FDA OKs Symfi, Mylan's Third Cut-Price Single-Tablet HIV Regimen

The tablet contains the same combo as Symfi Lo (efavirenz/lamivudine/tenofovir disoproxil fumarate) but with a higher dose of efavirenz.

April 2, 2018 By Benjamin Ryan

The Food and Drug Administration (FDA) has approved Mylan's Symfi (efavirenz 600 mg/lamivudine/tenofovir disoproxil fumarate), a single-tablet antiretroviral (ARV) regimen for the treatment of HIV among adults and children who weigh at least 40 kilograms (88 pounds).

The agency recently approved two other of Mylan's combination ARV tablets, Cimduo (tenofovir disoproxil fumarate/lamivudine) and Symfi Lo (efavirenz 400 mg/lamivudine/tenofovir disoproxil fumarate), which contains a lower dose of efavirenz than Symfi. Symfi Lo is approved for adults and children who weigh at least 35 kilograms (77 pounds).

Mylan intends to set the price of these tablets much lower than those of comparable ARV tablets.

Symfi and Symfi Lo have the same components as Atripla (efavirenz/tenofovir disoproxil fumarate/emtricitabine) but swap lamivudine for emtricitabine (both of those medications are in the nucleoside/nucleotide reverse transcriptase inhibitor class of ARVs). The 600 milligram dose of efavirenz contained in Symfi is the same dose as seen in Atripla.

Recent research conducted among adults living with HIV indicated that treating them with tenofovir and emtricitabine was comparably effective regardless of whether they also received 400 mg or 600 mg of efavirenz.

Symfi Lo is already available. Mylan plans to launch Symfi and Cimduo by the end of June.

Efavirenz, which is sold as an individual tablet under the brand name Sustiva, has fallen out of favor in the United States, as it is associated with various troubling side effects, including nightmares. A recent study added weight to previous findings that the drug is associated with an increased risk of suicidal behaviors.

To read a press release about the FDA approval, click here.

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