GILEAD | Medical Information

Biktarvy® (BIC/FTC/TAF) Efficacy and Safety in Virologically Suppressed Adults With HIV-1

This document is in response to your request for information from Gilead studies on the use of Biktarvy® (bictegravir/emtricitabine/tenofovir alafenamide [BIC/FTC/TAF]) in virologically suppressed (VS) adults with HIV-1.

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/biktarvy/biktarvy_pi.

Summary

Product Labeling[1]

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 integrase strand inhibitor 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.

Gilead Studies on BIC/FTC/TAF Use in VS PWH

In VS adults with HIV-1, switching to BIC/FTC/TAF demonstrated high rates of efficacy compared with staying on the following baseline regimens:

- Boosted DRV or ATV + 2 NRTIs through Week 140[2,3]
- DTG + ABC/3TC or DTG/ABC/3TC through Week 168[4,5]
- E/C/F/(TAF or TDF) or ATV+RTV+FTC/TDF at Weeks 48 and 96[6,7]
- DTG + FTC/(TAF or TDF) at Week 48[8]
- 2 NRTIs plus a third agent through Week 72[9]

There was no treatment-emergent resistance in phase 3 clinicals trials of participants treated with BIC/FTC/TAF.[2,4,6,7,10,11]

BIC/FTC/TAF was well tolerated.[2-4,6,7,10] The most common drug-related AEs for the BIC/FTC/TAF arm in any study included headache, flatulence, and nausea.[2,4,6,7,10]

Data on additional Gilead studies are presented below.[7-10,20,21]

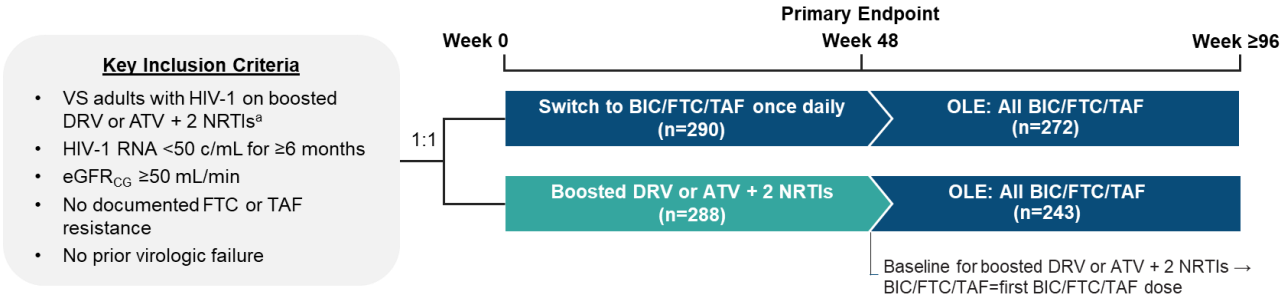
Gilead Studies on BIC/FTC/TAF Use in VS PWH

Study GS-US-380-1878

Study design and demographics

A phase 3, prospective, randomized, open-label clinical trial compared switching to BIC/FTC/TAF 50/200/25 mg STR (n=290) with staying on a baseline regimen of boosted DRV or ATV + 2 NRTIs (n=287) in VS adults with HIV-1 (Figure 1; Table 1). The primary endpoint was the proportion of participants with plasma HIV-1 RNA ≥50 c/mL at Week 48 by FDA Snapshot analysis with a pre-specified non-inferiority margin of 4%. Secondary endpoints included the proportion of participants with plasma HIV-1 RNA <50 c/mL at Week 48. Power was calculated for the primary efficacy endpoint only. As the study was not powered for secondary endpoints, *P*-values for those endpoints are nominal.[2]

Figure 1. Study 1878: Study Design[3,12]



[a]VS on regimen for ≥6 months; NRTIs included ABC/3TC or FTC/TDF, boosted with RTV or COBI.

