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Biktarvy® (BIC/FTC/TAF) Efficacy and Safety in ARV-Naive Participants

This document is in response to your request for information regarding the efficacy and general safety profile of Biktarvy® (bictegravir/emtricitabine/tenofovir alafenamide [BIC/FTC/TAF]) in ARV-naive participants with HIV-1. Please see summary below of Gilead registrational studies.

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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 virologically suppressed, 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.

BIC/FTC/TAF is not recommended in patients with estimated CrCl <30 mL/min, by Cockcroft-Gault, or patients with ESRD (estimated CrCl <15 mL/min) who are not receiving chronic dialysis, or patients with no ARV treatment history and ESRD who are receiving chronic dialysis, as the safety and/or efficacy of BIC/FTC/TAF have not been established in these populations.

Clinical Data on BIC/FTC/TAF Use in ARV-Naive Participants

Studies 1489 and 1490 compared BIC/FTC/TAF to triple therapy DTG-containing regimens in ARV-naive adults infected with HIV-1.[2,3]

- BIC/FTC/TAF demonstrated non-inferior efficacy to DTG + FTC/TAF and DTG/ABC/3TC at Week 48 (primary endpoint) and at Weeks 96 and 144 (secondary endpoints).[2-7]
- The most frequently reported AEs through Week 144 included nausea, diarrhea, URTI, headache, nasopharyngitis, and syphilis.[7]
- Among participants who continued BIC/FTC/TAF in the OLE phase, high efficacy rates were maintained through Week 240, including in subgroups by BL VL and CD4 count. Drug-related AEs occurred rarely, and few participants (n=5) discontinued treatment due to drug-related AEs. No treatment-emergent resistance was detected in any BIC/FTC/TAF-treated participant through Week 240.[8,9]

- In the OLE phase, the participants who switched from DTG-containing regimens to BIC/FTC/TAF maintained high rates of virologic suppression (HIV-1 RNA <50 c/mL) from Weeks 144 through 240.[10,11] During the OLE phase, numerically similar rates of AEs and study drug-related AEs were reported by both groups.[11]

Clinical Data on BIC/FTC/TAF Use in ARV-Naive Participants

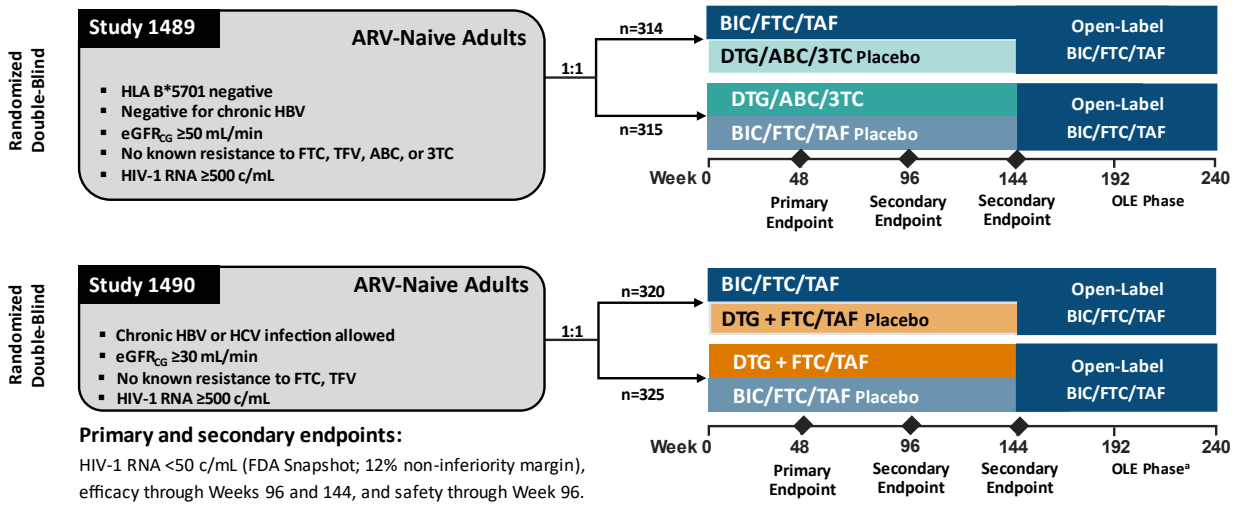
Studies GS-US-380-1489 and GS-US-380-1490

