GILEAD | Medical Information

Biktarvy® (BIC/FTC/TAF) Non-Daily Dosing

This document is in response to your request for information regarding Biktarvy® (BIC/FTC/TAF) and non-daily dosing. This response was developed according to principles of evidence-based medicine and only contains data from randomized controlled trials and observational studies.

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 warning are available at: www.gilead.com/~/media/files/pdfs/medicines/hiv/biktarvy/biktarvy_pi.

Summary

Product Labeling[1]

The recommended dosage in adults and pediatric patients weighing ≥25 kg is one tablet (BIC 50 mg, FTC 200 mg, and TAF 25 mg) taken orally once daily with or without food.

The recommended dosage in pediatric patients weighing ≥14 kg to <25 kg is one tablet (BIC 30 mg, FTC 120 mg, and TAF 15 mg) taken orally once daily with or without food.

Clinical Data on Non-Daily Dosing of BIC/FTC/TAF

In the randomized, open-label study, participants in the daily and 5-days-on-2-days off (FOTO) BIC/FTC/TAF groups had C_{trough} BIC levels >paEC$_{95}$ at Week 52, and those who switched to FOTO BIC/FTC/TAF in the OLE phase also had C_{trough} BIC levels >paEC$_{95}$ at OLE phase Week 4. At Week 52, 96.7% and 100% of participants in the daily and FOTO groups, respectively, had a plasma VL <50 c/mL, and 100% (56/56) were virologically suppressed at OLE phase Week 48. No VF (plasma VL >1000 c/mL) occurred during the study. No participants withdrew from the study due to AEs.[2]

In an observational study that included 85 PWH who received BIC/FTC/TAF 4 or 5 days per week, the overall virological success rate at Week 48 was 100% (95% CI: 95.8%–100%). Two VFs occurred: one at Week 49 and another at Week 70. Eight individuals discontinued treatment due to AEs, and no significant increase from baseline to the end of follow-up in body weight was observed.[3]

In a phase 4, open-label study, virologically suppressed participants who were receiving daily BIC/FTC/TAF were randomly assigned to continue daily BIC/FTC/TAF or switch to BIC/FTC/TAF TIW, BIW, or OW (n=10 per group). Rates of VL <50 c/mL at Week 48 ranged from 89% to 100% across treatment groups (ITT population). More participants in the OW group had VF (VL ≥50 c/mL) than those in the BIW and TIW groups. There were no significant changes from baseline in levels of glucose, lipid, and liver enzymes, eGFR, weight, sleep quality (via PSQI), and QoL (via EQ-5D-5L).[4]

Product Labeling[1]

Indications and Usage

BIC/FTC/TAF is indicated as a complete regimen for the treatment of HIV-1 infection in adults and pediatric patients weighing ≥14 kg:

- with no ARV treatment history, or
- with an ARV treatment history and not virologically suppressed, with no known or suspected substitutions associated with resistance to the integrase strand inhibitor class, FTC, or TFV, or
- to replace the current ARV regimen in those who are virologically suppressed (HIV-1 RNA <50 c/mL) on a stable ARV regimen with no known or suspected substitutions associated with resistance to BIC or TFV.

Dosage and Administration

Recommended dosage in adults and pediatric patients weighing ≥25 kg

The recommended dosage of BIC/FTC/TAF is one tablet containing 50 mg of BIC, 200 mg of FTC, and 25 mg of TAF taken orally once daily with or without food in:

- Adults and pediatric patients weighing ≥25 kg with an estimated CrCl ≥30 mL/min; or
- Virologically suppressed adults with an estimated CrCl <15 mL/min who are receiving chronic hemodialysis. On days of hemodialysis, administer the daily dose of BIC/FTC/TAF after completion of hemodialysis treatment.

Recommended dosage in pediatric patients weighing ≥14 kg to <25 kg

The recommended dosage of BIC/FTC/TAF is one tablet containing 30 mg of BIC, 120 mg of FTC, and 15 mg of TAF taken orally once daily with or without food in pediatric patients weighing ≥14 kg to <25 kg with an estimated CrCl ≥30 mL/min.

For children unable to swallow a whole tablet, the tablet can be split and each part taken separately as long as all parts are ingested within approximately 10 minutes.

