GILEAD | Medical Information

Descovy for PrEP® (FTC/TAF) Use in Diabetes

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 individuals with diabetes mellitus.

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.

Summary

Product Labelling

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

DISCOVER evaluated the safety and efficacy of once-daily FTC/TAF vs FTC/TDF for HIV-1 PrEP.[1] In participants with DM, FTC/TAF was associated with smaller declines in eGFR compared with FTC/TDF; however, the difference was not statistically significant between treatment groups. Participants with DM experienced greater declines in eGFR, regardless of treatment group, compared with participants who did not have DM.[2]

Among participants who experienced drug-related renal adverse events, DM at baseline was present in 2 participants who received FTC/TAF and 1 participant who received FTC/TDF (P=0.24).[2]

Clinical Data

DISCOVER Study

Study design and demographics

DISCOVER is a phase 3, randomized, double-blind, active-controlled, multinational study in 5387 HIV-negative adult MSM and TGW that is evaluating the safety and efficacy of once-

daily FTC/TAF (n=2694) vs FTC/TDF (n=2693). Eligible participants were randomized 1:1 to receive either FTC/TAF 200/25 mg or FTC/TDF 200/300 mg with a corresponding placebo once daily. All participants were unblinded after 96 weeks, and participants in both arms were offered the opportunity to continue on or switch to open-label, once-daily FTC/TAF for an additional 48 weeks.[1]

Baseline rates of DM among participants in DISCOVER were similar between the FTC/TAF and FTC/TDF arms, at 3% (n=79) and 3% (n=89), respectively.[2,3]

Renal outcomes at Week 96 in participants with baseline characteristics that predisposed them to renal dysfunction, including DM, were evaluated.[2]

Results[2]

Through Week 96, effects on renal biomarkers (urine RBP:Cr and β2M:Cr) and $eGFR_{CG}$ changes from baseline significantly favored FTC/TAF (all *P*<0.001) in the overall study population. In participants with DM, FTC/TAF was associated with smaller declines in eGFR compared with FTC/TDF; however, the difference was not statistically significant between treatment groups. Participants with DM experienced greater declines in eGFR, regardless of treatment group, compared with participants who did not have DM (Table 1).

FTC/TAF was associated with stable or improved biomarkers of proximal renal tubular function, and FTC/TDF with worsening biomarkers of proximal renal tubular function. The median changes observed in β2M:Cr were significantly different between treatment groups in participants with and without DM. The median percent changes from baseline observed in RBP:Cr were significantly different between treatment groups in participants without DM but not in participants with DM (Table 1).

Table 1. Changes in Renal Outcomes from Baseline to Week 96 by Treatment Group and DM Diagnosis (DISCOVER)[2]

Renal Outcome	FTC/TAF	FTC/TDF	*P*-value
eGFR change, median, mL/min			
History of DM	-2.5	-5.1	0.55
No history of DM	-0.5	-4	<0.001
Proximal tubule biomarker change			
β2M:Cr change, median, %			
History of DM	-22.8	+40	0.01
No history of DM	-14.5	+13.6	<0.001
RBP:Cr change, median, %			
History of DM	+5.2	+22.1	0.09
No history of DM	-0.3	+21.4	<0.001

Among participants who experienced drug-related renal adverse events (FTC/TAF, n=14; FTC/TDF, n=26), DM at baseline was present in 2 participants who received FTC/TAF and 1 participant who received FTC/TDF (*P*=0.24).

References

1. ClinicalTrials.gov. Safety and Efficacy of Emtricitabine and Tenofovir Alafenamide (F/TAF) Fixed-Dose Combination Once Daily for Pre-Exposure Prophylaxis in Men and Transgender Women Who Have Sex With Men and Are At Risk of HIV-1 Infection (DISCOVER). ClinicalTrials.gov Identifier: NCT02842086. Last Updated: 22 October 2024.

2. Daar E, Brunetta J, Cua E, et al. Impact of Age and Medical Comorbidities on Renal Outcomes in the DISCOVER Trial [Poster 985]. Paper presented at: IDWeek Virtual; 21-25 October, 2020.
3. Mills A, Workowski K, Campbell T, et al. Renal Outcomes for Participants Taking F/TAF vs. F/TDF for HIV PrEP in the DISCOVER Trial [Presentation]. Paper presented at: IDWeek; 05 October, 2019; Washington, D.C.

Abbreviations

β2M=β2-microglobulin
DM=diabetes mellitus
FTC=emtricitabine
MSM=men who have sex with men
PrEP=pre-exposure prophylaxis
RBP=retinol-binding protein
TAF=tenofovir alafenamide fumarate
TDF=tenofovir disoproxil fumarate
TGW=transgender women

Product Label

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