Study designs

Study 1489 was a phase 3, randomized, DB, active-controlled, non-inferiority clinical trial that was conducted to compare outcomes for BIC/FTC/TAF (n=314) with those for DTG/ABC/3TC (n=315) in ARV-naive adults with HIV-1 (Figure 1).[2] Key inclusion criteria were HIV-1 RNA ≥500 c/mL at screening, $eGFR_{CG}$ ≥50 mL/min, and genotypic sensitivity to NRTI components of study drugs.[2,4] 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 prespecified non-inferiority margin of 12%. Secondary endpoints were efficacy through Weeks 96 and 144 and safety through Week 96.[2] Participants who completed the DB phase were given BIC/FTC/TAF in an OLE phase for an additional 96 weeks.[12]

Study 1490 was a phase 3, randomized, DB, active-controlled, non-inferiority clinical trial that was conducted to compare BIC/FTC/TAF (n=320) to DTG + FTC/TAF (n=325) in ARV-naive adults with HIV-1 (Figure 1).[3] Key inclusion criteria were HIV-1 RNA ≥500 c/mL at screening, $eGFR_{CG}$ ≥30 mL/min, and genotypic sensitivity to NRTI components of study drugs.[3,5] 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 prespecified non-inferiority margin of 12%. Secondary endpoints were efficacy through Weeks 96 and 144 and safety through Week 96.[3] Participants who completed the DB phase were given BIC/FTC/TAF in an OLE phase for an additional 96 weeks.[12] BL characteristics were similar between treatment arms (Table 1).[6,7]

Figure 1. Studies 1489 and 1490: Study Designs[6,10]



Abbreviations: HLA, human leukocyte antigen; TFV=tenofovir.
[a]Participants transitioned into the OLE phase at the same time, after the last participant reached Week 144.

Table 1. Studies 1489 and 1490:
Baseline Demographics and Disease Characteristics[7,13,14]

Key Demographics and Characteristics	Study 1489		Study 1490	
	BIC/FTC/TAF (n=314)	DTG/ABC/3TC (n=315)	BIC/FTC/TAF (n=320)	DTG + FTC/TAF (n=325)
Age, median (range), years	31 (18–71)	32 (18–68)	33 (18–71)	34 (18–77)
Male, n (%)	285 (91)	282 (90)	280 (88)	288 (89)
Black or African descent, n (%)	114 (37)	112 (36)	97 (30)	100 (31)
Hispanic/Latinx ethnicity, n (%)	72 (23)	65 (21)	83 (26)	81 (25)
HIV-1 RNA, median (IQR), log_{10} c/mL	4.4 (4.0–4.9)	4.51 (4.04–4.87)	4.4 (4.0–4.9)	4.45 (4.03–4.84)
HIV-1 RNA >100,000 c/mL, n (%)	53 (17)	50 (16)	66 (21)	54 (17)
CD4 count, median (IQR), cells/mcL	443 (299–590)	450 (324–608)	440 (289–591)	441 (297–597)
CD4 count <200 cells/mcL, n (%)	36 (11)	32 (10)	44 (14)	34 (10)
$eGFR_{CG}$, median (IQR), mL/min	126 (108–146)	123 (107–144)	120 (101–142)	121 (103–145)
BMI, median (IQR), kg/m^2	25 (22–29)	25 (23–29)	25 (22–28)	25 (22–28)
Diabetes, %	6	3	7	7