Table 1. Study 1878: Baseline Demographics and Disease Characteristics[2]

Key Demographics and Characteristics		BIC/FTC/TAF (n=290)	Boosted DRV or ATV + 2 NRTIs (n=287)
Age, median (range), years		48 (20–74)	47 (21–79)
Male, %		84	82
Race or ethnicity, %	White	65	66
	Black or African descent	27	25
	Hispanic/Latinx	21	16
CD4 count, median, cells/mcL		617	626
HBV/HCV co-infection, n		8/5	6/5
$eGFR_{CG}$, median, mL/min		107	105
NRTIs at screening, %	FTC/TDF	84	84
	ABC/3TC	15	15
PIs at screening, %	DRV	56	53
	ATV	43	46

Results through Week 48

Efficacy[2]

Switching to BIC/FTC/TAF demonstrated non-inferior efficacy (HIV-1 RNA ≥50 c/mL) by the FDA Snapshot analysis compared with staying on a baseline regimen of boosted DRV or ATV + 2 NRTIs at the Week 48 primary endpoint (2% vs 2%, respectively; difference, 0%; 95% CI: -2.5% to 2.5%; *P*=1). Switching to BIC/FTC/TAF also demonstrated non-inferior

efficacy compared with staying on a baseline regimen of boosted DRV or ATV + 2 NRTIs based on the secondary endpoint of the proportion of participants with HIV-1 RNA <50 c/mL at Week 48 (92% vs 89%, respectively; difference 3.2%; 95% CI: -1.6% to 8.2%; *P*=0.2). Five participants in the BIC/FTC/TAF arm had HIV-1 RNA ≥50 c/mL: 2 participants with HIV-1 RNA ≥50 c/mL in the Week 48 window, 1 participant who discontinued treatment before Week 48 due to lack of efficacy, and 2 participants who discontinued treatment before Week 48 due to other reasons with last available HIV-1 RNA ≥50 c/mL.

The mean change in CD4+ count from baseline to Week 48 was +25 cells/mm^3 in participants who switched to BIC/FTC/TAF and +0 cells/mm^3 in participants who stayed on their baseline regimen of boosted DRV or ATV + 2 NRTIs.

Resistance

Eight participants met the protocol-defined criteria for resistance testing; of these, 1 of the 2 participants from the BIC/FTC/TAF arm and 2 of the 6 participants from the boosted PI arm resuppressed to HIV-1 RNA <50 c/mL without a change in regimen.[12]
No treatment-emergent resistance was detected in participants taking BIC/FTC/TAF.
One participant who remained on their baseline regimen of ABC/3TC + RTV-boosted DRV experienced virologic failure with a treatment-emergent L74V mutation in reverse transcriptase at Week 24.[2] This mutation is associated with reduced susceptibility to ABC.[13]

Safety

Both regimens were well tolerated. Any-grade AEs that occurred in ≥5% of participants in either the BIC/FTC/TAF or boosted DRV or ATV + 2 NRTIs arm included the following: headache (12% vs 4%, respectively), diarrhea (8% vs 6%), nasopharyngitis (7% vs 12%), URTI (7% vs 8%), back pain (4% vs 6%), and arthralgia (4% vs 5%). The most common (≥2%) drug-related AEs for BIC/FTC/TAF were headache (5%), flatulence (2%), and nausea (2%).[2]

Discontinuations due to AEs were reported in 2 participants in the BIC/FTC/TAF arm (rash, n=1 [unrelated to study drug] and schizophrenia, n=1) and in 1 participant who stayed on their baseline regimen of boosted DRV or ATV + 2 NRTIs (acetabular fracture and acute kidney injury). Two deaths occurred during the study (1 in each arm), and neither was considered related to study drug.[2]

There were no discontinuations due to renal AEs and no cases of proximal renal tubulopathy or Fanconi syndrome in participants on BIC/FTC/TAF.[2]

Median changes from baseline in eGFR$_{CG}$ of -4.3 mL/min vs +0.2 mL/min were observed in participants who received BIC/FTC/TAF vs stayed on boosted DRV or ATV + 2 NRTIs, respectively (*P*=0.0005). Participants who switched the NRTI component of their regimen from TDF or ABC to TAF had decreases or smaller increases in renal biomarkers, compared with those who stayed on their baseline regimens.[2] Switching to BIC/FTC/TAF was associated with small decreases in triglycerides and TC:HDL ratio (-6 mg/dL and -0.2, respectively).[14] At baseline, 16.2% of participants taking BIC/FTC/TAF and 15.7% of those taking boosted DRV or ATV + 2 NRTIs were also taking lipid-lowering agents (*P*=0.91). During the study, 3% of BIC/FTC/TAF and 3% of ATV + 2 NRTIs participants initiated lipid-lowering medications (*P*=0.64).[2]

Extension phase results

The long-term efficacy and safety of BIC/FTC/TAF were evaluated in an OLE.[3,12] Of the 532 participants who completed the 48-week randomized phase, 515 entered the OLE

phase. The all-BIC/FTC/TAF arm consisted of participants who received ≥1 dose of BIC/FTC/TAFbaseline values for participants who switched from their previous regimen at Week 48 were considered to be those measured at the first dose of BIC/FTC/TAF in the OLE.[12]

