FDA Approves Mylan’s Cut-Price HIV Tablets Symfi Lo and Cimduo

Symfi Lo contains efavirenz, lamivudine and tenofovir disoproxil fumarate (TDF); Cimduo contains TDF and lamivudine.

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The Food and Drug Administration (FDA) has approved two new antiretroviral (ARV) combination tablets, the single-tablet regimen Symfi Lo (efavirenz/lamivudine/tenofovir disoproxil fumarate) and the two-drug tablet Cimduo (tenofovir disoproxil fumarate/lamivudine). Mylan has indicated that the company intends to offer the tablets at a significant discount compared with the price of similar ARV treatments.

Symfi Lo has the same components of Atripla (efavirenz/tenofovir disoproxil fumarate/emtricitabine) but swaps lamivudine for emtricitabine; both are nucleoside/nucleotide reverse transcriptase inhibitors (NRTIs). The tablet contains only 400 milligrams of efavirenz, which is associated with numerous troublesome side effects, compared with the typical 600 mg used in other approved combination tablets. Symfi Lo is approved as a complete regimen for HIV treatment in adults as well as children who weigh at least 35 kilograms (77 pounds).

A recent study conducted among first-timers to HIV treatment found that treating the virus with tenofovir and emtricitabine was comparably effective whether participants also received 400 mg or 600 mg of efavirenz.

Cimduo is similar to Truvada (tenofovir disoproxil fumarate/emtricitabine) and also swaps lamivudine for emtricitabine. The tablet is approved for use in combination with other ARVs for the same population as Symfi Lo. It is not approved for use as pre-exposure prophylaxis (PrEP).

According to Mylan, Symfi Lo will be available within weeks, and Cimduo will hit the shelves by the end of May.

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