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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.

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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.

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

In a randomized, open-label study, participants in the BIC/FTC/TAF FOTO (n=30) compared with once daily (n=30) administration had C_{trough} BIC levels >paEC$_{95}$ at Week 52, and those who switched to BIC/FTC/TAF FOTO in the OLE phase (n=27) also had C_{trough} BIC levels >paEC$_{95}$ at Week 4 of the OLE. At Week 52, 96.7% and 100% of participants in the once daily and FOTO groups, respectively, had a plasma VL <50 c/mL, and 100% (56/56) were VS at Week 48 in the OLE. No VF (plasma VL >1000 c/mL) occurred during the study. No participants discontinued 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. No significant increase in body weight from baseline to the end of follow-up was observed.[3]

In a phase 4, open-label study, VS participants receiving once daily BIC/FTC/TAF were randomly assigned to continue once 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, lipids, or liver enzymes, or in 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 VS, with no known or suspected substitutions associated with resistance to the INSTI class, FTC, or TFV, or
- To replace the current ARV regimen in those who are VS (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
- VS 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.

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

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

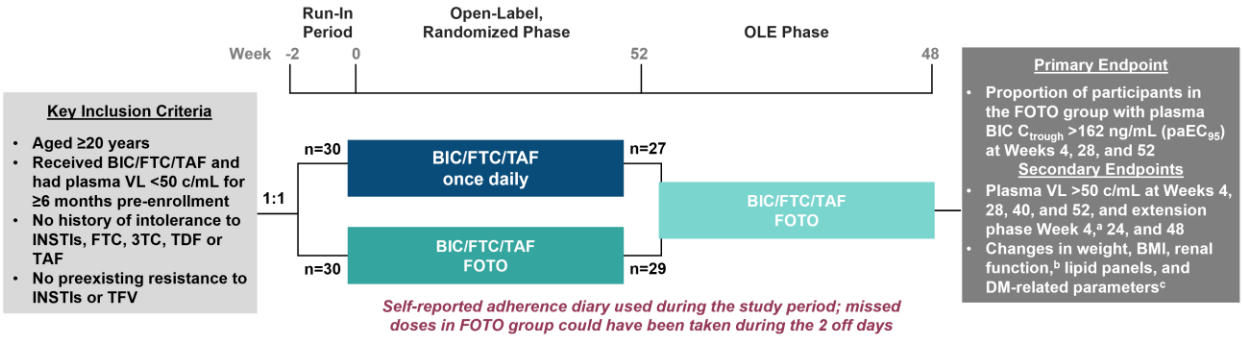
Study design and demographics

A single-center, randomized study in Taiwan compared the PKs, efficacy, and safety of BIC/FTC/TAF FOTO compared with once daily administration in PWH who were VS for ≥6 months. Participants were randomly assigned to receive BIC/FTC/TAF FOTO (n=30) or once daily (n=30) dosing for 52 weeks; after which they could enter an OLE phase and receive BIC/FTC/TAF FOTO 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 a participant in the FOTO group, they

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 had resistance-associated mutations to NRTIs: K103N and E138EG; M184V, V106I, Y181C, and H221Y; T215TA; E138EG; M184V (each, n=1).[2,5]

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



Abbreviations: 3TC=lamivudine; TDF=tenofovir disoproxil fumarate.
[a]Week 4 assessments in the OLE phase were only performed in participants who were 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]

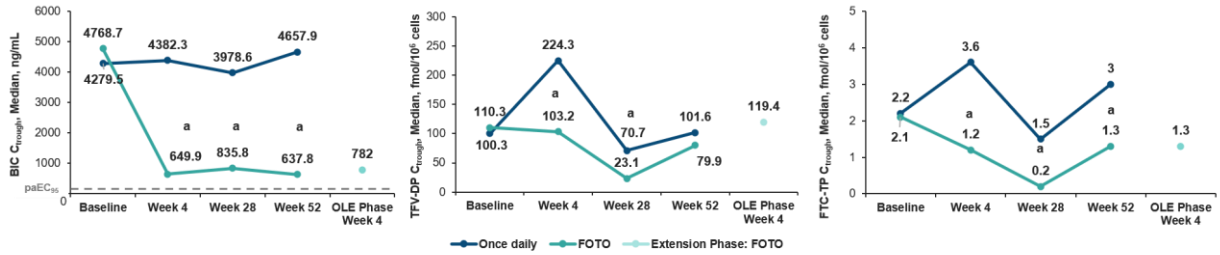
Key Demographics and Characteristics	Once Daily BIC/FTC/TAF (n=30)	FOTO BIC/FTC/TAF (n=30)
Age, median (IQR), years	41 (34–54)	43 (36–49)
Duration since HIV diagnosis, median (IQR), years	12 (8–15.5)	13 (8.5–15)
Duration of prior BIC/FTC/TAF treatment, median (IQR), days	694 (621–945)	878 (659–940)
HIV-1 VL <50 c/mL, n (%)	30 (100)	29 (96.7)[a]
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]One participant had an HIV-1 VL of 227 c/mL and a BIC C_{trough} of 3564 ng/mL.