The median (Q1, Q3) duration of BIC/FTC/TAF exposure was 101 (72,120) weeks, with a maximum duration of 181 weeks.[12] High rates (96–100%) of virologic suppression were maintained through 180 weeks in the all-BIC/FTC/TAF arm in an M=E analysis; 100% of participants (n=14) who remained in the study through Week 180 maintained HIV-1 RNA <50 c/mL.[12] CD4 cell counts remained stable at Weeks 96 and 120 of the OLE.[3]

No treatment-emergent resistance to BIC/FTC/TAF was detected throughout the randomized or OLE phases, and 98% of BIC/FTC/TAF participants (212/217) with any primary baseline resistance maintained HIV-1 RNA <50 c/mL at the last study visit.[12]

BIC/FTC/TAF was well tolerated, and no participant discontinued treatment due to renal or bone AEs during the OLE phase. Four AEs occurred that were considered related to BIC/FTC/TAF and led to study discontinuation: diarrhea and vomiting, rash and pruritus, insomnia, and suicidal ideation (each, n=1). Two additional serious AEs occurred during the OLE phase that were attributed to BIC/FTC/TAF: suicidal ideation in a participant with preexisting bipolar and borderline personality disorder [n=1], and deep vein thrombosis [n=1]).[3]

From baseline to 96 weeks after BIC/FTC/TAF initiation, the median change in $eGFR_{CG}$ was -3.4 mL/min, and the median change in body weight was +2.2 kg.[3]

Study GS-US-380-1844[4]

Study design and demographics

A phase 3, randomized, double-blind study evaluated the safety and efficacy of switching to BIC/FTC/TAF (n=282) vs staying on a baseline regimen of DTG + ABC/3TC or DTG/ABC/3TC STR (n=281) in VS adults with HIV-1 (Figure 2; Table 2). The primary endpoint was the proportion of participants with plasma HIV-1 RNA ≥50 c/mL at Week 48 by the FDA Snapshot analysis with a pre-specified non-inferiority margin of 4%.[4] Secondary endpoints at Week 48 included the proportion of participants with plasma HIV-1 RNA <50 c/mL by the FDA Snapshot analysis, change from baseline in CD4+ count, and change from baseline in hip and spine BMD.[15] Power was calculated for the primary efficacy endpoint only. As the study was not powered to detect differences in secondary endpoints, p-values for those endpoints are nominal.[4]

Figure 2. Study 1844: Study Design[4]

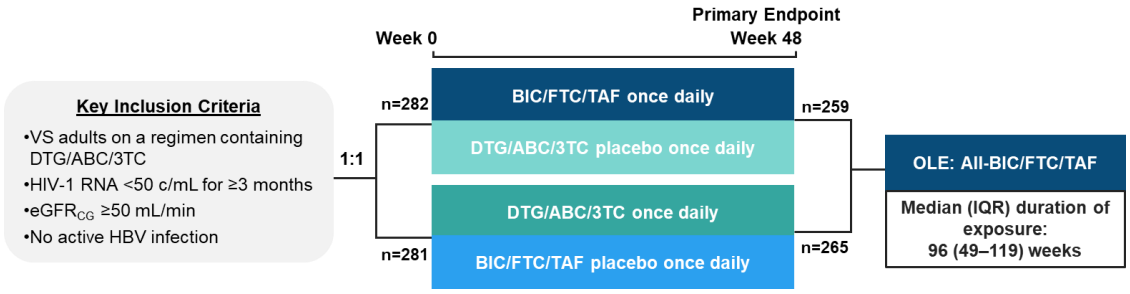


Table 2. Study 1844: Baseline Demographics and Disease Characteristics[4]

Key Demographics and Characteristics		BIC/FTC/TAF (n=282)	DTG/ABC/3TC (n=281)
Age, median (range), years		47 (21–71)	45 (20–70)
Male, %		88	90
Race or ethnicity, %	White	73	73
	Black or African descent	21	22
	Hispanic/Latinx	16	19
CD4 count, median, cells/mcL		732	661
$eGFR_{CG}$, median, mL/min		101	101

Results through Week 48[4]

Efficacy

Switching to BIC/FTC/TAF demonstrated non-inferior efficacy compared with staying on a baseline regimen of DTG/ABC/3TC by FDA Snapshot analysis at the Week 48 primary endpoint (HIV-1 RNA ≥50 c/mL: 1% vs <1%, respectively; difference, 0.7%; 95% CI: -1% to 2.8%; *P*=0.62). Virologic suppression (HIV-1 RNA <50 c/mL) was maintained in 94% of participants who switched to BIC/FTC/TAF vs 95% of participants who stayed on a baseline regimen of DTG/ABC/3TC (difference, -1.4%; 95% CI: -5.5% to 2.6%; *P*=0.59).

