Tenofvir Alafenamide vs Tenofovir DF in Women: Pooled Analysis of 7 Clinical Trials

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Introduction

- Globally, the majority of people living with HIV (PLH) are cis-women, and the number of women acquiring HIV infection continues to rise.
- Research guidelines have long advocated for sex-based assessment of drug efficacy, toxicity, and tolerability profiles, but women continue to be underrepresented in clinical trials assessing efficacy and safety of antiretroviral treatment (ART) among PLH.¹⁵
- One of the consequences of this restricted representation is the absence of definitive information about the specific efficacy and safety of ART in women.¹⁶
- Tenofovir alafenamide (TAF) has demonstrated an improved renal and bone safety profile relative to tenofovir disoproxil fumarate (TDF) in multiple randomised trials with similar efficacy.¹⁷⁻²⁰

Objective

- To evaluate the efficacy and safety of TAF vs TDF for ART initiation or switch in cis-women in a pooled analysis of 7 studies (only including cis-women, referred to as women herein), and to compare outcomes to those in men.

Methods

- Studies Included in Integrated Analysis: Studies included were GS-US-292-0104, 292-0111, 292-0109, 311-1089, 366-1160, 366-1878, and 380-1878. Special thanks to the Gilead study teams. These studies were funded by Gilead Sciences, Inc.

Results

- Pooled Baseline Characteristics

- Most Common AEs in Treatment-Naïve Women Through Week 144

- Virologic Outcomes at Week 96 by FDA Snapshot

- Treatment-Emergent Renal AEs at Week 96

Conclusions

- Cis-women who initiated or switched to TAF had significantly improved BMD and renal tubular biomarkers compared to those on TDF, with similar rates of virologic suppression through Week 96.
- Results were similar to those in men.
- These pooled data from 7 studies demonstrate a safety advantage for initiating therapy with or switching to TAF compared to TDF in women.


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