FDA Approves Dovato for Teens Living With HIV

The single-tablet antiretroviral regimen is now approved for adolescents ages 12 and older.

April 15, 2024 By Liz Highleyman

On April 8, the Food and Drug Administration approved ViiV Healthcare's Dovato (dolutegravir/lamivudine) pill as a new all-in-one daily HIV treatment option for adolescents ages 12 years and older.

"This expanded indication for Dovato brings an oral, two-drug, single-tablet regimen to adolescents living with HIV, providing a complete HIV therapy with fewer antiretroviral medicines—an important consideration for young people who will require lifelong treatment," Lynn Baxter, ViiV Healthcare head of North America, said in a news release.

Dovato combines the integrase inhibitor dolutegravir (sold separately as Tivicay) plus the nucleoside reverse transcriptase inhibitor lamivudine in a one-pill, once-daily regimen. Dovato was initially approved in April 2019 for adults starting HIV treatment for the first time, and the indication was expanded in August 2020 to include those switching from another regimen with a fully suppressed viral load.

The new approval extends the indication to adolescents ages 12 to 18 who weigh at least 25 kilograms, or about 55 pounds. It is approved both for those new to treatment and those with viral suppression on a stable antiretroviral regimen who wish to switch. Teens who take Dovato should have no history of treatment failure and no known viral mutations associated with resistance to dolutegravir or lamivudine.

The expanded approval is supported by findings from the ongoing Phase IIIb DANCE trial (NCT03682848), which evaluated Dovato in previously untreated adolescents, as well as trials in adults, including GEMINI-1 and GEMINI-2 (previously untreated) and TANGO (treatment-experienced).

The DANCE study enrolled adolescents ages 12 to 18 who weighed at least 25 kg and had an HIV viral load between 1,000 and 500,000. It showed that 26 out of 30 participants (87%) achieved and maintained viral suppression at 48 weeks.

Dovato was generally safe and well tolerated, with safety and efficacy similar to those observed in adults. Although drug exposure was higher among teens, the difference was not clinically significant, according to ViiV.

The most commonly reported adverse reactions are headache, nausea, diarrhea, insomnia, fatigue and anxiety. The product label includes warnings about hypersensitivity reactions, liver toxicity, lactic acidosis and immune reconstitution syndrome.

People who wish to use Dovato should first be tested for hepatitis B virus (HBV). The lamivudine component is active against HBV as well as HIV, but an additional medication may be needed to keep HBV under control. Severe hepatitis flare-ups can occur when a person taking lamivudine stops treatment.

Click here for full prescribing information for Dovato.
Click here for more news about youth living with HIV.