Study GS-US-380-1489 – Blinded Phase

Efficacy results through Week 144

In Study 1489, BIC/FTC/TAF demonstrated non-inferior efficacy (HIV-1 RNA <50 c/mL) to DTG/ABC/3TC by FDA Snapshot analysis at the Week 48 primary endpoint (92% vs 93%; difference, -0.6%; 95% CI: -4.8% to 3.6%; *P*=0.78) and at the secondary endpoints at Weeks 96 (88% vs 90%; difference, -1.9%; 95% CI: -6.9% to 3.1%) and 144 (82% vs 84%; difference, -2.6%, 95% CI: -8.5% to 3.4%).[2,4,7] The rates of participants with HIV-1 RNA ≥50 c/mL for the BIC/FTC/TAF and DTG/ABC/3TC treatment arms were <1% and 3%, respectively. In the BIC/FTC/TAF arm, 1 participant with HIV-1 RNA ≥50 c/mL discontinued the study drug for other reasons (ie, at investigator or participant discretion, participant decision, LTFU, non-compliance with treatment, protocol violation, pregnancy, and study terminated by sponsor), and 1 participant had HIV-1 RNA ≥50 c/mL at Week 144. No treatment-emergent resistance to study drugs developed in either treatment arm at Week 144.[7]

The mean increases from BL in CD4 cell counts were 233 cells/mcL vs 229 cells/mcL (*P*=0.81) at Week 48, 287 cells/mcL vs 288 cells/mcL at Week 96, and 299 cells/mcL vs 317 cells/mcL (*P*=0.3) at Week 144 for the BIC/FTC/TAF and DTG/ABC/3TC arms, respectively.[2,4,7]

There were no significant differences in efficacy between the two treatment groups in the subgroups of age (<50 years vs ≥50 years), sex, race (non-Black vs Black), BL VL (≤100,000 c/mL vs >100,000 c/mL), BL CD4 cell count (<200 cells/mcL vs ≥200 cells/mcL), region (US vs outside of the US), and study drug adherence (<95% vs ≥95%) at Week 48.[4] Retrospective genotyping of BL samples identified BL resistance in some clinical trial participants that was previously undetected with historical genotyping. The presence of BL NRTI or INSTI RAMs in a small percentage of participants did not affect outcomes through Week 96. Additional data available through Week 144 showed that all 8 participants with BL INSTI RAMs in the study achieved and maintained virologic suppression.[2,7]

Safety results through Week 144

Participants treated with BIC/FTC/TAF reported fewer drug-related AEs than those taking DTG/ABC/3TC (*P*=0.0021; Table 2). Serious AEs occurred in 13% of participants in the BIC/FTC/TAF arm and in 17% of participants in the DTG/ABC/3TC arm. Three deaths were documented, none of which were considered treatment-related: 2 deaths in the BIC/FTC/TAF arm before Week 96 (drug overdose, n=1; suicide, n=1) and 1 death in the DTG/ABC/3TC after Week 96 (drug overdose).[7]

Table 2. Study 1489: Safety Results Through Week 144[7]

AEs, %		BIC/FTC/TAF (n=314)	DTG/ABC/3TC (n=315)
AEs that occurred in ≥10% of participants	Diarrhea	17	18
	URTI	14	19
	Headache	14	18
	Nasopharyngitis	13	17
	Nausea[a]	12	24
	Syphilis	12	16
	Back pain	11	12
	Fatigue	11	12
	Cough	11	6
	Insomnia	8	11
	Oropharyngeal pain	7	11
Any drug-related AE[b]		30	42
Drug-related AEs that occurred in ≥5% of participants	Nausea[c]	6	18
	Diarrhea	6	4
	Headache	5	5
AE that led to study drug discontinuation		0	2

[a]*P*=0.0001 for BIC/FTC/TAF vs DTG/ABC/3TC based on Fisher exact test.
[b]*P*=0.0021 for BIC/FTC/TAF vs DTG/ABC/3TC based on Fisher exact test.
[c]*P*<0.0001 for BIC/FTC/TAF vs DTG/ABC/3TC based on Fisher exact test.

