Biktarvy®: Post-Exposure Prophylaxis

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This document is in response to your request for information regarding Biktarvy® (bictegravir/emtricitabine/tenofovir alafenamide [BIC/FTC/TAF]) and its use for HIV-1 infection post-exposure prophylaxis. Please be aware that BIC/FTC/TAF is not indicated for PEP in the US.[1]

The full indication, important safety information, and boxed warnings are available at:

http://www.gilead.com/~/media/files/pdfs/medicines/hiv/biktarvy/biktarvy_pi

Ongoing Clinical Trial

Biktarvy for Non-Occupational Post-Exposure Prophylaxis (nPEP) Study

Study Design and Available Baseline Demographics[2,3]

This is an ongoing, phase 4, non-randomized, single site, open label single arm trial to evaluate the safety, tolerability, and acceptability of a fixed-dose formulation of BIC/FTC/TAF for prophylaxis following potential non-occupational exposure to HIV-1. Key inclusion criteria are HIV uninfected and possible sexual exposure to HIV-1 recent enough to permit receiving the first dose of study medication within 72 hours from the end of the exposure. Participants receive BIC/FTC/TAF for 28 days and are seen for 3 visits over a period of four months. The primary endpoints are nPEP failure as measured by HIV seroconversion during study participation, and safety and tolerability of BIC/FTC/TAF. Currently available baseline demographics for the first 48 participants enrolled in the study are listed in Table 1.[3] Additional information regarding this study is available at www.clinicaltrials.gov (NCT03499483).

Table 1. Available Baseline Demographics (Mayer et al.)[3]

	BIC/FTC/TAF (N=48)
Age, median years (range)	32 (22-71)
Race/ethnicity, %	
White	79.2
Mixed	12.4
Hispanic/Latino ethnicity	8.3
Black/African American	4.2
Asian/Pacific Islander	4.2
Sexual Orientation/Gender Identity, %	
Gay/CG Male	75.0
Bisexual/CG Male	12.5
Heterosexual/CG Male	4.2
Heterosexual/CG Female	4.2
Queer/Transgender Male	2.1
Don't Know/CG Male	2.1

Results To Date[3]

At present, 48 participants have completed the study. No HIV seroconversions were detected among these participants. Reasons for initiating nPEP include receptive anal intercourse (49.7%), insertive anal intercourse (43.6%), receptive oral intercourse (15.4%), and insertive or receptive vaginal intercourse (7.7% for each). Two participants were lost to follow-up; 85.4% of the remaining participants completed the 28-day BIC/FTC/TAF course.

The most commonly reported adverse events included nausea with or without vomiting (15%), fatigue (6%), and diarrhea (6%). All adverse events were grade 1, except for a single report of grade 2 fatigue which was associated with discontinuation of BIC/FTC/TAF. Lab abnormalities were observed in 3 participants (increased transaminases [2], decreased CrCl [1]) and lab values returned to normal upon completion of the BIC/FTC/TAF course.

When compared to historical PEP regimens AZT/3TC/PI, FTC/TDF + RAL, and E/C/F/TDF, participants using BIC/FTC/TAF for PEP were statistically more likely to complete the regimen as prescribed and less likely to experience diarrhea, headache, and dizziness/lightheadedness.

References

1. Enclosed, Gilead Sciences Inc. BIKTARVY® (bictegravir, emtricitabine, and tenofovir alafenamide) tablets, for oral use. US Prescribing Information. Foster City, CA. In.
2. ClinicalTrials.gov. *Biktarvy for Non-Occupational Post-Exposure Prophylaxis (nPEP). ClinicalTrials.gov Identifier: NCT03499483. Available at: https://clinicaltrials.gov/ct2/show/record/NCT03499483?view=record. Accessed: 22 November 2019. Last Updated: 08 April.* 2019.
3. Mayer KH, Holmes J, Gelman M, Kraft J, Melbourne K, Mimiaga M. Safety and Tolerability of Once Daily BIC/FTC/TAF for Post-Exposure Prophylaxis [Poster P-S04, 1996]. Paper presented at: Conference on Retroviruses and Opportunistic Infections (CROI); 08-11 March, 2020; Boston, MA.

Abbreviations

3TC=lamivudine
AZT=zidovudine
BIC=bictegravir
CG=cisgender
CrCl=creatinine clearance
E/C/F/TDF=elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate
FTC=emtricitabine
PEP=post-exposure prophylaxis
PI=protease inhibitor
RAL=raltegravir
TAF=tenofovir alafenamide
TDF=tenofovir disoproxil fumarate

Product label

For the full indication, important safety information, and Boxed Warning(s), please refer to the Biktarvy US Prescribing Information available at: http://www.gilead.com/-/media/files/pdfs/medicines/hiv/biktarvy/biktarvy_pi.

Follow up

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

☎1-866-MEDI-GSI (1-866-633-4474) or 🌐 https://www.gilead.com/medicines/request-information

Adverse event reporting

Please report all adverse events to:

Gilead Pharmacovigilance and Epidemiology ☎ 1-800-445-3235, option 3

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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