Three participants in the BIC/FTC/TAF arm had HIV-1 RNA ≥50 c/mL, with 1 participant in each of the following categories: HIV-1 RNA ≥50 c/mL in the Week 48 window; treatment discontinued before Week 48 due to AE or death, with last available HIV-1 RNA ≥50 c/mL; and treatment discontinued before Week 48 due to reasons other than lack of efficacy, AEs, or death, with last available HIV-1 RNA ≥50 c/mL.

The mean change in CD4+ count from baseline to Week 48 was -31 cells/mm^3 in participants who switched to BIC/FTC/TAF and +4 cells/mm^3 in participants who stayed on DTG/ABC/3TC.

Resistance

Five participants met protocol-defined criteria for resistance testing (BIC/FTC/TAF, n=3; DTG/ABC/3TC, n=2). No treatment-emergent resistance was detected in participants in either arm. One participant with possible intermittent adherence in each arm was virologically resuppressed without changing their regimen. Two participants in the BIC/FTC/TAF arm and 1 in the DTG/ABC/3TC arm discontinued the study early with HIV-1 RNA >200 c/mL.

Safety

Any-grade TRAEs were reported in 8% in the BIC/FTC/TAF arm and 16% in the DTG/ABC/3TC arm. The difference in the incidence of TRAEs between arms resulted mainly from drug-related gastrointestinal (ie, flatulence, nausea, and diarrhea) and neuropsychiatric (ie, abnormal dreams and insomnia) AEs in the DTG/ABC/3TC arm (Table 3).

Table 3. Study 1844: Most Common TRAEs[4]

TRAE, %	BIC/FTC/TAF (n=282)	DTG/ABC/3TC (n=281)	*P*-Value
Headache	2	3	0.8
Diarrhea	1	1	0.45
Abnormal dreams	<1	2	0.12

TRAE, %	BIC/FTC/TAF (n=282)	DTG/ABC/3TC (n=281)	*P*-Value
Fatigue	<1	1	0.37
Flatulence	0	2	0.03
Nausea	0	2	0.03
Insomnia	0	1	0.12

Note: Safety was summarized using descriptive statistics; *P*-values were nominal.

There were no discontinuations due to renal AEs, and there were no cases of proximal renal tubulopathy or Fanconi syndrome in either arm.

Two deaths occurred during the study (both in the BIC/FTC/TAF arm), but neither was considered related to study drug.

There were small numerical differences in the median change from baseline in $eGFR_{CG}$ between treatment arms: +1 mL/min for BIC/FTC/TAF vs -1.8 mL/min for DTG/ABC/3TC. Changes in BMD from baseline to Week 48 were similar and did not differ significantly between treatment arms. The mean percent change from baseline to Week 48 in the BIC/FTC/TAF vs DTG/ABC/3TC arms in lumbar spine BMD was 0.69% vs 0.42%, respectively, (*P*=0.33) and in hip BMD was 0.3% vs 0.16% (*P*=0.47). Switching to BIC/FTC/TAF was associated with similar changes in fasting lipid parameters compared with remaining on DTG/ABC/3TC, with the exception of a small, significant decrease in triglycerides in the BIC/FTC/TAF arm. Lipid-lowering mediations were initiated during the study by 1% and 4% of participants in the BIC/FTC/TAF and DTG/ABC/3TC arms, respectively (*P*=0.033).

PROs through Week 48[16,17]

Methods

In Study 1844, PRO instruments were evaluated at baseline, and at Weeks 4, 12, and 48 to assess the relationship between treatments and bothersome HIV symptoms, and/or AEs with adherence and persistence. PRO instruments included the HIV-SI, PSQI, SF-36 PCS/MCS, and WPAI, and treatment differences were assessed using logistic regression models. Longitudinal modeling was also performed to show the prevalence of bothersome symptoms and poor sleep quality over time using generalized mixed models that included treatment, time, time-by-treatment interaction, and covariates in the logistic regression model.