Grade 3 or 4 laboratory abnormalities reported in ≥2% of either the BIC/FTC/TAF or DTG/ABC/3TC arm, respectively, were decreased neutrophils (3% vs 4%), increased ALT (2% vs 2%), increased amylase (3% vs 4%), increased AST (5% vs 3%), increased creatine kinase (8% vs 8%), increased γ-glutamyl transferase (2% vs 2%), increased fasting LDL (5% vs 5%), glycosuria (1% vs 2%), and hematuria (1% vs 3%).[15]

There were no reports of proximal renal tubulopathy in either arm and no discontinuations due to renal AEs in the BIC/FTC/TAF arm.[7] One discontinuation was noted in the DTG/ABC/3TC arm due to renal failure, although this occurrence was not deemed study drug related.[2,7] At Week 144, median changes from BL in SCr, $eGFR_{CG}$, quantitative proteinuria, and tubular proteinuria did not differ significantly between treatment arms.[15]

Statistically significant differences between treatment arms were observed in the change from BL values for TC, LDL, and the TC:HDL ratio at Week 144 (Table 3).[15] During the study, lipid-lowering therapy was initiated by 6% of participants in the BIC/FTC/TAF arm and 5% in the DTG/ABC/3TC arm.[13] LDL elevations were reported as a Grade 3 or 4 laboratory abnormality in 5% of participants in each arm.[15,7] Low rates of treatment-emergent diabetes (1%) and/or hypertension (≤10%) occurred in both arms in the overall population through Week 144. Subgroups of participants by sex at birth or race (Black or non-Black) showed similar findings.[13]

Table 3. Study 1489: Change in Fasting Lipid Levels From Baseline to Week 144[15]

Lipid Parameters	BIC/FTC/TAF (n=314)		DTG/ABC/3TC (n=315)		*P*-Value[a]
	Baseline Values	Median Change From Baseline	Baseline Values	Median Change From Baseline	
TC, mg/dL	159	+14	162	+10	0.034
LDL, mg/dL	101	+21	101	+14	0.004
HDL, mg/dL	42	+5	42	+6	0.096
TG, mg/dL	93	+6	96	+5	0.23
TC:HDL ratio	3.7	-0.1	3.7	-0.3	0.007

[a]*P*-values were calculated from the two-sided Wilcoxon rank sum test that compared the median change from BL between the two treatment arms.

The mean percentage changes in both hip and lumbar spine BMD from BL to Week 144 were statistically nonsignificant between the two arms (spine, *P*=0.26; hip, *P*=0.39).[7]

Study GS-US-380-1490 – Blinded Phase

Efficacy results through Week 144

BIC/FTC/TAF demonstrated non-inferior efficacy (HIV-1 RNA <50 c/mL) to DTG + FTC/TAF by FDA Snapshot analysis at the Week 48 primary endpoint (89% vs 93%; difference, -3.5%; 95% CI: -7.9% to 1%; *P*=0.12) and at the secondary efficacy endpoint at Weeks 96 (84% vs 86%; difference, -2.3%; 95% CI: -7.9% to 3.2%) and 144 (81% vs 84%; difference, -1.9%; 95% CI: -7.8% to 3.9%).[3,5,7] Rates of virologic failure (HIV-1 RNA ≥50 c/mL) for the BIC/FTC/TAF and DTG + FTC/TAF treatment arms were 5% and 3%, respectively. The majority of participants (14/15) in the BIC/FTC/TAF arm with HIV-1 RNA ≥50 c/mL discontinued treatment due to non-efficacy–related reasons, and no discontinuations were due to lack of efficacy. Seven participants in the BIC/FTC/TAF arm did not have any data available after the BL visit; thus, the only HIV-1 RNA data available for these participants were collected before study drug initiation. No treatment-emergent resistance to study drugs developed in either treatment arm at Week 144.[7]