Clinical Data on Non-Daily Dosing of BIC/FTC/TAF

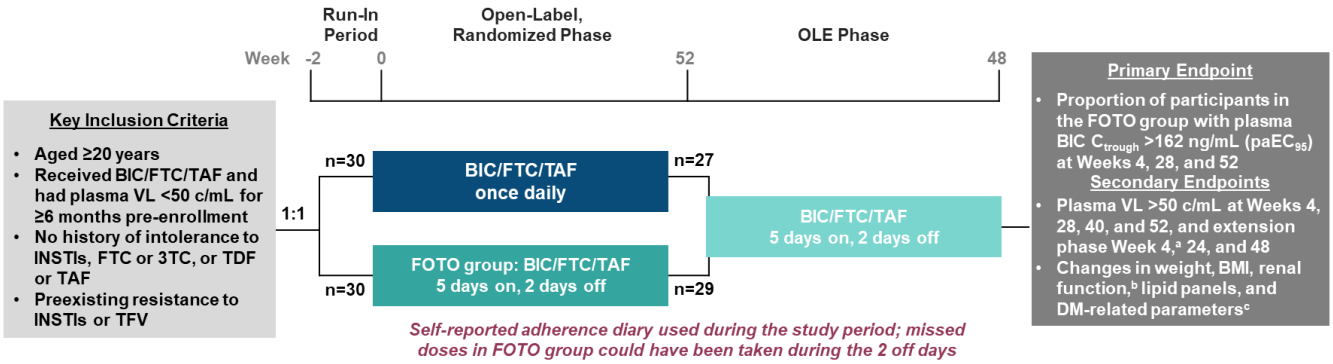
Open-Label Randomized Study of FOTO vs Once-Daily BIC/FTC/TAF

Study design and demographics

A single-center, randomized study in Taiwan compared PKs, efficacy, and safety in PWH treated with BIC/FTC/TAF once daily or FOTO. PWH who were virologically suppressed for ≥6 months were randomly assigned to receive once-daily (n=30) or FOTO (n=30) BIC/FTC/TAF for 52 weeks; following this, participants were able to enter an OLE phase during which all participants received FOTO BIC/FTC/TAF for 48 weeks (Figure 1).[2]

If VF occurred (defined as plasma HIV-1 VL >1000 c/mL at any time point), participants were withdrawn from the study. If VF occurred in the FOTO group, the participant would undergo genotypic resistance testing, restart daily ART, and have plasma VL assessments every 3 months until the VL was <50 c/mL. Thirty-seven participants (61.7%) had genotypic resistance test data available pre-enrollment; 5 participants had resistance-associated mutations to NRTIs (each, n=1): K103N and E138EG; M184V, V106I, Y181C, and H221Y; T215TA; E138EG; M184V.[2,5]

Figure 1. Study Design (Sun et al)[2]



Abbreviations: 3TC=lamivudine; TDF=tenofovir disoproxil fumarate.
[a]Week 4 assessments were only performed for those previously in the once-daily group during the randomized phase.
[b]Assessments included eGFR, UPCR, UACR, and urine β2M.
[c]Assessments included fasting glucose, HbA1c, insulin, and HOMA-IR.

Table 1. Baseline Demographics and Disease Characteristics (Sun et al)[2]

