolutegravir/lamivudine) is also a feasible option when drug-resistance testing is unavailable.

November 13, 2024 By [Liz Highleyman](#)

Dovato, a single-tablet regimen containing dolutegravir and lamivudine, can be a good option for people starting antiretroviral therapy for the first time with a CD4 T-cell count of 200 or lower, according to data presented this week at the [HIV Drug Therapy](#) meeting in Glasgow.

“It’s encouraging to see additional new data that continue to support the efficacy and safety of two-drug regimens compared to traditional three-drug regimens,” Pedro Cahn, MD, PhD, scientific director of Fundación Huésped in Buenos Aires, said in a [news release](#). “The results from DOLCE provide health care providers with further confidence in prescribing [dolutegravir/lamivudine] and are important findings for people living with HIV taking medicines to suppress their virus.”

ViiV Healthcare’s Dovato is currently approved by the Food and Drug Administration (FDA) for people who have never received HIV treatment and for those who are switching from another stable antiretroviral regimen with viral suppression, no history of treatment failure and no known viral mutations associated with resistance to dolutegravir or lamivudine.

The Phase IV DOLCE trial ([NCT04880395](#)) assessed the efficacy of Dovato for previously untreated adults with a CD4 count below 200, meaning they have advanced immune suppression and meet the criteria for an AIDS diagnosis. The 230 participants in this open-label study, recruited at 11 sites across Argentina and Brazil, had no known antiretroviral resistance and did not have hepatitis B virus coinfection.

The participants were randomly assigned in a 2:1 ratio to receive either Dovato or dolutegravir (Tivicay) plus tenofovir disoproxil fumarate/emtricitabine (the drugs in Truvada) or tenofovir alafenamide/emtricitabine (the drugs in Descovy).

The regimens showed comparable effectiveness at 48 weeks: 82% of people in the Dovato group and 80% of those taking a three-drug regimen had an undetectable viral load (below 50). The time to viral suppression and CD4 cell recovery (gains of 200 versus 177 cells, respectively) were also similar. Among people with a high baseline viral load (above 500,000 copies), 74% in the Dovato group and 67% in the three-drug group achieved viral suppression. A post-hoc analysis found that

Dovato was noninferior to triple therapy.

Treatment was safe and well tolerated. Rates of serious adverse events and immune reconstitution inflammatory syndrome (worsening opportunistic infection symptoms as the immune system recovers) were similar across groups. More people discontinued treatment in the Dovato group (13% versus 7%), but the difference was not statistically significant.

In another Phase IV trial, researchers assessed the safety and efficacy of Dovato for previously untreated people with no available baseline HIV resistance results. The FDA indication for Dovato is limited to people with “no known substitutions associated with resistance to the individual components,” but resistance testing may not be widely available in resource-limited settings.

Participants in the D2ARLING study ([NCT04549467](#)) were randomly assigned to receive Dovato or the same three-drug regimens used in DOLCE. Genotypic resistance testing was done at the start of the trial, but results were blinded and not used to guide drug selection. At 48 weeks, Dovato was found to be noninferior to triple therapy, confirming that it is a feasible option when resistance testing is unavailable.

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