The mean increases from BL in CD4 cell count were 180 cells/mcL vs 201 cells/mcL at Week 48 (*P*=0.1) and 237 cells/mcL vs 281 cells/mcL at Week 96 (*P*=0.008) for the BIC/FTC/TAF and DTG + FTC/TAF arms, respectively.[3,5]

There were no significant differences in efficacy between the two treatment groups in the subgroups of age (<50 years vs ≥50 years), sex, race (non-Black vs Black), BL VL (≤100,000 c/mL vs >100,000 c/mL), BL CD4 cell count (<200 cells/mcL vs ≥200 cells/mcL), region (US vs outside of the US), and study drug adherence (<95% vs ≥95%) at Weeks 48, 96, and 144.[7,15,16] Retrospective genotyping of 642/645 BL samples identified primary INSTI RAMs in 1% of participants and primary NRTI RAMs in 2% of participants that were previously undetected with historical genotyping.[3] The presence of BL NRTI or INSTI RAMs did not affect efficacy outcomes through Week 96. Additional data available through Week 144 showed that all 9 participants with BL INSTI RAMs in the study achieved and maintained virologic suppression.[3,7]

Safety results through Week 144

Participants treated with BIC/FTC/TAF reported rates of drug-related AEs similar to those of participants taking DTG + FTC/TAF (Table 4). Serious AEs occurred in 20% of participants

in the BIC/FTC/TAF arm and in 12% of participants in the DTG + FTC/TAF arm. Three deaths were documented in the BIC/FTC/TAF arm, none of which were considered treatment related: cardiac arrest following appendicitis and septic shock (n=1), gastric adenocarcinoma (n=1), and hypertensive heart disease and congestive cardiac failure (n=1). Four deaths were documented in the DTG + FTC/TAF arm, and none were considered treatment related: death by unknown cause (n=2), lymphoma (n=1), and pulmonary embolism (n=1).[7]

Table 4. Study 1490: Safety Results Through Week 144[7]

AE, %		BIC/FTC/TAF (n=320)	DTG + FTC/TAF (n=325)
AEs that occurred in ≥10% of participants	Nausea	10	13
	Diarrhea	21	16
	URTI	13	16
	Headache	18	18
	Nasopharyngitis	16	19
	Syphilis	10	10
	Back pain	9	12
	Fatigue	9	11
Any drug-related AE		22	29
Drug-related AEs that occurred in ≥5% of participants	Nausea	3	5
AEs that led to study drug discontinuation		6	6

Grade 3 or 4 laboratory abnormalities reported in ≥2% of participants in the BIC/FTC/TAF or DTG + FTC/TAF arms, respectively, were decreased neutrophils (3% vs 2%), increased amylase (3% vs 4%), increased ALT (3% vs 1%), increased AST (2% vs 3%), increased creatine kinase (6% vs 4%), increased fasting serum glucose (2% vs 4%), increased non-fasting serum glucose (1% vs 2%), increased fasting TC (2% vs 0.9%), increased fasting LDL (4% vs 6%), glycosuria (1% vs 4%), and hematuria (1% vs 2%).[15]

There were no reports of proximal renal tubulopathy in either arm and no discontinuations due to renal AEs in the BIC/FTC/TAF arm.[7] At Week 144, the median increases from BL in SCr and median decreases in $eGFR_{CG}$ did not differ significantly between treatment arms.[15]

Median changes from BL in fasting lipid levels were similar at Week 144 between participants on BIC/FTC/TAF and DTG + FTC/TAF (Table 5).[7] Low rates of treatment-emergent diabetes (2%) and hypertension (6%) occurred in both arms in the overall population through Week 144. There were no statistically significant differences between treatment arms in subgroups of participants by sex at birth or race (Black or non-Black).[13]

Table 5. Study 1490: Changes in Fasting Lipid Levels From Baseline to Week 144[15]