Results

Switching to BIC/FTC/TAF was associated with a significantly lower prevalence of select patient-reported bothersome symptoms and poor sleep quality compared to remaining on DTG/ABC/3TC (Table 4). Hair loss/changes at Week 4 was the only symptom that favored DTG/ABC/3TC, but there was no difference in the prevalence of hair loss/changes between treatment arms from Week 4 to Week 48.

No treatment differences between arms were noted using the SF-36 PCS/MCS and WPAI tools.

Table 4. Study 1844: Select PROs After Switching to BIC/FTC/TAF vs DTG/ABC/3TC[16,17]

PROs		Results[a]
HIV-SI Bothersome Symptoms	Dizzy/lightheadedness	Favors BIC/FTC/TAF
	Sad/down/depressed	Favors BIC/FTC/TAF
	Nervous/anxious	Favors BIC/FTC/TAF
	Nausea/vomiting	Favors BIC/FTC/TAF
	Loss of appetite	Favors BIC/FTC/TAF
	Difficulty sleeping	Favors BIC/FTC/TAF
PSQI	Poor sleep quality	Favors BIC/FTC/TAF

[a]Statistically significant (P<0.05) at ≥2 time points in adjusted logistic regression model or at 1 time point in adjusted logistic regression model and longitudinal model.

Extension phase results

The efficacy and safety of BIC/FTC/TAF through Week 168 were evaluated in an OLE. The all-BIC/FTC/TAF arm consisted of participants who received ≥1 dose of BIC/FTC/TAF (N=547); baseline values for participants who switched from their previous regimen at Week 48 were considered to be those measured at the first dose of BIC/FTC/TAF in the OLE.[5]

HIV-1 RNA <50 c/mL was maintained in 99% to 100% of participants taking BIC/FTC/TAF at all measured time points through 168 weeks (M=E analysis). At Week 168, 14 participants in the all-BIC/FTC/TAF arm were still in the study, and 100% had HIV-1 RNA <50 c/mL. In the 4 participants who met criteria for resistance testing, no treatment-emergent resistance to BIC/FTC/TAF was reported. Overall, 99% of BIC/FTC/TAF participants (159/161) with any primary baseline resistance mutation maintained HIV-1 RNA <50 c/mL.[5]

The most common (≥10% of participants) AEs included URTI (14%), nasopharyngitis (10%), and diarrhea (10%). There were no reports of proximal renal tubulopathy or study discontinuations due to renal AEs. Most fasting lipid levels remained stable in the all-BIC/FTC/TAF arm through the randomized and OLE phases. Median LDL levels increased slightly from Week 48 to Week 96, and 3% of participants began lipid-modifying agents during the study.[5] The median weight change from baseline to Week 120 was +1.8 kg among all-BIC/FTC/TAF participants.[18]

Table 5. Study 1844: Safety Outcomes[19]

AE, n (%)	BIC/FTC/TAF (n=547)
Any AE	446 (82)
Any Grade 3 or 4 AE	33 (6)
Any TRAE[a]	39 (7)
Any serious AE	47 (9)
Any AE leading to study discontinuation[b]	7 (1)
Death[c]	3 (1)

[a]Most TRAEs were Grade 1 or 2 in severity, and the most common TRAE was headache (1.6%).
[b]In the OLE, 1 participant experienced a treatment-related headache that led to discontinuation.
[c]One treatment-emergent death occurred during the OLE (hypertensive cardiovascular disease in a participant with medical history), which was not considered related to treatment. The other 2 deaths were previously reported (Week 48).

Additional Gilead Studies[7-9,20-22]

Additional Gilead clinical trials were conducted in the several populations of participants with HIV-1 who were VS and switched to BIC/FTC/TAF (Table 6). High rates of virologic suppression were maintained, with no new safety signals. Real-world cohorts also showed high rates of virologic suppression and a similar safety profile to what was found in phase 3 clinical trials.

