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Descovy for PrEP® (FTC/TAF) Use in Pediatric and Adolescent Patients

This document is in response to your request for information regarding the use of Descovy for PrEP® (emtricitabine/tenofovir alafenamide [FTC/TAF] for HIV-1 pre-exposure prophylaxis [PrEP]) in pediatric patients.

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 use of FTC/TAF for prevention of HIV-1 in individuals at risk of HIV-1 from receptive vaginal sex is investigational and has not been approved by any regulatory authority. The full indication, important safety information, and boxed warnings are available at:
www.gilead.com/-/media/files/pdfs/medicines/hiv/descovy/descovy_pi;
www.gilead.com/-/media/files/pdfs/medicines/hiv/truvada/truvada_pi;
www.gilead.com/-/media/files/pdfs/medicines/hiv/yeztugo/yeztugo_pi.

Summary

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 infection 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 use of FTC/TAF in individuals at risk of HIV-1 from receptive vaginal sex because effectiveness in this population has not been evaluated.

Clinical Data on FTC/TAF Use in Pediatric and Adolescent Individuals

PURPOSE 1 is an ongoing, phase 3, double-blind, randomized study evaluating the efficacy and safety of once-daily oral FTC/TAF (n=2136) and twice-yearly SUBQ LEN (n=2134) or FTC/TDF (active control; n=1068) for HIV-1 PrEP in 5338 cisgender women and adolescent girls (16–25 years old) across South Africa and Uganda.[2]

- Zero HIV cases occurred in adolescent participants aged 16 and 17 years in the FTC/TAF, LEN, and FTC/TDF arms.[3]
- Safety data for adolescent participants treated with FTC/TAF or FTC/TDF were not reported separately. FTC/TAF, LEN, and FTC/TDF were all generally well tolerated, with few discontinuations due to study drug-related AEs. The overall incidences of non-ISR AEs, including Grade ≥3 and serious AEs, were generally similar across treatment groups. Nausea and vomiting occurred at higher rates in the FTC/TAF and FTC/TDF groups than in the LEN group.[2]

Product Labeling[1]

Use in Specific Populations

Pediatric use for HIV-1 PrEP

Safety and effectiveness of FTC/TAF for HIV-1 PrEP in at-risk adolescents weighing ≥35 kg, excluding individuals at risk from receptive vaginal sex, are supported by data from an adequate and well-controlled trial of FTC/TAF for HIV-1 PrEP in adults, with additional data from safety and pharmacokinetic studies in previously conducted trials with the individual drug products, FTC and TAF, with EVG + COBI in adults and pediatric participants with HIV-1.

While using FTC/TAF for HIV-1 PrEP, HIV-1 testing should be repeated at least every 3 months and upon diagnosis of any other STIs. Previous studies in at-risk adolescents indicated waning adherence to a daily oral PrEP regimen once visits were switched from monthly to quarterly. Adolescents may therefore benefit from more frequent visits and counseling.

Safety and effectiveness of FTC/TAF for HIV-1 PrEP in pediatric individuals weighing <35 kg have not been established.

Clinical Data on FTC/TAF Use in Pediatric and Adolescent Individuals

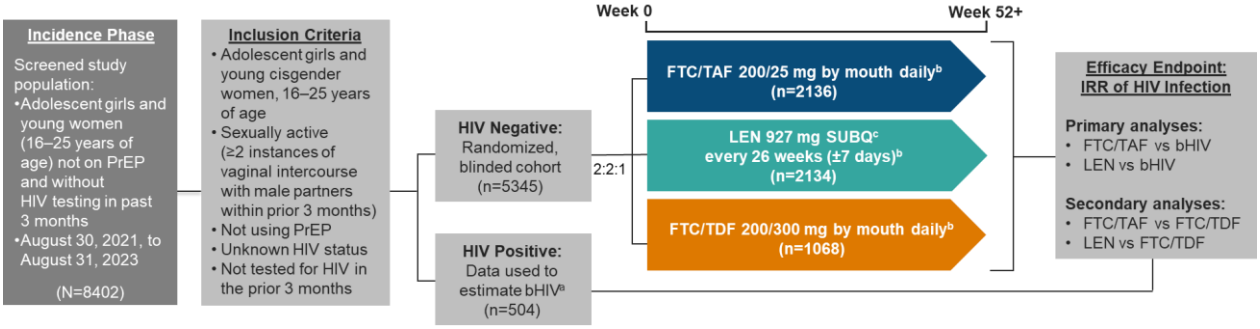
PURPOSE 1 Study

Study design and demographics[2]

PURPOSE 1 (NCT04994509) is an ongoing, phase 3, double-blind, randomized, active-controlled study evaluating the efficacy and safety of once-daily oral FTC/TAF and twice-yearly SUBQ LEN for HIV-1 PrEP in cisgender women and adolescent girls (aged 16–25 years) across South Africa and Uganda. Additionally, a third group was assigned to once-daily oral FTC/TDF, which served as the active control. Eligible women and adolescent girls were tested for HIV at screening, and those who tested negative were randomly assigned in a 2:2:1 ratio to receive FTC/TAF 200/25 mg orally daily, LEN 927 mg SUBQ every 26 weeks, or FTC/TDF 200/300 mg orally daily, respectively (Figure 1).