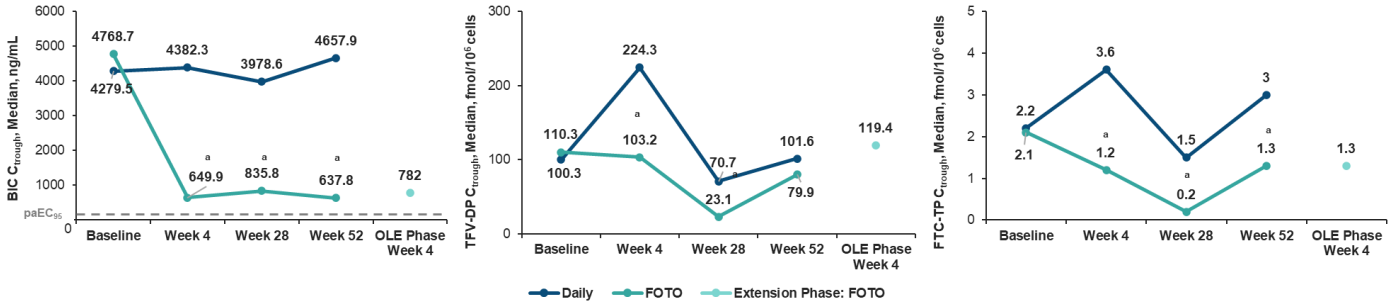
Key Demographics and Characteristics	Daily BIC/FTC/TAF (n=30)	FOTO BIC/FTC/TAF (n=30)
Age, median (IQR), years	41 (34–54)	43 (36–49)
Duration of HIV infection, median (IQR), years	12 (8–15.5)	13 (8.5–15)
Duration of prior BIC/FTC/TAF treatment, median (IQR), days	694 (621–945)	878 (659–940)
HIV-1 VL <50 c/mL, n (%)	30 (100)	29[a] (96.7)
CD4 count, median (IQR), cells/mm^3	690 (517–842)	675.5 (509–942.3)
HBsAg+, n (%)	5 (16.7)	4 (13.3)
HBV DNA <15 IU/mL, n/N (%)	5/5 (100)	4/4 (100)

[a]This participant had an HIV-1 VL of 227 c/mL and a BIC C_{trough} of 3564 ng/mL.

PK and efficacy results[2]

Plasma BIC C_{trough} levels decreased once participants began FOTO BIC/FTC/TAF; however, 90% to 100% of participants had values >paEC$_{95}$ at each time point during the randomized phase (Figure 2). In the FOTO group, 90%, 93.3% and 100% of participants achieved a BIC C_{trough} of >162 ng/mL at Weeks 4, 28 and 52, respectively. Three participants at Week 4 and 2 participants at Week 28 had levels <paEC$_{95}$, and all maintained plasma VL >50 c/mL. Seven participants had a plasma VL >50 c/mL (range: 62–227 c/mL), though each had a plasma BIC C_{trough} >paEC$_{95}$ at the same time point. Intracellular TFV-DP and FTC-TP C_{trough} levels are also shown in Figure 3.

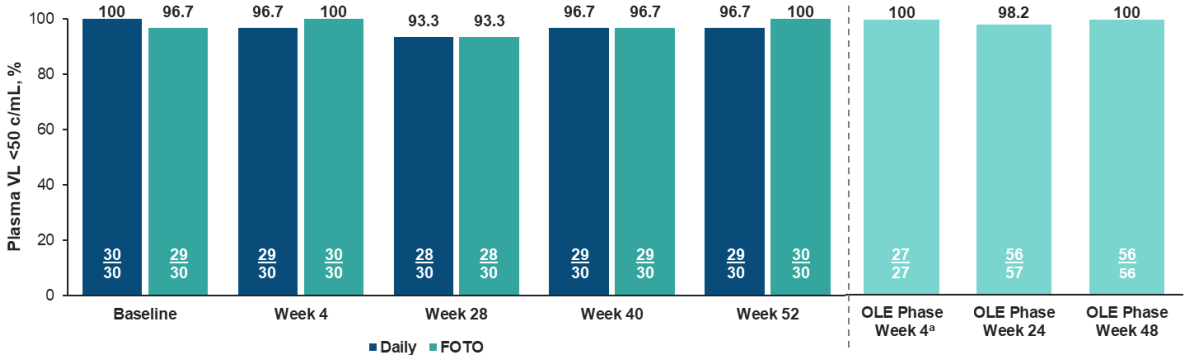
Figure 2. C_{trough} Levels of Plasma BIC (Primary Endpoint) and Intracellular TFV-DP and FTC-TP Among Participants Who Received FOTO BIC/FTC/TAF (Sun et al)[2,5]



[a]*P*<0.05 for between-group comparisons.
Note: Extension phase Week 4 data were evaluated only in those who were previously randomized to receive daily BIC/FTC/TAF. Values that differed significantly between time points were observed for FTV-DP and FTC-TP.

Rates of virologic suppression were similar between the daily and FOTO groups (*P*>0.05 for each comparison) and remained high with FOTO during the OLE phase (Figure 3). No cases of VF occurred during the study (plasma VL >1000 c/mL).

