



FDA Reviews First Single-Tablet HIV Regimen Containing TAF

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Gilead Sciences has submitted a new drug application (NDA) to the U.S. Food and Drug Administration for a single-pill combination HIV therapy that contains the same antiretrovirals as Stribild (elvitegravir/cobicistat/emtricitabine/tenofovir), but with a new version of Viread (tenofovir). The current form of Viread is known as tenofovir disoproxil fumarate, or TDF, while the new version is called tenofovir alafenamide, or TAF, which is a novel prodrug of tenofovir. If the FDA gives the green light, this new tablet would be the first once-daily, single-pill combination drug to contain TAF.

Gilead will continue to manufacture Stribild in its current form if the new tablet is approved.

TAF is less toxic than TDF: Because TAF more effectively targets immune cells, where it is needed, there is less of the drug in the rest of the body. The dose is just one-tenth of the amount of TDF needed for high efficacy, which further improves TAF's toxicity profile. This lower dose also means that the physical amount of TAF is small enough that it may be placed into other potential combination drugs. In addition, a more targeted drug may mean it is more likely to be effective even when someone has some resistance to tenofovir.

"This TAF-based regimen has the potential to provide a range of HIV patients with a highly effective and well-tolerated new treatment option with a favorable safety profile," said Norbert Bischofberger, PhD, executive vice president for research and development and chief scientific officer at Gilead, in a press release. "Gilead remains focused on advancing next-generation therapies that have the potential to improve HIV treatment over the long-term, and TAF will be the cornerstone of future Gilead single tablet regimens."

Gilead submitted to the FDA 48-week data from two Phase III studies, called 104 and 111, in which the TAF-containing combination tablet proved as effective as Stribild with TDF when given to treatment-naive people with HIV. The new tablet boasted improved kidney and bone safety. The NDA application also contains data from Phase III studies that tested the TAF-including tablet among virally suppressed people with HIV who switched from another antiretroviral regimen to the combination drug, as well as among those with kidney impairment. Research on the individual components of the new tablet is also included in the application.

Gilead plans to seek European approval for the TAF-containing tablet by the end of the year.

Editor's Note: An earlier version of this article incorrectly stated that the new combination tablet would be called Stribild. If approved, the new tablet will receive its own name, while Gilead will continue to manufacture Stribild with its current components, including TDF.

To read the press release, [click here](#).

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