Lipid Parameters	BIC/FTC/TAF (n=320)		DTG + FTC/TAF (n=325)		*P*-Value[a]
	Baseline Values	Median Change From Baseline	Baseline Values	Median Change From Baseline	
TC, mg/dL	156	+12	161	+12	0.88
LDL, mg/dL	98	+19	99	+19	0.68

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Lipid Parameters	BIC/FTC/TAF (n=320)		DTG + FTC/TAF (n=325)		*P*-Value[a]
	Baseline Values	Median Change From Baseline	Baseline Values	Median Change From Baseline	
HDL, mg/dL	43	+3	43	+5	0.17
TG, mg/dL	97	+2	95	+2	0.97
TC:HDL ratio	3.7	0	3.7	-0.1	0.24

[a]*P*-values were calculated from the two-sided Wilcoxon rank sum test that compared the median change from BL between the two treatment arms.

Study GS-US-380-1489/GS-US-380-1490 OLE

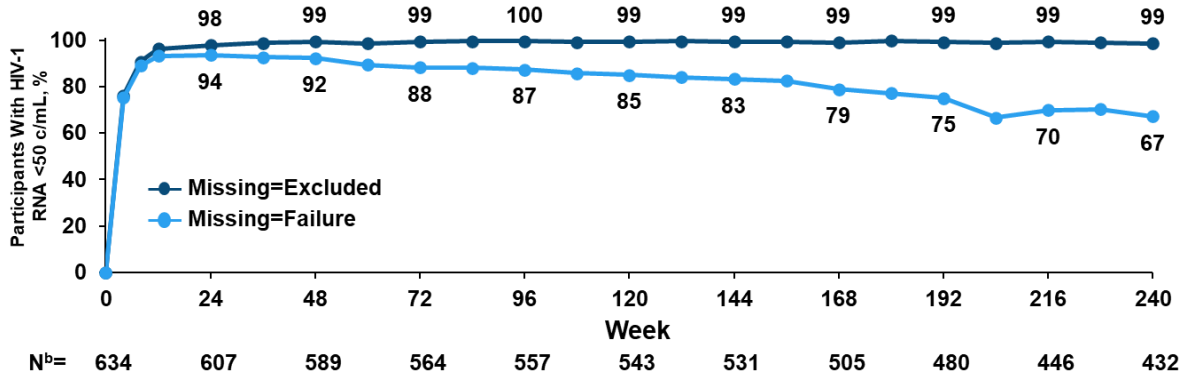
At Week 144, all participants were offered enrollment in the OLE phase with BIC/FTC/TAF. In Studies 1489 and 1490, 254 participants who were receiving DTG/ABC/3TC switched to BIC/FTC/TAF, and 265 participants who were receiving DTG + FTC/TAF switched to BIC/FTC/TAF.[10] A total of 252 and 254 participants who were initially randomly assigned to receive BIC/FTC/TAF in Studies 1489 and 1490, respectively, continued on to the OLE phase.[8,14]

OLE: pooled analysis for participants initially assigned to BIC/FTC/TAF[8]

Efficacy results through Week 240

In a pooled analysis of participants from both studies who were initially randomly assigned to receive BIC/FTC/TAF, high efficacy rates (99% had HIV-1 RNA <50 c/mL using a M=E analysis) were observed at each study visit from Week 144 through Week 240 (Figure **2**). Six participants had HIV-1 RNA ≥50 c/mL at Week 240; of these, 5 participants were resuppressed at Week 252 while BIC/FTC/TAF was continued, and the sixth participant was LTFU after Week 240. The overall median change in CD4 cell count from treatment initiation to Week 240 was +317 cells/mcL.

Figure 2. Pooled Analysis of Studies 1489 and 1490: Virologic Outcomes Through Week 240 With BIC/FTC/TAF[8a]



[a]HIV-1 RNA <50 c/mL, which was calculated using the FDA Snapshot algorithm. An M=E analysis was conducted to accurately calculate virologic outcomes in participants who chose to enter the OLE.
[b]Only included participants who were not missing an HIV-1 RNA value.