Figure 3. Proportion of Participants With Virologic Suppression (Plasma VL <50 c/mL; Sun et al)[2]



[a]Only evaluated in participants who switched from the daily group to receive FOTO during the OLE phase.

Safety[2]

Treatment with both regimens was well tolerated, and no participants discontinued from the study due to AEs.

Between treatment groups, there were no significant differences at time points in weight, BMI, kidney function, lipid profiles, DM-related parameters, UPCR, UACR, and urine β2M; however, those in the FOTO group had a significantly higher AST level at Week 52 than those in the once-daily group (no *P*-value provided). Further, there were no significant between-group differences in the changes from baseline to Week 52 in those selected laboratory parameters (Table 2). In the FOTO group, relative to baseline, Cr and eGFR improved, and HbA1c levels increased.

Table 2. Selected Laboratory Parameters Throughout the Study (Sun et al)[5]

Parameter, Median	Baseline		Week 4		Week 28		Week 52		EP Week 24		EP Week 48	
	Daily	FOTO	Daily	FOTO	Daily	FOTO	Daily	FOTO	Daily	FOTO	Daily	FOTO
Weight, kg	70	72.5	70	73.5	70	73	69	71.5	68	71.9	69	73
BMI, kg/m^2	23	23.5	23	23.5	22.8	23.3	23	23.5	22.7	24	22	24

Parameter, Median	Baseline		Week 4		Week 28		Week 52		EP Week 24		EP Week 48	
	Daily	FOTO	Daily	FOTO	Daily	FOTO	Daily	FOTO	Daily	FOTO	Daily	FOTO
Cr, mg/dL	1	1	1.1	1	1	1[a]	1	1[a]	1	1	1	1[a]
eGFR, mL/min/1.73 m^2	86.3	81.6	83.3	84.8	82.6	93.1[a]	88.9	89.7[a]	89.7	85.1[a]	89.4	85.1[a]
HbA1c, %	5.5	5.5	5.6	5.5	5.7[a]	5.7[a]	5.7[a]	5.8[a]	5.6	5.7[a]	5.5[b]	5.6[a]
HOMA-IR	1.81	1.4	1.7	1.4	1.7	1.4	1.6	1.6	1.4	1.2	1.7	1.3
TG, mg/dL	127	121.5	116	115	108	113	96	109	100	97	106	88
TC, mg/dL	177.5	181.5	175.5	179	179.5	189	173	185.5	173	186	169[b]	167
LDL, mg/dL	104	111	105.5	109	111	113.5	108	112	102	110	100[b]	97
HDL, mg/dL	48.5	51.5	47.5	54	52	54.5	49	55.5	46	55[a]	50	55
UPCR, mg/g	68.2	76.1	68.2	78	67.4	64.8	64.8	73.2	67.3	70.2	71.4	83
UACR, mg/g	6.2	7.6	6.1	7.6	8.5	5.6	6.6	5.8	7.7	10.8	7.2	9.3
Urine β2M, mg/dL	0.18	0.18	0.2	0.2	0.2	0.2	0.19	0.19	0.2	0.2	0.2	0.2[b]

Abbreviation: EP=extension phase.
[a]*P*<0.05 for comparison with baseline levels within the same group.
[b]*P*<0.05 for comparison with levels at Week 52, among those in the daily group.
Note: Group names for the EP columns denote the group to which participants were originally assigned.

No participants in the FOTO group needed to begin anti-DM or lipid-lowering agents after enrollment; however, 1 participant each required initiation of an anti-DM agent or lipid-lowering agent in the daily group.

Of the participants who were HBsAg+ at baseline (n=6, each group), all had HBV DNA VLs <15 IU/mL through Week 52 and OLE phase Week 48, and no hepatitis flares occurred.

Single-Center, Observational Study: 5D or 4D[3]

Study design and demographics

A retrospective study at a single hospital in Paris, France, assessed the real-life effectiveness of intermittently administered BIC/FTC/TAF in maintaining virologic suppression. Eighty-seven PWH who began treatment with BIC/FTC/TAF 5D or 4D between November 28, 2018, and July 30, 2020, were included in the analysis. The primary outcome was the rate of virological success at Week 48, which was defined as no VF (2 successive plasma VLs ≥50 c/mL, a single plasma VL ≥200 c/mL, or a single plasma VL ≥50 c/mL with a change in ART [eg, ART drug switch or restarted daily BIC/FTC/TAF]).

