FDA Approves Truvada-Like HIV Tablet Temixys

The tablet from the South Korean company Celltrion contains tenofovir disoproxil fumarate and lamivudine.

November 28, 2018 By Benjamin Ryan

The Food and Drug Administration (FDA) has approved the dual-antiretroviral (ARV) combination tablet Temixys (lamivudine/tenofovir disoproxil fumarate), which is manufactured by South Korean biopharmaceutical company Celltrion Inc., Pulse reports.

The tablet, which is to be used in combination with at least one other ARV to treat HIV, is similar to Gilead Sciences' Truvada (tenofovir disoproxil fumarate/emtricitabine). They both contain tenofovir disoproxil fumarate, which is manufactured as an individual tablet under the brand name Viread and is a nucleoside/nucleotide reverse transcriptase inhibitor (NRTI). The second medications in each tablet are also NRTIs: Lamivudine (brand name Epivir) is in Temixys, and emtricitabine (brand name Emtriva) is in Truvada.

Temixys is not approved for use as pre-exposure prophylaxis (PrEP). Truvada is the only medication currently approved for that purpose. Various studies are under way investigating different medications and forms of PrEP, including a long-acting injectable medication.

Celltrion intends to sell Temixys at a discount price compared with Truvada. The new tablet should be available in early 2019.

Technically, the FDA approved Teva Pharmaceuticals' generic version of Truvada in June 2017, but the Israeli company has not launched production. Some have speculated that Teva has engaged in a "pay to delay" agreement with Gilead to hold off on production until the full tablet of Truvada loses patent protection in 2021 (the tenofovir disoproxil fumarate component has already lost such protection).

A group of activists is currently trying to force a break of Truvada's patent before 2021.

To read the Pulse article, click here.

To read the Temixys drug label, click here.

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