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Descovy for PrEP® (FTC/TAF) Duration of Protection After Last Dose

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 [PrEP]) and the duration of protection after the last dose is administered. This response was developed according to principles of evidence-based medicine and contains data from phase 3 clinical trials.

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; www.gilead.com/-/media/files/pdfs/medicines/hiv/truvada/truvada_pi.

Product Labeling[1]

Indications and Usage

HIV-1 PrEP

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 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.

Dosage and Administration

Recommended dosage for HIV-1 PrEP in adults and adolescents weighing ≥35 kg

The dosage of FTC/TAF for HIV-1 PrEP is one tablet (containing 200 mg of FTC and 25 mg of TAF) once daily taken orally with or without food in adults and adolescents without HIV-1 weighing ≥35 kg and with a CrCl ≥30 mL/min, or adults without HIV-1 and with CrCl <15 mL/min who are receiving chronic hemodialysis. On days of hemodialysis, administer the daily dose of FTC/TAF after completion of hemodialysis treatment.

Warnings and Precautions

Comprehensive management to reduce the risk of STIs, including HIV-1, and development of HIV-1 resistance when FTC/TAF is used for HIV-1 PrEP

Use FTC/TAF for HIV-1 PrEP to reduce the risk of HIV-1 infection as part of a comprehensive prevention strategy, including adherence to daily administration and safer sex practices, including condoms, to reduce the risk of STIs. The time from initiation of FTC/TAF for HIV-1 PrEP to maximal protection against HIV-1 infection is unknown.

Use FTC/TAF to reduce the risk of acquiring HIV-1 only in individuals confirmed to be HIV-1 negative. HIV-1 resistance substitutions may emerge in individuals with undetected HIV-1 infection who are taking only FTC/TAF, because FTC/TAF alone does not constitute a complete regimen for HIV-1 treatment; therefore, care should be taken to minimize the risk of initiating or continuing FTC/TAF before confirming the individual is HIV-1 negative.

If recent (<1 month) exposures to HIV-1 are suspected or clinical symptoms consistent with acute HIV-1 infection are present, use a test approved or cleared by the FDA as an aid in the diagnosis of acute or primary HIV-1 infection.

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 STI. If an HIV-1 test indicates possible HIV-1 infection, or if symptoms consistent with acute HIV-1 infection develop following a potential exposure event, convert the HIV-1 PrEP regimen to an HIV treatment regimen until negative infection status is confirmed using a test approved or cleared by the FDA as an aid in the diagnosis of acute or primary HIV-1 infection.

Counsel individuals without HIV-1 to strictly adhere to the once daily FTC/TAF dosing schedule. The effectiveness of FTC/TAF in reducing the risk of acquiring HIV-1 is strongly correlated with adherence, as demonstrated by measurable drug levels in a clinical trial of FTC/TAF for HIV-1 PrEP. Some individuals, such as adolescents, may benefit from more frequent visits and counseling to support adherence.

Clinical Data on the Duration of Protection After the Last Dose of FTC/TAF

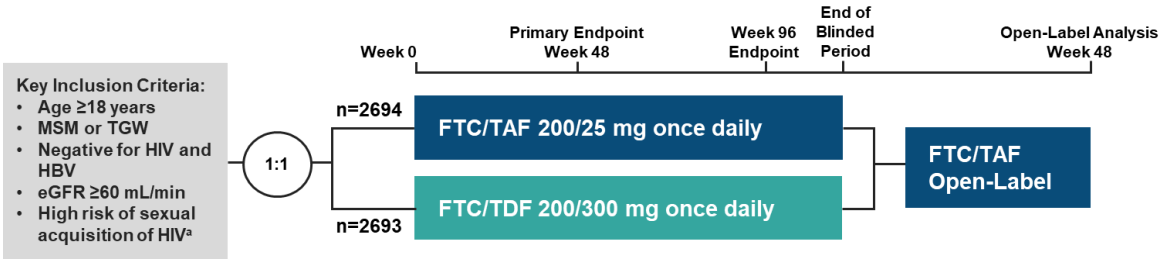
DISCOVER: FTC/TAF vs FTC/TDF for HIV-1 PrEP in MSM and TGW

Study design

DISCOVER was a phase 3, double-blind, active controlled, multinational study that included 5387 HIV-negative, adult MSM and TGW and evaluated the safety and efficacy of FTC/TAF vs FTC/TDF for HIV-1 PrEP (Figure 1).[2] Prior use of FTC/TDF for HIV-1 PrEP was allowed.[3] The primary outcome was the incidence of HIV acquisition.[2]

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Figure 1. DISCOVER: Study Design[2,4]



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

PK results

An analysis of PK data was conducted. TFV-DP concentrations in PBMCs were compared with PK data from historical phase 1 studies to estimate the onset and duration of HIV protection between the two arms. Based on a simulation at steady state with daily dosing, study investigators expected median PBMC TFV-DP levels to remain above EC_{90} longer with FTC/TAF (16 days) than FTC/TDF (10 days) after the last dose.[5]

However, the impact of these data has not been established in any clinical study. EC_{90} has not been shown to correlate with efficacy. The clinical relevance of these PK data and the correlate of HIV protection is unknown.

References

1. Enclosed. Gilead Sciences Inc, DESCOVY® (emtricitabine and tenofovir alafenamide) tablets, for oral use. U. S. Prescribing Information. Foster City, CA.
2. Wohl DA, Spinner CD, Flamm J, et al. HIV-1 infection kinetics, drug resistance, and long-term safety of pre-exposure prophylaxis with emtricitabine plus tenofovir alafenamide (DISCOVER): week 144 open-label extension of a randomised, controlled, phase 3 trial. *Lancet HIV.* 2024;11(8):508-521.
3. 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.
4. Wohl DA, Spinner CD, Flamm J, et al. HIV-1 infection kinetics, drug resistance, and long-term safety of pre-exposure prophylaxis with emtricitabine plus tenofovir alafenamide (DISCOVER): week 144 open-label extension of a randomised, controlled, phase 3 trial [Supplementary Appendix]. *Lancet HIV.* 2024;11(8):508-521.
5. Spinner CD, Brunetta J, Shalit P, et al. DISCOVER STUDY for HIV Pre-Exposure Prophylaxis: F/TAF has a more Rapid Onset and Longer Sustained Duration of HIV Protection Compared with F/TDF [Presentation]. Paper presented at: IAS 2019; 21-24 July, 2019; Mexico City, Mexico.

Abbreviations

EC_{90}=90% of maximum effective concentration
FTC=emtricitabine
MSM=men who have sex with men
PBMC=peripheral blood mononuclear cells
PK=pharmacokinetic(s)
PrEP=pre-exposure prophylaxis
STI=sexually transmitted infection
TAF=tenofovir alafenamide
TDF=tenofovir disoproxil fumarate
TFV-DP=tenofovir diphosphate
TGW=transgender women

Product Label

For the full indication, important safety information, and boxed warning(s), please refer to the Descovy and Truvada 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.

Follow-Up

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

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

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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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