Safety results through Week 240

AEs reported during the OLE phase among participants initially randomly assigned to receive BIC/FTC/TAF included the following: COVID-19 (10%); syphilis (8%); nasopharyngitis and back pain (7% each); arthralgia, URTI, and cough (6% each); headache (5%); diarrhea, anxiety, and influenza (4% each); nausea and insomnia (3% each); and fatigue (2%).

Drug-related AEs were reported in 4% of participants during the OLE phase and included headache, diarrhea, nausea, fatigue, and dizziness (<1% each). Through Week 240, 5 participants discontinued BIC/FTC/TAF due to AEs that were unrelated to study drug, including 3 AEs that occurred during the OLE phase; study drug-related AEs led to discontinuation in 5 participants, including 1 discontinuation that occurred during the OLE phase (Table 6).

Table 6. Pooled Analysis of Studies 1489 and 1490: Study Drug Discontinuations Due to AEs Through Week 240[8a]

	AEs That Led to Discontinuation	
	Weeks 0–144	**OLE: Weeks 144–240**
Unrelated to BIC/FTC/TAF, n=5 (<1%)	• Cardiac arrest (Day 28) • Paranoia (Day 299)	• Intervertebral discitis (Day 1366) • Toxicity to various agents* (Day 1549) • COVID-19 (Day 1748)
Related to BIC/FTC/TAF, n=5 (<1%)	• Chest pain (Day 1) • Abdominal distension (Day 1) • Sleep disorder, dyspepsia, and tension headache (Day 15); depressed mood and insomnia (Day 63) • Depression (Day 337)	• Morbid obesity (Day 1634)

[a]Amphetamine, methamphetamine, and fentanyl.

Grade 3 or 4 laboratory abnormalities through Week 240 reported in ≥2% of participants initially randomly assigned to receive BIC/FTC/TAF are presented in Table 7. Four deaths were reported after Week 144: sudden cardiac arrest on Day 1060, toxicity to various agents (amphetamine, methamphetamine, and fentanyl) on Day 1549, unknown cause on Day 1697, and COVID-19 on Day 1748.

Table 7. Pooled Analysis of Studies 1489 and 1490: Grade 3 or 4 Laboratory Abnormalities in BIC/FTC/TAF Group Through Week 240[8]

Laboratory Abnormalities, %		BIC/FTC/TAF (n=634)
Any Grade 3 or 4 laboratory abnormality		33
Grade 3 or 4 laboratory abnormalities in ≥2% of participants	Increased creatine kinase (10 to <20 × ULN)[a]	11
	Increased LDL (fasting; >190 mg/dL)	6
	Increased AST (>5 to 10 × ULN)[b]	4
	Increased amylase (>2 to 5 × ULN)[c]	4
	Increased ALT (>5 to 10 × ULN)[b]	3
	Decreased neutrophils (WBC: 1000 to <1500/mm^3)	3
	Increased TC (fasting; >300 mg/dL)	2
	Urine RBC (hematuria; >75 RBC/high-power field)	2

Abbreviation: ULN=upper limit of normal.
[a]Participants experienced no symptoms associated with increases in creatine kinase levels, and no cases of myositis were reported. Observed increases in creatine kinase levels were not clinically significant and commonly occurred after exercise.
[b]No cases of drug-related hepatitis were reported.
[c]One case of drug-related pancreatitis was reported on Day 572 and resolved on Day 574 without discontinuing treatment.

