GILEAD | Medical Information

Descovy for PrEP® (FTC/TAF) Use in People Who Inject Drugs

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 use in people who inject drugs (PWID).

Some data may be outside of the US FDA-approved Prescribing Information. In providing this data, Gilead Sciences, Inc. is not making any representation as to its clinical relevance or to the use of any Gilead product(s). For information about the approved conditions of use of any Gilead drug product, please consult the FDA approved prescribing information.

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

Product Labeling[1]

FTC/TAF is indicated in at-risk adults and adolescents weighing ≥35 kg for PrEP to reduce the risk of HIV-1 from sexual acquisition, excluding individuals at risk from receptive vaginal sex. Individuals must have a negative HIV-1 test immediately prior to initiating FTC/TAF for HIV-1 PrEP.

Limitations of Use: The indication does not include the use of FTC/TAF in individuals at risk of HIV-1 from receptive vaginal sex because effectiveness in this population has not been evaluated.

Available Data

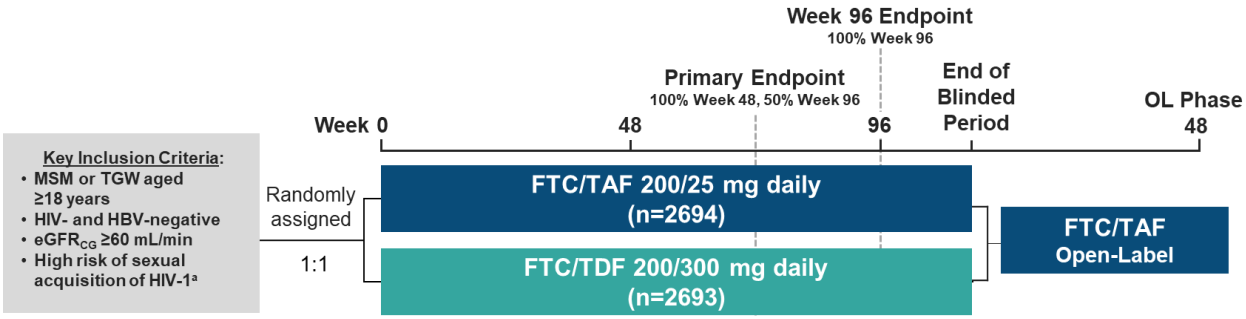
Currently there are no data regarding the efficacy of FTC/TAF for PrEP in PWID. Please see available information below regarding baseline HIV risk factors in the DISCOVER study, including recreational drug use. An analysis of seroconversions among PWID in DISCOVER is not available at this time.

DISCOVER: Once Daily FTC/TAF vs FTC/TDF for HIV-1 PrEP in MSM and TGW

Study Design and Demographics

DISCOVER (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.[2,3]

Figure 1. DISCOVER: Study Design[2,3]



[a]High 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.[2] 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 risk factors for HIV acquisition (Table 1).[2,4]

Table 1. Baseline Demographics and HIV Risk Factors[2,4]

	FTC/TAF (n=2694)	FTC/TDF (n=2693)
Baseline Demographics		
Median age, years (range)	34 (18–76)	34 (18–72)
Race, n (%)		
White	2264 (84)	2247 (84)
Black[a]	240 (9)	234 (9)
Asian	113 (4)	120 (4)
Hispanic or Latinx ethnicity, n (%)	635 (24)	683 (25)
Proportion TGW, n (%)	45 (2)	29 (1)
Sexual orientation, %		
Gay	92	91
Straight	1	1
Bisexual	6	8
Other	1	<1
Region, %		
USA	59	60
European Union	34	33
Canada	7	6
HIV Risk Factors, %		
≥2 receptive condomless anal sex partners, past 12 weeks	62	60
Rectal gonorrhea, past 24 weeks	10	10
Rectal chlamydia, past 24 weeks	13	12
Syphilis, past 24 weeks	9	10
Binge drinking[b]	23	22

	FTC/TAF (n=2694)	FTC/TDF (n=2693)
Taking FTC/TDF for HIV-1 PrEP at baseline	17	16
Recreational drug use, past 12 weeks	67	67

[a] Includes mixed black race.
[b] ≥6 drinks on ≥1 occasion, at least monthly.

Recreational Drug Use

In both arms at baseline, 67% of participants self-reported recreational drug use in the past 12 weeks in a confidential, computer-assisted self-interview questionnaire. Recreational drug use was similar between the two study arms (Table 2), with the exception of self-reported speed use (9% in the FTC/TAF arm vs 6% in the FTC/TDF arm, P<0.001).[4]

Table 2. Self-Reported Substance Use in the 12 Weeks Prior to Enrollment (% of Participants)[4]

	FTC/TAF (n=2694)	FTC/TDF (n=2693)
Any	67	67
Acid, LSD (d-lysergic acid diethylamide), Mushrooms	6	5
Anabolic Steroids	3	3
Cannabis	40	39
Cocaine	24	23
Codeine	1	1
Crack	1	1
Crystal Methamphetamine	10	9
Ecstasy	19	17
GHB (γ-hydroxybutyrate)	18	16
Heroin	0.4	0.2
Ketamine	11	10
Mephedrone	6	6
Morphine	0.4	0.5
Opium	0.4	0.4
Other	2	3
Poppers	46	46
Sildenafil	23	22
Speed	9	6

A subgroup analysis of substance use and the route of administration is not available at this time.

References

1. Enclosed. Gilead Sciences Inc, DESCOVY® (emtricitabine and tenofovir alafenamide) tablets, for oral use. U.S. Prescribing Information. Foster City, CA.
2. 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.
3. Ogbuagu O, Ruane PJ, Podzamczer 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.
4. Mounzer K, Carter CC, Johnson B, et al. Substance Use Was Common in Persons at Risk for and Diagnosed With HIV in a Trial of F/TAF for PrEP (DISCOVER) [Poster 2230]. Paper presented at: STD Prevention Conference; 14-24 September, 2020.

Abbreviations

FTC=emtricitabine
MSM=men who have sex with men
OL=open-label
PrEP=pre-exposure prophylaxis
PWID=people who inject drugs
PY=person-years
TAF=tenofovir alafenamide
TDF=tenofovir disoproxil fumarate
TFV=tenofovir
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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FDA MedWatch Program by ☎ 1-800-FDA-1088 or ✉MedWatch, FDA, 5600 Fishers Ln, Rockville, MD 20852 or 🖱 www.accessdata.fda.gov/scripts/medwatch

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