During the study, 46 individuals (54%) were in the 4D group, and 39 individuals (46%) were in the 5D group (Table 3). The median (IQR) duration of follow-up was 101 (82–111) weeks; all individuals had a plasma VL <50 c/mL at study entry.

Table 3. Single-Center, Observational Study: Baseline Demographics and Disease Characteristics[3]

Key Demographics and Characteristics	Overall (N=85)
Age, median (IQR), years	52 (46–59)
Male, n (%)	68 (80)
Weight, median (IQR), kg	85 (66–89)
Transmission group, MSM/heterosexual/other, n (%)	53 (62)/27 (32)/5 (6)
Time from HIV diagnosis, median (IQR), years	16 (6–24)
Time from ART initiation, median (IQR), years	13 (6–22)
Duration of virologic suppression, median (IQR), years	9 (3–13)

Key Demographics and Characteristics		Overall (N=85)
Past resistance to ART,[a] n/N (%)	≥1 NNRTI	16/51 (31)
	≥1 NRTI	16/55 (29)
	≥1 PI	7/53 (13)
	≥1 INSTI	1/33 (3)
CDC Stage C, n (%)		17 (20)
CD4 count, median (IQR), cells/mm^3		633 (461–781)
Nadir, median (IQR), cells/mm^3		234 (124–338)
CD4/CD8 ratio, median (IQR)		1 (0.65–1.26)
Previous type of ARV strategy, n (%)	Daily triple therapy	57 (67)
	5D or 4D triple therapy (not BIC/FTC/TAF)	28 (33)
Previous type of ARV regimen, n (%)	INSTI-based regimen	79 (93)
	BIC-based regimen	32 (38)

Abbreviations: CDC=Centers for Disease Control and Prevention; MSM=men who have sex with men; NNRTI=non-nucleoside reverse transcriptase inhibitor; PI=protease inhibitor.
[a]From cumulative historical HIV RNA and available sequences of HIV-DNA genotypes for reverse transcriptase, protease, and/or integrase.

Efficacy

The overall virological success rate was 100% (95% CI: 95.8–100%) at Week 48 and 97.6% (95% CI: 91.8–99.7%) at Week 96. Two VFs occurred between Week 48 and 96; both occurred in individuals who had poor compliance. The first individual had a plasma VL of 332 c/mL at Week 49, did not have available ARV concentrations, did not have any acquired resistance mutations, and was resuppressed with daily BIC/FTC/TAF. The second individual had a plasma VL of 758 c/mL at Week 70, had adequate BIC and FTC plasma C_{24h} and C_T levels, had low plasma TAF C_{24h} and C_T levels, did not have any acquired resistance mutations, and was resuppressed after continuing 4D dosing of BIC/FTC/TAF.

The strategy success rate (defined as no discontinuation of BIC/FTC/TAF due to VF or other reasons, including AEs; 95% CI) was 92.9% (85.3–97.4%) at Week 48 and 89.4% (80.8–95%) at Week 96. From baseline to the end of follow-up, there was no significant increase in the CD4 count (+7 cells/mm^3; 95% CI: -38 to +54; *P*=0.74) or in the rate of residual viremia (defined as ultra-sensitive HIV RNA of 1–20 c/mL; 44% to 30%, respectively; *P*=0.09; n=66); a small but significant increase in the CD4/CD8 ratio was also noted (+0.06; 95% CI: -0.01 to +0.11; *P*=0.02).

Safety

Eight individuals discontinued intermittent BIC/FTC/TAF due to AEs: weight gain, n=3; neuropsychiatric disorder, n=2; renal dysfunction, n=2; and digestive disorder, n=1. No significant increase in body weight from baseline to the last follow-up was observed (+1.2 kg; 95% CI: -0.08 to 3 kg; *P*=0.26).

Plasma ARV concentrations

Thirty-eight individuals had available plasma ARV levels (C_{24} and C_T). Twenty-two of these individuals (58%) had a BIC C_T less than the $paEC_{95}$ (162 ng/mL for wild-type HIV-1). Median (IQR) BIC, FTC, and TAF C_{24} levels were 1598 (1163–2281), 105 (48–305), and 10 (<5 to 20) ng/mL, respectively. Median (IQR) BIC, FTC, and TAF C_T levels were 114 (68–191), <5 (<5 to <5), and <5 (<5 to <5) ng/mL, respectively.