Table 6. Additional Gilead Studies in VS Participants Who Switched to BIC/FTC/TAF[7-9,20-22]

Trial Number	Comparator Arm	Patient Population	Efficacy Endpoints	Safety Summary
Clinical Trials				
GS-US-380-1961[7]	E/C/F/(TAF or TDF) or ATV + RTV + FTC/TDF	VS adult women (N=470)	Week 48: Switching to BIC/FTC/TAF, vs SBR, demonstrated non-inferior efficacy by FDA Snapshot analysis. VL ≥50 c/mL, 1.7% vs 1.7%, respectively; difference, 0%; 95% CI: -2.9% to 2.9%	AEs occurring in ≥5% of participants (all grades) in either the BIC/FTC/TAF or baseline arms at Week 48: nasopharyngitis, urinary tract infection, URTI, headache, and vulvovaginal candidiasis
GS-US-380-4030[8]	DTG + FTC/(TAF or TDF)	VS adults, including those with known BL resistance mutations, except INSTI-R mutations (N=565)	Week 48: Switching to BIC/FTC/TAF, vs SBR, demonstrated non-inferior efficacy by FDA Snapshot analysis: VL ≥50 c/mL, <1% vs 1%, respectively; difference, -0.7%; 95% CI: -2.8% to +1% Rates of virologic suppression were high regardless of preexisting NRTI–R	AEs occurring in ≥5% of participants (all grades) in either the BIC/FTC/TAF or baseline arms at Week 48: nasopharyngitis, diarrhea, URTI, headache, arthralgia, influenza, fatigue, insomnia, back pain, bronchitis, cough
GS-US-380-4580 (BRAAVE 2020)[9,20]	2 NRTIs + third agent[a]	VS adults self-identifying as African American; Black; or mixed race, including Black (N=495)	Week 24: Switching to BIC/FTC/TAF, vs SBR, demonstrated non-inferior efficacy by FDA Snapshot analysis: VL ≥50 c/mL,0.6% vs 1.8%, respectively; difference, -1.2%; 95% CI: -4.8% to 0.9%	AEs occurring in ≥5% of participants (all grades) in either the BIC/FTC/TAF or baseline arms at Week 24: URTI
Real-World Data				
OPERA cohort[21]	DTG/3TC	Adults who were VS at the time of switch (N=6040)	Confirmed virologic failure (2 consecutive VLs of ≥200 c/mL or ARV discontinuation after a VL ≥200 c/mL) in weighted population: BIC/FTC/TAF, 2% (84/3527); DTG/3TC, 3% (59/2213; HR, 0.84; 95% CI: 0.59–1.18).	Of all DCs, side effects led to DC: BIC/FTC/TAF, 3% (17/631); DTG/3TC, 4% (18/443) Deaths: BIC/FTC/TAF, <1% (22/3713); DTG/3TC, <1% (9/2327)
BICSTaR study[22]	None, single-arm, observational study	ARV-naive and TE participants with HIV (N=2074)	Month 24: 96% of TE participants (1198/1247) were VS (VL <50 c/mL) using an M=E analysis	DRAEs in and 12% (197/1591) of TE participants at 24 months. The most common DRAEs were weight increased, headache, and depression

Abbreviations: BL=baseline; DRAE=drug-related adverse event; INSTI-R=integrase strand transfer inhibitor resistance; NNRTI=non-nucleos(t)ide reverse transcriptase inhibitor; OPERA=observational pharmaco-epidemiology research and analysis; SBR=stay on baseline regimen; VL=viral load.
[a]The allowed third agents included any INSTI except BIC, any PI, maraviroc, or any NNRTI except etravirine.

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Abbreviations

3TC=lamivudine
ABC=abacavir
AE=adverse event
ARV=antiretroviral
ATV=atazanavir
BIC=bictegravir
c/mL=copies/mL
CD4=cluster of differentiation-4
CG=Cockcroft-Gault equation
COBI=cobicistat
DRV=darunavir
DTG=dolutegravir
E/C/F/(TAF or TDF)=elvitegravir/cobicistat/emtricitabine/(tenofovir alafenamide or tenofovir disoproxil fumarate)
FTC=emtricitabine
HIV-SI=HIV Symptom Index
MCS=Mental Component Summary
M=E=missing equals excluded
NRTI=nucleos(t)ide reverse transcriptase inhibitor
OLE=open-label extension
PCS=Physical Component Summary
PI=protease inhibitor
PRO=patient-reported outcome
PSQI=Pittsburgh Sleep Quality Index
PWH=people with HIV
Q=quartile
RTV=ritonavir
SF-36=36-Item Short Form Health Survey
STR=single-tablet regimen
TAF=tenofovir alafenamide
TC=total cholesterol
TDF=tenofovir disoproxil fumarate
TE=treatment-experienced
TFV=tenofovir
TN=treatment-naive
TRAE=treatment-related adverse event
URTI=upper respiratory tract infection
VS=virologically suppressed
WPAI=Work Productivity and Activity Impairment

Product Label

For the full indication, important safety information, and boxed warning(s), 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:

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🖱 https://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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