

Descovy for PrEP[®] (FTC/TAF) Effect on Blood Pressure

This document is in response to your request for information regarding Descovy for PrEP[®] (emtricitabine/tenofovir alafenamide [FTC/TAF] for HIV-1 pre-exposure prophylaxis) and its effect on blood pressure.

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The full indication, important safety information, and boxed warnings are available at: www.gilead.com/-/media/files/pdfs/medicines/hiv/descovy/descovy_pi

Summary

Phase 3 DISCOVER Study

Daily FTC/TAF was compared to FTC/TDF for HIV-1 PrEP in adult cisgender MSM and TGW in a phase 3, randomized, double-blind, active-controlled, multinational clinical study.^{1,2}

- Median change from baseline to Week 96 in SBP and DBP among participants in the DISCOVER study was stable in both arms. Hypertension was not flagged as a safety signal during the study.³

Real-World Analysis

A retrospective cohort analysis was conducted using EHRs from Kaiser Permanente Southern California that evaluated outcomes including risk of incident HTN among health plan adults who started PS-matched FTC/TAF or FTC/TDF.

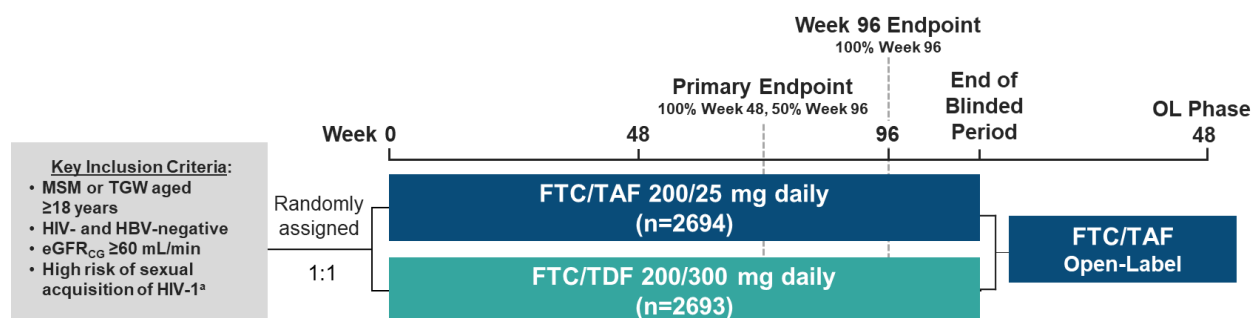
- The incidence of HTN was higher among those prescribed FTC/TAF vs matched FTC/TDF, although the incidence magnitude was small, differing by 2 cases per 100,000 PY of follow-up.⁴

Phase 3 DISCOVER Study

Study Design and Demographics

DISCOVER ([NCT02842086](https://clinicaltrials.gov/ct2/show/study/NCT02842086)) was a phase 3, double-blind, active-controlled multinational study in 5387 HIV-negative adult MSM and TGW that evaluated the safety and efficacy of FTC/TAF vs FTC/TDF for HIV-1 PrEP. Figure 1 below includes the study design and key inclusion criteria. Prior use of FTC/TDF for HIV-1 PrEP was allowed.^{1,2}

Figure 1. DISCOVER: Study Design^{1,2}



^aHigh risk was defined as ≥2 episodes of condomless anal intercourse with ≥2 unique male partners with HIV or with an unknown HIV status within the previous 12 weeks, or a documented history of syphilis, rectal gonorrhea, or rectal chlamydia in the previous 24 weeks.

The primary outcome was the incidence of HIV-1 per 100 PY after all participants had ≥48 weeks of follow-up and ≥50% of participants had 96 weeks of follow-up.¹ All participants were unblinded after 96 weeks, and participants in both arms were offered the opportunity to continue or switch to OL FTC/TAF for an additional 48 weeks. Participant baseline characteristics were similar between the FTC/TAF and FTC/TDF arms, including HIV risk factors. Blood pressure was not a pre-specified or secondary safety outcome.²

Blood Pressure through Week 96

Median changes from baseline to Week 96 in SBP and DBP among participants in the DISCOVER study are shown below (Table 1). Overall, blood pressure was stable in both arms and median changes in both SBP and DBP were similar across treatment arms. Hypertension was not flagged as a safety signal during the study.³