Those who tested positive for HIV at screening were referred for care at a local center, and their samples underwent additional testing to determine the recency of HIV; these data were used to estimate the bHIV that would be expected without PrEP. Participants who discontinued blinded study drug were given the option to take open-label FTC/TDF. Testing for HIV in the randomized cohort was conducted at Weeks 4, 8, and 13 and every 13 weeks thereafter.

Figure 1. PURPOSE 1: Study Design[2]



Abbreviation: IRR=incidence rate ratio.
[a]The bHIV was determined based on a cross-sectional incidence estimate derived from rates of recent HIV in 8094 screened participants; these participants were not followed longitudinally.
[b]Participants in the LEN SUBQ group also received placebo tablets that matched FTC/TAF or FTC/TDF (2:1), and participants in the FTC/TAF and FTC/TDF groups also received placebo tablets that matched LEN oral loading doses and placebo LEN SUBQ.
[c]All participants randomly assigned to receive LEN received an initial loading dose of LEN, which consisted of 600 mg (two 300-mg tablets) administered on Days 1 and 2.

A total of 5345 participants were randomly assigned and received ≥1 dose of study drug. Baseline HIV was identified in 7 participants after they had received ≥1 dose of study drug. Baseline characteristics at randomization among the three groups were similar (Table 1). Overall retention in the study was high and was similar across groups, with 4855/5020 participants (96.7%) completing 26 weeks of follow-up, 2439/2612 participants (93.4%) completing 52 weeks, and 39/43 participants (91%) completing 104 weeks.

An independent committee determined that the planned interim efficacy analysis (when 50% of participants had completed ≥52 weeks of follow-up; data cutoff for clinical data, May 28, 2024, and data cutoff for laboratory data, May 29, 2024) met the prespecified criteria for stopping the randomized, blinded portion of the trial. Starting July 8, 2024, all participants were offered open-label LEN.

Table 1. PURPOSE 1: Baseline Demographics and Disease Characteristics[2]

Key Demographics and Characteristics		FTC/TAF (n=2137)	LEN (n=2138)	FTC/TDF (n=1070)
Age	Median (range), years	21 (16–26)	21 (16–25)	21 (16–25)
	16 or 17 years of age, n (%)	45 (2.1)	56 (2.6)	23 (2.1)
Black race, n (%)		2136 (>99.9)	2135 (99.9)	1068 (99.8)
Living with primary partner, n/N (%)		132/2134 (6.2)	148/2136 (6.9)	73/1069 (6.8)
Previous use of PrEP, n (%)		121 (5.7)	143 (6.7)	71 (6.6)
Previously tested for HIV, n (%)		1731 (81)	1713 (80.1)	860 (80.4)
Time since last HIV test, median (IQR), months		6.6 (4.8–11)	6.8 (4.7–11.5)	6.5 (4.6–11)
STIs, n (%)	*Chlamydia trachomatis*	562 (26.3)	520 (24.3)	263 (24.6)
	Neisseria gonorrhoeae	178 (8.3)	197 (9.2)	90 (8.4)
	Trichomonas vaginalis	165 (7.7)	154 (7.2)	82 (7.7)
	Syphilis	63 (2.9)	57 (2.7)	29 (2.7)
Country, n (%)	South Africa	1790 (83.8)	1809 (84.6)	909 (85)
	Uganda	347 (16.2)	329 (15.4)	161 (15)

Efficacy

In the overall randomized cohort, 55 incident HIV cases occurred as follows: 39 participants in the FTC/TAF group (1932 PY; incidence rate, 2.02 per 100 PY; 95% CI: 1.44–2.76);

no participants in the LEN group (1939 PY; incidence rate, 0 per 100 PY; 95% CI: 0–0.19); and 16 participants in the FTC/TDF group (949 PY; incidence rate, 1.69 per 100 PY; 95% CI: 0.96–2.74). The bHIV in the screened population was 2.41 per 100 PY.[2]

Zero HIV cases occurred in adolescent participants aged 16 to 17 years in any treatment group (Table 2).[3]

Table 2. PURPOSE 1: Incident HIV Cases Among Adolescent Participants[3]

	FTC/TAF (n=45)	LEN (n=56)	FTC/TDF (n=23)
Incidence rate	0 cases per 33 PY	0 cases per 42 PY	0 cases per 18 PY

Safety

Safety data for adolescent participants treated with FTC/TAF or FTC/TDF were not reported separately.

