TAF: Will an Exciting New Gilead Drug Achieve its Full Potential?

June 13, 2013 By Tim Horn

Every now and then, a new HIV drug moves through the pipeline that generates a great deal of hope and encouragement. Gilead Science's new nucleotide reverse transcriptase inhibitor, tenofovir alafenadine fumarate (TAF), is one such drug.

TAF works very much like tenofovir disoproxil fumarate (TDF)--the active ingredient in Viread and a component of Truvada, Atripla, Complera, and Stribild--though with better distribution in lymph tissues (where roughly 98 percent of HIV resides) and, at least in test tube studies, greater antiviral activity. Best of all, it can be used as a once-daily drug at doses that are roughly ten times less than that of TDF, which means that it will potentially have fewer kidney- and bone-related side effects.

Activists and the scientific community have known about the potential benefits of TAF, over that of TDF, for twelve years--it is both disappointing and curious that its development was delayed until TDFs patent expiration could be seen on the immediate horizon (2017). Still, the encouraging interim 24-week analysis from Study GS-US-292-0102, presented at the 20th Conference on Retroviruses and Opportunistic Infections, indicate that TAF shows significant potential as an effective alternative to TDF in first-line therapy regimens, with reduced impact on bone and kidney markers.

The problem? Gilead seems only to have plans to develop the drug as a component of fixed-dose combinations (FDCs): a tablet containing elvitegravir, cobicistat, emtricitabine, and TAF (a newer version of Stribild); an FDC containing darunavir, cobicistat, emtricitabine, and TAF; and, possibly, an FDC containing emtricitabine and TAF (a newer version of Truvada).

But we also need a stand-alone version of TAF--a tablet containing only TAF that can be used in combination with other HIV meds of a person's choosing. Unfortunately, this does not appear to be on Gilead's to-do list.

This is an issue because not everyone can, should, or wants to take one of the TAF-inclusive FDCs in development. First, it needs to be available for use as a component of generic-based treatment in the US, particularly once efavirenz (found in Sustiva and Atripla) is approved as such (~2017) and now that generic lamivudine is widely available. Second, for generic versions of TAF to be approved for use in resource-poor countries, it needs to be studied in regimens that do not contain boosting agents like cobicistat (which alters the pharmacokinetics of TAF). Third, according to exciting new test tube data, TAF may actually be active against some HIV strains resistant to TDF and other NRTIs, which means TAF absolutely needs to be studied and made available for individualized second-line and salvage regimens.

Though Gilead is interested in utilizing TAF to ensure its place as the leading developer of highly effective

one-tablet regimens for years to come, a decision to focus solely on FDCs would be shortsighted. Gilead stands to make a nice chunk of change from the availability of a stand-alone version of TAF. Most importantly, ignoring its development will effectively keep the drug out of the hands of millions of people living with HIV who need a less toxic version of tenofovir, or a drug effective against TDF, for use in a variety of possible combinations.

Please consider signing on to a letter co-developed by TAG, Project Inform and UK's HIV i-Base to request that Gilead carefully consider the importance of stand-alone TAF.

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