BETAF: Single-Center, Open-Label Randomized Dose-Reduction Study[4]

Study design and demographics

A phase 4, single-center, open-label, randomized study evaluated the feasibility of non-daily dosing of BIC/FTC/TAF. Consecutive PWH who were receiving once-daily BIC/FTC/TAF for ≥6 months, had a plasma VL <50 c/mL, CD4 count >350 cells/mcL, had no resistance to components of BIC/FTC/TAF, and did not have HBV or HCV were randomly assigned to receive BIC/FTC/TAF once-daily (n=10), TIW (on Monday, Wednesday, and Friday; n=10), BIW (on Tuesday and Friday; n=10), or OW (on Wednesday; n=10) for 48 weeks.

The primary endpoint was VL <50 c/mL (by FDA Snapshot in the on-treatment and ITT populations) at Weeks 12 and 48. Participants who experienced VF (defined as confirmed VL ≥50 c/mL) underwent genotypic resistance testing and restarted once-daily BIC/FTC/TAF. If >30% of participants had VF in any treatment arm, then that arm's treatment would be halted.

Table 4. BETAF Study: Baseline Demographics and Disease Characteristics[4]

Key Demographics and Characteristics	Overall (N=40)	BIC/FTC/TAF Dosing Frequency			
		Daily (n=10)	TIW (n=10)	BIW (n=10)	OW (n=10)
Age,[a] years	41 (35–45)	37 (33–41)	44 (33–47)	43 (37–49)	34 (30–46)
Male, n or n (%)	36 (92)	9	10	8	9
Time since HIV diagnosis,[a] years	8 (4–12)	8 (4–11)	9 (4–13)	9 (4–12)	8 (3–12)
CD4,[a] cells/mcL	635 (517–762)	635 (592–799)	525 (478–706)	629 (546–731)	689 (538–762)
CD4/CD8 ratio[a]	0.98 (0.83–1.14)	0.94 (0.91–1.19)	1.01 (0.87–1.13)	0.95 (0.62–1.01)	0.98 (0.98–1.14)

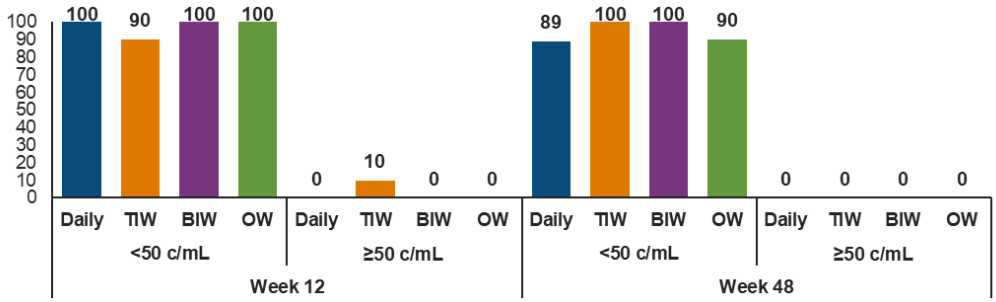
[a]The presentation of data (ie, median [IQR] or mean [range]) was not specified.

Efficacy

Of the 40 participants who underwent randomization, 33 completed the study; 1 participant withdrew consent at baseline (daily group; not included in analysis). Two discontinued treatment due to the participant's decision (BIW and OW groups, n=1 each, and at Weeks 24 and 12, respectively), 1 was lost to follow-up (daily group; at Week 12); these 3 participants had HIV VL <50 c/mL at their last visit. Three additional participants discontinued treatment due to VF, including 1 in the TIW group (at Week 12) and 2 in the OW group (both at Week 4).

In the ITT population, rates of VL <50 c/mL at Week 48 ranged from 89% to 100% across treatment groups (Figure 4). Rates of VF (≥50 c/mL) were higher among those in the OW group than the BIW and TIW groups; however, there was no emergent resistance, and participants were virologically suppressed once they reverted to once-daily BIC/FTC/TAF.

