Gilead Seeks FDA OK for 3rd Combo Pill With New Tenofovir

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Gilead Sciences has applied to the U.S. Food and Drug Administration (FDA) for approval of yet another combination HIV tablet including an updated version of tenofovir. Intended for adults and children 12 years or older, the single-tablet regimen combines Gilead's Emtriva (emtricitabine) and the investigational tenofovir alafenamide (TAF) with Janssen's Edurant (rilpivirine).

Gilead submitted trial data of the regimen's use among treatment-naive people with HIV as well as those who are virologically suppressed and seeking to switch regimens.

Granted priority review by the FDA, the tablet should be approved within six months.

TAF is an updated version of Viread (tenofovir disoproxil fumarate, or TDF), which targets cells more effectively and therefore requires less than 10 percent of the dose. Studies have suggested it has lowered toxicities to the bones and kidneys when compared with TDF.

The FDA is already reviewing two other TAF-inclusive combination tablets: an updated version of Stribild (elvitegravir/cobicistat/tenofovir/emtricitabine), which Gilead submitted to the agency in November 2014; and a new version of Truvada (tenofovir/emtricitabine), submitted in April 2015. The expected dates for an FDA decision about the two tablets are November 5, 2015, and April 7, 2016, respectively. All the TAF-inclusive tablets will receive new names to distinguish them from the TDF-inclusive versions.

To read a Gilead press release on the FDA application, click here.