

CROI 2019 PRESS CONFERENCE ABSTRACTS

Embargoed until delivery on Wednesday, March 6, 2019

Abstract Number 104LB

THE PHASE 3 DISCOVER STUDY: DAILY F/TAF OR F/TDF FOR HIV PRE-EXPOSURE PROPHYLAXIS

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Background:

Emtricitabine/tenofovir disoproxil fumarate (F/TDF) prevents HIV infection when used as daily pre-exposure prophylaxis (PrEP). Compared to TDF, tenofovir alafenamide (TAF) has higher intracellular tenofovir (TFV)-DP levels, lower plasma TFV levels, and improved renal and bone safety when used for HIV treatment. This study describes the efficacy and safety of F/TAF vs F/TDF for PrEP in cis-men who have sex with men (MSM) and transgender women (TGW) who are at high risk of HIV acquisition.

Methods:

This randomized (1:1), double-blind, active-controlled study was conducted in North America and Europe at sites with high HIV prevalence in MSM. Entry required ≥ 2 episodes of condomless anal sex (CAS) in past 12W or rectal gonorrhea/chlamydia or syphilis in past 24W. Participants received daily blinded F/TAF (200/25 mg) or F/TDF (200/300 mg), with matching placebo; pill counts and blood levels were used to measure adherence. Primary endpoint was the HIV infection rate per 100 person years (PY) when 50% completed 96W. Renal safety, 3 anatomic site sexually transmitted infection (STI) testing and risk behavior were assessed every 12W. Using CDC reported HIV surveillance data we calculated the background "HIV incidence rate" in at risk individuals not on PrEP from 105 US metropolitan statistical areas (MSAs) for comparison.

Results:

5387 adults were treated at 94 sites in 11 countries, with 3226 (60%) in the US. Mean age was 36, range 18-76 years, 9% Black, 1% TGW, 23% had prior PrEP use and 41% had >3 receptive CAS partners in the 90 days before study entry. 90% of participants completed ≥ 48 W on study, with median follow up of 84W. For this analysis, 85% remained on study drug: 6% discontinued by participant choice and 6% were lost to follow up. On-study sexual HIV risk persisted with an STI rate of 99.5/100PY. Across both arms, there were 21 HIV diagnoses-an infection rate of 0.26/100 PY-a figure significantly lower than the expected HIV infection rate for those at risk but not on PrEP in the US (Table). Both drugs were tolerated well with 1.5% AE-related discontinuations, with GI most common.

Conclusion:

In a multinational population of cis-MSM and TGW at risk of sexual HIV infection, the HIV incidence rate on either F/TAF or F/TDF was very low and significantly less than the background rate in those at risk but not on PrEP in the US. In almost 2 years of follow up, both F/TAF and F/TDF, given daily, were tolerated and had low discontinuation rates.