Figure 4. BETAF Study: Efficacy Outcomes at Weeks 12 and 48 by Treatment Group (ITT Population; FDA Snapshot Algorithm)[4]



Note: At Week 48, in the once-daily and OW groups, 1 participant in each group had missing virologic data.

In the daily and TIW groups, the CD4/CD8 ratio increased significantly from baseline to Week 48. From baseline to Weeks 12 or 48, there were no significant differences in the changes of CD4 and CD8 counts or CD4/CD8 ratio between the TIW, BIW, and OW groups relative to the daily group.

Levels of inflammatory markers by treatment group were also not significantly different between treatment groups at Week 12 and 48 (*P*-value not provided).

Safety and PK results

There were no significant changes from baseline in levels of glucose, lipid, and liver enzymes, eGFR, weight, sleep quality (via PSQI), and QoL (via EQ-5D-5L).

At Weeks 12 and 48, relative to values in the daily group, there were significant differences in mean plasma and intracellular C_{trough} values of BIC, FTC, and TAF; additionally, there were significant intra-group differences from baseline in those PK values in the TIW, BIW, and OW groups. The observed mean trough levels were generally greater than the inhibitory concentration for each drug component at Weeks 12 and 48, though they were not the OW group.

References

1. Enclosed, Gilead Sciences Inc. BIKTARVY® (bictegravir, emtricitabine, and tenofovir alafenamide) tablets, for oral use. US Prescribing Information. Foster City, CA.
2. Sun HY, Lin YT, Chang WC, et al. Five-days-on-two-days-off (FOTO) versus daily bictegravir/emtricitabine/tenofovir alafenamide in virologically suppressed people with HIV: a pilot randomized clinical trial. *J Antimicrob Chemother.* 2025;80(8):2179-2186.
3. Sellem B, Abdi B, Le M, et al. Intermittent Bictegravir/Emtricitabine/Tenofovir Alafenamide Treatment Maintains High Level of Viral Suppression in Virally Suppressed People Living with HIV. *Journal of Personalized Medicine.* 2023;13(4):583.
4. Chivite I, De Lazzari E, Sempere A, et al. Safety, Tolerability, and Efficacy of a BIC/FTC/TAF Dose Reduction Strategy [Poster 659]. Paper presented at: Conference on Retroviruses and Opportunistic Infections (CROI); March 9-12, 2025; San Francisco, CA.
5. Sun HY, Lin YT, Chang WC, et al. Five-days-on-two-days-off (FOTO) versus daily bictegravir/emtricitabine/tenofovir alafenamide in virologically suppressed people with HIV: a pilot randomized clinical trial [Supplementary Materials]. *J Antimicrob Chemother.* 2025;80(8):2179-2186.

Abbreviations

4D/5D=4/5 days per week
β2M=β-2 microglobulin
AE=adverse event
ART=antiretroviral therapy
ARV=antiretroviral
BIC=bictegravir
BIW=twice weekly
c/mL=copies/mL
C_T=concentration at the end of the discontinuation window
C_{24h}=concentration 24 hours after dose
C_{trough}=trough concentration
CD=cluster of differentiation
DM=diabetes mellitus
FOTO=5-days-on-2-days off
FTC=emtricitabine
FTC-TP=emtricitabine triphosphate
HBsAg=hepatitis B surface antigen
HOMA-IR=homeostatic model assessment for insulin resistance
INSTI=integrase strand transfer inhibitor
NRTI=nucleoside reverse transcriptase inhibitor
OLE=open-label extension
OW=once weekly
$paEC_{95}$=protein-adjusted effective concentration to cause inhibition by 95%
PK=pharmacokinetic(s)
PSQI=Pittsburgh Sleep Quality Index
PWH=people with HIV
QoL=quality of life
TAF=tenofovir alafenamide
TC=total cholesterol
TFV-DP=tenofovir diphosphate
TG=triglycerides
TIW=three times per week
UACR=urine albumin-to-Cr ratio
UGT1A1=uridine diphosphate glucuronosyl transferase family 1 member A1
UPCR=urine protein-to-Cr ratio
VF=virologic failure
VL=viral load

Product Label

For the full indication, important safety information, and boxed warning, please refer to the Biktarvy US Prescribing Information available at: 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 www.askgileadmedical.com

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Please report all adverse events to:

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