Overall, FTC/TAF, LEN, and FTC/TDF were generally well tolerated, with fewer gastrointestinal AEs in the LEN group than either the FTC/TAF or FTC/TDF groups (Table 3). Six deaths occurred, all in the FTC/TAF group; none were considered by the investigator to be related to study drug.[2]

Table 3. PURPOSE 1: Safety Summary (Excluding ISRs)[2]

Safety Outcomes, n (%)		FTC/TAF (n=2137)	LEN (n=2138)	FTC/TDF (n=1070)
Any AE (excluding ISRs)		1665 (77.9)	1631 (76.3)	830 (77.6)
Grade ≥3 AE		95 (4.4)	88 (4.1)	50 (4.7)
Serious AE		85 (4)	59 (2.8)	35 (3.3)
AEs that led to discontinuation of study drug[a]		2 (<0.1)	5 (0.2)	0
Common AEs (≥5% of participants in any group; excluding ISRs)	Headache	352 (16.5)	285 (13.3)	155 (14.5)
	Genitourinary tract chlamydia infection	317 (14.8)	300 (14)	129 (12.1)
	Urinary tract infection	305 (14.3)	307 (14.4)	163 (15.2)
	Upper respiratory tract infection	274 (12.8)	271 (12.7)	121 (11.3)
	Vomiting	235 (11)	125 (5.8)	107 (10)
	Nausea	234 (10.9)	144 (6.7)	142 (13.3)
	Vaginal discharge	191 (8.9)	166 (7.8)	87 (8.1)
	Vulvovaginal candidiasis	172 (8)	146 (6.8)	67 (6.3)
	Diarrhea	161 (7.5)	133 (6.2)	67 (6.3)
	Genitourinary tract gonococcal infection	157 (7.3)	141 (6.6)	66 (6.2)
	Dizziness	141 (6.6)	120 (5.6)	79 (7.4)
Laboratory abnormalities[b]	Any	1904 (90.1)	1929 (90.7)	959 (91)
	Grade 3	81 (3.8)	92 (4.3)	50 (4.7)
	Grade 4	22 (1)	20 (0.9)	11 (1)

[a]AEs that led to discontinuation in the FTC/TAF group were suicide attempt, depressive symptoms, and drug overdose (n=1, all in the same participant) and angioedema (n=1); in the LEN group, AEs that led to discontinuation were nausea (n=1), decreased CrCl (n=1), increased liver enzyme levels (n=1), spontaneous abortion (n=1), and suicide attempt with major depression (n=1).

[b]Percentages shown are based on the number of participants who had ≥1 postbaseline laboratory result (LEN, n=2126; FTC/TAF, n=2113; FTC/TDF, n=1054).

References

1. Enclosed. Gilead Sciences Inc, DESCOVY® (emtricitabine and tenofovir alafenamide) tablets, for oral use. U. S. Prescribing Information. Foster City, CA.
2. Bekker LG, Das M, Abdool Karim Q, et al. Twice-Yearly Lenacapavir or Daily F/TAF for HIV Prevention in Cisgender Women. *N Engl J Med.* 2024;391(13):1179-1192.
3. Gill K, Ndlovu N, Brumskine W, et al. Lenacapavir Efficacy, Safety, and Pharmacokinetics in Adolescents and Adults in PURPOSE 1 [Presentation]. Paper presented at: Conference on Retroviruses and Opportunistic Infections (CROI); March 9-12, 2025; San Francisco, CA.

Abbreviations

AE=adverse events
bHIV=background HIV incidence
COBI=cobicistat
EVG=elvitegravir
FTC=emtricitabine
ISR=injection site reaction
LEN=lenacapavir
PrEP=pre-exposure prophylaxis
PY=person-years
STI=sexually transmitted infections
SUBQ=subcutaneous(ly)
TAF=tenofovir alafenamide
TDF=tenofovir disoproxil fumarate

Product Label

For the full indication, important safety information, and boxed warning(s), please refer to the Descovy, Truvada, and Yeztugo US Prescribing Information available at:
www.gilead.com/-/media/files/pdfs/medicines/hiv/descovy/descovy_pi;
www.gilead.com/-/media/files/pdfs/medicines/hiv/truvada/truvada_pi;
www.gilead.com/-/media/files/pdfs/medicines/hiv/yeztugo/yeztugo_pi.

Follow Up

For any additional questions, please contact Gilead Medical Information at:

☎1-866-MEDI-GSI (1-866-633-4474) or 🖱 www.askgileadmedical.com

Adverse Event Reporting

Please report all adverse events to:

Gilead Global Patient Safety ☎ 1-800-445-3235, option 3 or
🖱 www.gilead.com/utility/contact/report-an-adverse-event

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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