PK and efficacy results

Plasma BIC C_{trough} levels decreased with BIC/FTC/TAF FOTO; 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 C_{trough} 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), although each had a plasma BIC C_{trough} >paEC$_{95}$ at the same time point. Intracellular TFV-DP and FTC-TP C_{trough} levels are shown in Figure 3.[2]

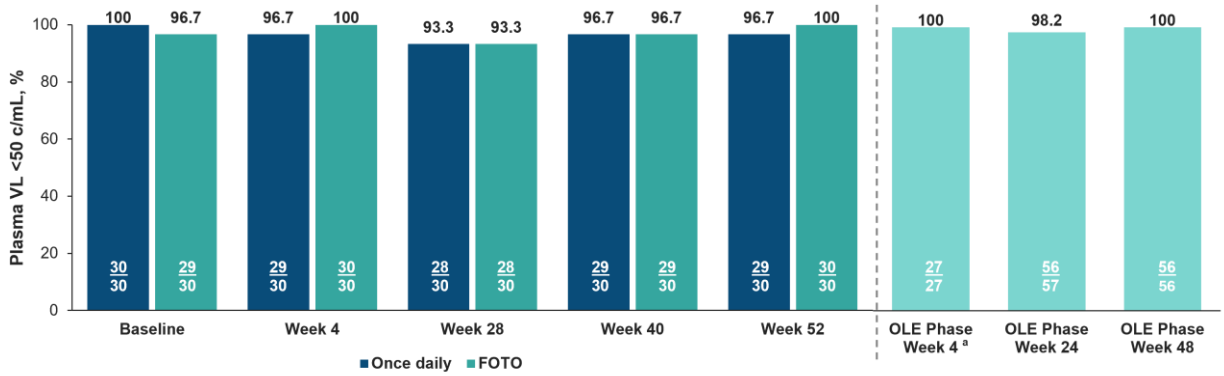
Figure 2. C_{trough} Levels of Plasma BIC, Intracellular TFV-DP and FTC-TP in the Randomized and OLE Phases From Baseline to OLE Phase Week 4 (Sun et al)[2,5]



[a]*P*<0.05 for between-group comparisons.
Note: OLE phase Week 4 data were evaluated only in those who received BIC/FTC/TAF once daily in the randomized phase. Intracellular TFV-DP and FTC-TP concentrations differed significantly across time points within the FOTO group (both *P*<0.05).

Rates of virologic suppression (plasma VL <50 c/mL) were similar between the FOTO and once daily groups (*P*>0.05 for each comparison) and remained high with FOTO during the OLE phase (Figure 3). No cases of VF (plasma VL >1000 c/mL) occurred during the study.[2]

Figure 3. Proportion of Participants With Virologic Suppression From Baseline Through OLE Phase Week 48 (Sun et al)[2]



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

Safety

Treatment with both regimens was well tolerated, and no participants discontinued due to AEs.[2]

Between treatment groups, there were no significant differences in weight, BMI, kidney function, lipid profiles, DM-related parameters, UPCR, UACR, and urine β2M at the assessed timepoints (Table 2). However, at Week 52, AST levels were higher in participants in the FOTO group than in the once daily group (no *P*-value provided). No significant between-group differences in changes in selected laboratory parameters from baseline to Week 52 were observed. In the FOTO group, relative to baseline, Cr and eGFR improved, and HbA1c levels increased.[2]

Table 2. Changes in Selected Laboratory Parameters From Baseline Through OLE Phase Week 48 (Sun et al)[5]

Parameter, Median	Baseline		Week 4		Week 28		Week 52		OLE Week 24		OLE 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
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]

Abbreviations: TC=total cholesterol; TG=triglycerides.
[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 once 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 once daily group.[2]

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.[2]

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

Study design and demographics

A retrospective study at a hospital in Paris, France, assessed the real-world effectiveness of intermittently administered BIC/FTC/TAF in maintaining virologic suppression. Eighty-five PWH who began treatment with BIC/FTC/TAF 5D or 4D between November 2018 and July 2020, were included in the analysis. The primary outcome was the virological success rate 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 switch or restarting daily BIC/FTC/TAF]).

The median (IQR) duration of follow-up was 101 (82–111) weeks. All participants were VS (plasma VL <50 c/mL) at study entry (Table 3).

