FDA OKs Gilead's Genvoya, First HIV Combo Pill With New Tenofovir

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The U.S. Food and Drug Administration (FDA) has approved Gilead's fixed-dose, single-tablet combination antiretroviral regimen Genvoya (elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide), the first HIV treatment to include an updated version of tenofovir. Genvoya has the same components as Gilead's Stribild (elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate), but substitutes tenofovir alafenamide, or TAF, for Stribild's tenofovir disoproxil fumarate, or TDF.

TAF has been shown to be less toxic to bones and kidneys than TDF. Because TAF enters cells more efficiently than TDF, a lower dose is required and 91 percent less of the tenofovir winds up in the bloodstream, where it may lead to toxicities.

Genvoya is intended as a complete regimen for HIV treatment in adults and adolescents 12 and older. Those who take the tablet should either never have taken antiretrovirals (ARVs) before or have been virally suppressed for at least six months on a different regimen and never have experienced treatment failure or drug substitutions associated with resistance to the medications included in Genvoya.

In its application to the FDA, Gilead submitted 48-week data from two Phase III studies in which Genvoya proved as effective as Stribild among treatment-naive people with HIV. The application also included Phase III studies that tested Genvoya among virally suppressed study participants switching from another regimen, as well as among people with kidney impairment.

The FDA is reviewing two other TAF-containing regimens: an updated Truvada (tenofovir/emtricitabine), for use in combination with other ARVs; and an updated Complera (rilpivirine/tenofovir/emtricitabine).

The TAF-inclusive Truvada is currently being studied in animals as a potential new form of pre-exposure prophylaxis (PrEP). Gilead intends to evaluate the results of this study to determine the next steps to take in potential future research. Researchers are also conducting studies of how well TAF-inclusive Truvada penetrates human tissues. At this time it is not known if TAF-inclusive Truvada will be effective as PrEP.

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