FDA Approves Dovato as HIV Switch Option

The single-tablet regimen is now approved for previously treated people with an undetectable viral load.

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On August 6, the Food and Drug Administration approved ViiV Healthcare's Dovato (dolutegravir/lamivudine) as a new all-in-one, single-pill antiretroviral option for people with fully suppressed HIV who wish to change their treatment.

Dovato was initially approved in April 2019 for people starting HIV treatment for the first time. The new expanded approval was based on findings from the Phase III TANGO trial, which showed that people who switched from a three- or four-drug regimen to Dovato maintained an undetectable viral load for a year.

"This expanded approval for Dovato is particularly important for my virologically suppressed patients living with HIV who are seeking a new option that can reduce the number of drugs they are exposed to each day," Charlotte-Paige Rolle, MD, director of research operations at the Orlando Immunology Center, said in a ViiV press release.

Dovato combines the integrase inhibitor dolutegravir (sold separately as Tivicay) and the nucleoside reverse transcriptase inhibitor (NRTI) lamivudine in a one-pill, once-daily regimen.

TANGO (ClinicalTrials.gov number NCT03446573) is an open-label, randomized clinical trial evaluating the safety and effectiveness of switching from a stable combination antiretroviral regimen to Dovato after at least six months with viral suppression.

The study included 741 people who had an undetectable viral load (less than 50) for at least six months. Most were men, a majority were white and the median age was 40. The median CD4 count was high, at approximately 700. They had no history of prior virological treatment failure, no viral mutations conferring resistance to NRTIs or integrase inhibitors and no evidence of hepatitis B coinfection.

At study entry, the participants were taking an antiretroviral regimen that included tenofovir alafenamide (TAF). About 80% were taking an integrase inhibitor, 14% were taking a non-nucleoside reverse transcriptase inhibitor and 8% were on a protease inhibitor. They were

randomly assigned to either switch to Dovato or remain on their TAF-containing regimen for about three years.

As reported at the 2019 International AIDS Society Conference on HIV Science, 93.2% of people who switched to Dovato and 93.0% of those who stayed on their baseline regimen maintained a fully suppressed viral load. The researchers concluded that Dovato is noninferior to TAF-containing regimens, meaning it works at least as well. No one who switched to Dovato and only one person who on stayed on their baseline regimen met the criteria for confirmed virological failure, and no resistance mutations were observed.

The most common adverse reactions seen in people taking Dovato are headache, diarrhea, nausea, insomnia and fatigue. In the TANGO study, just 6% of people who switched to Dovato and 1% of those who stayed on their baseline regimen experienced moderate to severe drug-related adverse events. Nine people taking Dovato (2%) and one person in the control group (less than 1%) stopped treatment due to side effects. Changes in biomarkers of kidney function, bone density and lipid levels were small and similar in both groups. Few people in either group reported weight gain (1% and 2%, respectively).

“As HIV treatment and care progress, people living with HIV will be on medication for decades and need solutions to challenges that may arise from prolonged use of antiretroviral therapy,” said ViiV’s Lynn Baxter. “At ViiV Healthcare, we’ve proven that with Dovato, adults living with HIV can reduce the number of antiretrovirals they take every day without compromising efficacy or barrier to resistance.”

Click here for full prescribing information for Dovato.