Table 3. Single-Center, Observational Study: Baseline Demographics and Disease Characteristics (Sellem et al)[3]

Key Demographics and Characteristics	Overall (N=85)[a]
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)

Key Demographics and Characteristics		Overall (N=85)[a]
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)
Past resistance to ART,[b] 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-nucleos(t)ide reverse transcriptase inhibitor; PI=protease inhibitor.
[a]Forty-six participants (54%) received BIC/FTC/TAF 4D, and 39 (46%) received BIC/FTC/TAF 5D.
[b]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 participants with poor compliance. The first participant had a plasma VL of 332 c/mL at Week 49, did not have available ARV concentrations, had no documented treatment-emergent resistance mutations, and was resuppressed with once daily BIC/FTC/TAF. The second participant had a plasma VL of 758 c/mL at Week 70, with adequate BIC and FTC plasma C_{24h} and C_T levels but low plasma TAF C_{24h} and C_T levels, no treatment-emergent resistance mutations, and was resuppressed while continuing BIC/FTC/TAF 4D dosing.

The strategy success rate (defined as no discontinuation of BIC/FTC/TAF due to VF or other reasons, including AEs) was 92.9% (95% CI: 85.3–97.4%) at Week 48 and 89.4% (95% CI: 80.8–95%) at Week 96. From baseline to the end of follow-up, there was no significant increase in 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-1 RNA of 1–20 c/mL), which decreased from 44% to 30% (*P*=0.09; n=66). A small but significant increase in the CD4/CD8 ratio was observed (+0.06; 95% CI: -0.01 to +0.11; *P*=0.02).

Safety

Eight participants discontinued intermittent BIC/FTC/TAF due to AEs of 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 participants had available plasma ARV levels (C_{24} and C_T). Of these, 22 (58%) had a BIC C_T below 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 receiving once daily BIC/FTC/TAF for ≥6 months, with plasma VL <50 c/mL, CD4 count >350 cells/mcL, no resistance to components of BIC/FTC/TAF, and without 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 plasma 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 treatment in that arm would be stopped.

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)

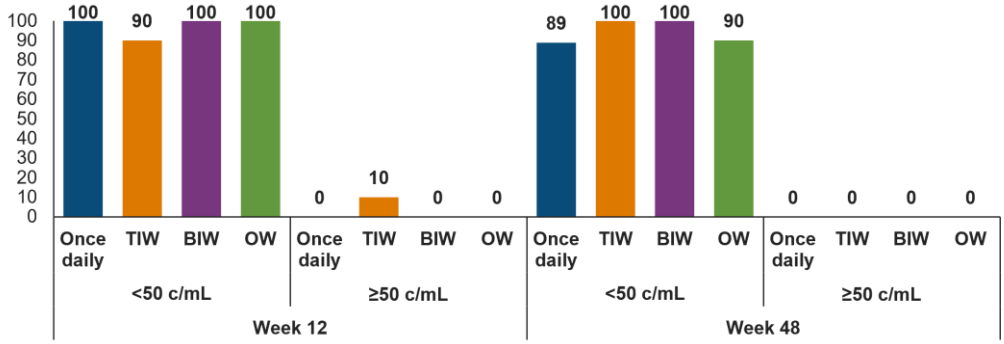
[a]The presentation of data (ie, median [IQR] or mean [range]) was not specified.

Efficacy

A total of 33 participants completed the study; 1 withdrew consent at baseline (once daily group; not included in analysis), 2 discontinued treatment by participant decision (BIW and OW groups, n=1 each, and at Weeks 24 and 12, respectively), and 1 was lost to follow-up (once daily group; at Week 12). All 3 participants had HIV-1 VL <50 c/mL at their last visit. An additional 3 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 (VL ≥50 c/mL) were higher among those in the OW group than the BIW and TIW groups; however, there was no treatment-emergent resistance, and participants were VS after reverting 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 once daily and TIW groups, the CD4/CD8 ratio increased from baseline to Week 48. From baseline to Weeks 12 or 48, there were no significant differences in the changes in CD4 and CD8 counts or CD4/CD8 ratio between the TIW, BIW, and OW groups relative to the once daily group.

In addition, no significant differences in inflammatory marker levels between treatment groups at Weeks 12 and 48 were observed (*P*-value not provided).

Safety and PK results

There were no significant changes from baseline in levels of glucose, lipids, or liver enzymes, or in eGFR, weight, sleep quality (via PSQI), or QOL (using the EQ-5D-5L).

Relative to values in the once daily group, differences in mean plasma and intracellular C_{trough} values of BIC, FTC, and TAF were observed in the TIW, BIW, and OW groups at Weeks 12 and 48. Additionally, there were 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, except in 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.

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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_{τ}=concentration at the end of the dosing interval
C_{24h}=concentration 24 hours after dose
C_{trough}=trough concentration
CD4/8=cluster of differentiation 4/8
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=nucleos(t)ide 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-1
QOL=quality of life
TAF=tenofovir alafenamide
TFV=tenofovir
TFV-DP=tenofovir diphosphate
TIW=three times per week
UACR=urine albumin-to-Cr ratio
UPCR=urine protein-to-Cr ratio
VF=virologic failure
VL=viral load
VS=virologically suppressed

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

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