Gilead Applies for FDA Approval of New Version of Truvada

April 8, 2015

Gilead Sciences has filed for U.S. Food and Drug Administration (FDA) approval of a new version of the dual-combination HIV antiretroviral (ARV) Truvada that is less toxic to the bones and kidneys. The tablet, which will receive a new name, is intended for use in combination with other ARVs to treat HIV in adults and youths age 12 or older.

Truvada, which is taken by an estimated 84 percent of Americans on ARV treatment, is made up of two components: Viread (tenofovir disoproxil fumarate, or TDF) and Emtriva (emtricitabine). The new take on the tablet replaces TDF with an updated version of that drug, known as tenofovir alafenamide fumarate, or TAF.

Because TAF more effectively targets the cells where it is needed when compared with TDF, the drug requires a dose less than one-tenth that of TDF. Additionally, TAF has a much more favorable side effect profile where bone density and kidney damage are concerned.

Gilead has applied for approval of two doses of the TAF-inclusive version of Truvada: either 25 milligrams or 10 mg of TAF, plus 200 milligrams of emtricitabine. The lower dose is intended for use in combination with a Norvir (ritonavir)– or Tybost (cobicistat)–boosted protease inhibitor; otherwise 25 mg of TAF is recommended.

In November, Gilead filed for FDA approval for a TAF-inclusive version of Stribild (elvitegravir/cobicistat/tenofovir/emtricitabine).

The application for the updated Truvada tablet is backed by Phase III clinical trials among treatment-naive adults in which the drug proved “non-inferior” in its ability to suppress HIV and in which it demonstrated improved kidney and bone toxicities when compared with traditional Truvada, which was given as a part of Stribild. Also included in the application are findings from Phase III research of the new Truvada among treatment-naive adolescents, adults with a fully suppressed virus who switched to a regimen including the TAF-inclusive Truvada, and adults with mild-to-moderate kidney function impairment. Lastly, Gilead has provided research findings showing that the TAF-inclusive Truvada led to the same drug levels in the blood as the TDF/emtricitabine components of Stribild.

Gilead is not filing for approval of the new Truvada for use as pre-exposure prophylaxis (PrEP) to

prevent HIV, as there has been no clinical trials of the tablet for that purpose.

To read the Gilead press release, click here.

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