

## Temixys™ (lamivudine/tenofovir disoproxil fumarate) – New drug approval

- On November 16, 2018, the [FDA approved](#) Celltrion's [Temixys \(lamivudine/tenofovir disoproxil fumarate\)](#), to be used in combination with other antiretroviral agents for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults and pediatric patients weighing at least 35 kg.
- Lamivudine (3TC) and tenofovir disoproxil fumarate (TDF) are both nucleoside reverse transcriptase inhibitors.
  - A fixed-dose combination of 3TC/TDF is also available as brand [Cimduo™](#).
- The approval of Temixys was based on data from a study comparing 3TC 300 mg + TDF 300 mg + efavirenz (EFV) 600 mg vs. stavudine (d4T) 40 mg + 3TC 300 mg + EFV 600 mg in 600 antiretroviral-naïve adult patients with HIV-1 infection.
  - At week 48, 79% of patients were responders (HIV-1 RNA < 400 copies/mL) in the 3TC/TDF/EFV group vs. 82% in the d4T/3TC/EFV group. At week 144, 68% of patients were responders in the 3TC/TDF/EFV group vs. 62% in the d4T/3TC/EFV group.
- Temixys carries a boxed warning for post-treatment exacerbations of hepatitis B.
- Other warnings and precautions of Temixys include lactic acidosis and severe hepatomegaly with steatosis, risk of hepatic decompensation when used with interferon- and ribavirin-based regimens, pancreatitis, new onset or worsening renal impairment, immune reconstitution syndrome, bone effects, and early virologic failure.
- The most common adverse reactions (> 10%) with Temixys use were headache, pain, depression, diarrhea, and rash.
- The recommended dose of Temixys is one tablet taken orally once daily with or without food.
  - Prior to initiation of Temixys, patients should be tested for hepatitis B virus infection.
  - Serum creatinine, serum phosphorous, estimated creatinine clearance (CrCL), urine glucose, and urine protein should be assessed before initiating Temixys and during therapy in all patients as clinically appropriate.
- Celltrion's launch plans for Temixys are pending. Temixys will be available in a fixed-dose combination tablet containing 300 mg 3TC and 300 mg TDF.