Gilead Begins Phase III Studies of Low-Dose Prodrug Tenofovir Alafenamide

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Following encouraging Phase II data announced in the fall, Gilead Sciences has begun two Phase III clinical trials of a single-tablet, once-a-day antiretroviral regimen containing tenofovir alafenamide fumarate (TAF) among treatment-naive adults. TAF is a prodrug formulation of the active agent in Viread (tenofovir disoproxil fumarate, TDF). Prodrugs are medications that are inactive until metabolized by the body, a process that allows for lower dosing.

Both of the new trials are randomized and double-blind and will be conducted for 96 weeks among HIV-positive participants with viral loads greater than 1,000 at the outset. Half of the 840 people in each study will be randomized between receiving a once-a-day tablet of TAF/elvitegravir/cobicistat/emtricitabine or Gilead's Stribild (elvitegravir/cobicistat/emtricitabine/TDF), which was approved by the U.S. Food and Drug Administration in 2012. The study's primary endpoint will be the proportion of participants who reach an undetectable viral load after 48 weeks of treatment. After the Phase II results showed the TAF-based combination therapy showed improved kidney and bone safety, the study will include patients with impaired kidney function and will assess bone mineral density of all participants.

"We believe that TAF's smaller milligram size has the potential to offer safety and tolerability advantages over existing therapies, and may enable the creation of new single tablet regimens for HIV," said Norbert Bischofberger, PhD, executive vice president of research and development and chief scientific officer at Gilead.

To read the Gilead release, click here.