Table 1. Median Change in Blood Pressure from Baseline at Week 96³

	FTC/TAF	FTC/TDF
Baseline SBP, mmHg	126	126
Change in SBP from baseline, mmHg	-1	-2
Baseline DBP, mmHg	78	78
Change in DBP from baseline, mmHg	+1	0

Real-World Analysis

A retrospective cohort analysis conducted at Kaiser Permanente Southern California examined incident hypertension and risk of statin initiation using EHRs of health plan members ≥18 years between October 2019 and May 2022. PS-matching was conducted to generate 1 FTC/TAF:4 FTC/TDF matched sets. 5523 individuals without HTN at baseline were identified (371 FTC/TAF, 5152 FTC/TDF) to serve as a pool for matching. The PS model for the HTN analysis adjusted for factors including baseline age, sex, race/ethnicity, insurance, clinical measures (BMI and lipids), ASCVD risk score, and cardiometabolic comorbidities (diabetes, dyslipidemia). Compared with unmatched individuals taking FTC/TDF, those taking FTC/TAF were older, more likely to be non-Hispanic White, and have diabetes at baseline. Despite matching, ASCVD risk score remained higher in those taking FTC/TAF vs FTC/TDF in the HTN analysis. Incidence of HTN was higher in those who used

FTC/TAF, but was small, differing by 2 cases per 100,000 PY of follow-up. In the time-to-event analysis, the association of FTC/TAF use (vs FTC/TDF use) with hypertension risk was not statistically significant (HR 1.63, 95% CI: 0.67–3.96).⁴

Table 2. Differences in HTN Risk in Adults Initiating FTC/TAF vs FTC/TDF⁴

Population	Cumulative incidence per 100 persons		Incidence per 1,000 person-years		HR (95% CI)
	FTC/TAF	Matched FTC/TDF (95% CI)	FTC/TAF	Matched FTC/TDF (95% CI)	
140/90 mm/Hg cutoff					
Matched eligible (n _{TAF} = 371)	2.2	1.3 (1.0–1.7)	0.06	0.04 (0.03–0.05)	1.63 (0.67–3.96)
≥ 40 years at index (n _{TAF} = 100)	5	2.6 (2.0–3.2)	0.15	0.08 (0.04–0.11)	1.97 (0.65–6.00)
130/80 mm/Hg cutoff					
Matched eligible (n _{TAF} = 287)	10.8	5.5 (4.8–6.3)	0.36	0.18 (0.14–0.22)	2.03 (1.29–3.22)
≥ 40 years at index (n _{TAF} = 69)	17.4	7.7 (6.6–8.8)	0.56	0.24 (0.16–0.32)	2.32 (1.12–4.81)

References

1. Mayer KH, Molina JM, Thompson MA, et al. Emtricitabine and tenofovir alafenamide vs emtricitabine and tenofovir disoproxil fumarate for HIV pre-exposure prophylaxis (DISCOVER): primary results from a randomised, double-blind, multicentre, active-controlled, phase 3, non-inferiority trial. *Lancet*. 2020;396(10246):239-254.
2. Ogbuagu O, Ruane PJ, Podzamczar D, et al. Long-term safety and efficacy of emtricitabine and tenofovir alafenamide vs emtricitabine and tenofovir disoproxil fumarate for HIV-1 pre-exposure prophylaxis: week 96 results from a randomised, double-blind, placebo-controlled, phase 3 trial. *Lancet HIV*. 2021;8:e397-e407.
3. Gilead Sciences Inc. Data on File.
4. Rivera AS, Pak KJ, Mefford MT, Hechter RC. Use of Tenofovir Alafenamide Fumarate for HIV Pre-Exposure Prophylaxis and Incidence of Hypertension and Initiation of Statins. *JAMA Netw Open*. 2023;6(9):e2332968.

Abbreviations

ASCVD=Atherosclerotic Cardiovascular Disease
DBP=diastolic blood pressure
EHRs=electronic health records
FTC=emtricitabine

HTN=hypertension
MSM=men who have sex with men
OL=open-label
PrEP=pre-exposure prophylaxis
PS=propensity score

PY=person-years
SBP=systolic blood pressure
TAF=tenofovir alafenamide
TDF=tenofovir disoproxil fumarate
TGW=transgender women

Product Label

For the full indication, important safety information, and boxed warning, please refer to the Descovy US Prescribing Information available at:

www.gilead.com/-/media/files/pdfs/medicines/hiv/descovy/descovy_pi

Follow Up

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