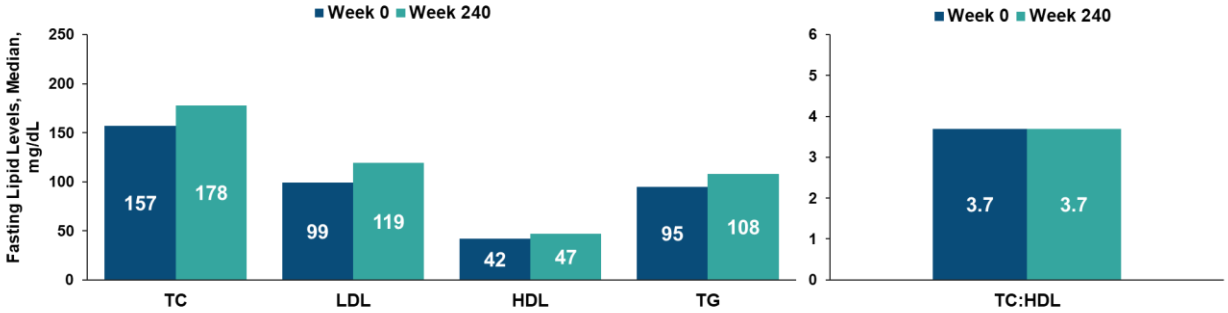
There were no reports of proximal renal tubulopathy or discontinuations due to renal AEs in the BIC/FTC/TAF arms in either study. The median $eGFR_{CG}$ change from BL to Week 240 was -8.4 mL/min. The initial decline followed by a stable $eGFR_{CG}$ is in alignment with the known inhibition of tubular creatinine secretion by organic cation transporter-2 that results from BIC.

Participants who were initially randomly assigned to receive BIC/FTC/TAF experienced a median cumulative weight gain of 6.1 kg from BL to Week 240.

Median weight gains of approximately 3 kg in the first 48 weeks of BIC/FTC/TAF and 0.5 to 1.2 kg/year thereafter are consistent with data from previous studies in the general population. The 1.2 kg weight gain observed between Weeks 192 and 240 coincided with the first 2 years of the COVID-19 pandemic, when faster weight gain has been reported.

In participants who were initially randomly assigned to receive BIC/FTC/TAF, increases in fasting lipid levels from BL through Week 240 were reported, with little to no change in the TC:HDL ratio (Figure 3). At BL, 5% of participants were taking lipid-lowering medications, and ≤2% of participants began lipid-lowering medications each year thereafter.

Figure 3. Pooled Analysis of Studies 1489 and 1490: Fasting Lipid Changes and the Proportion of Participants Initiating Lipid-Lowering Therapy Through Week 240 Among Those Initially Randomized to BIC/FTC/TAF[8]



	At Baseline	Week 48	Weeks 48–96	Weeks 96–144	Weeks 144–192	Weeks 192–240
Initiated lipid-lowering agents, %	5	2	2	1	2	<1

Note: The rates of initiation of lipid-lowering agents were calculated as differences in the rates for Weeks 48 to 96, 96 to 144, 144 to 192, and 192 to 240.

Overall, there were small declines in spine and hip BMD from BL to Week 240, with mean changes of -0.2% in spine BMD and -0.3% in hip BMD at Week 240.

Resistance results through Week 240

In participants initially randomly assigned to receive BIC/FTC/TAF, no treatment-emergent resistance was detected to the components of the regimen through Week 240.

Through Week 240, 9 participants met the criteria for resistance testing, and no NRTI or INSTI resistance was detected.

OLE: pooled analysis for participants initially assigned to BIC/FTC/TAF according to BL VL and CD4 counts[9]

Demographics and disposition by BL VL and CD4 counts

Baseline demographics and disease characteristics of participants initially randomized to receive BIC/FTC/TAF according to the BL stratification subgroups (VL and CD4 values) are shown in Table 8. At study entry, 20 participants had a BL VL >400,000 c/mL, and 99 participants had a BL VL of 100,000 to 400,000 c/mL; of these, 14 and 65 participants, respectively, completed the OLE phase.

Table 8. Pooled Analysis of Studies 1489 and 1490: Baseline Demographics and Disease Characteristics of BTC/FTC/TAF-Treated Participants According to Baseline Stratification Subgroups[9]

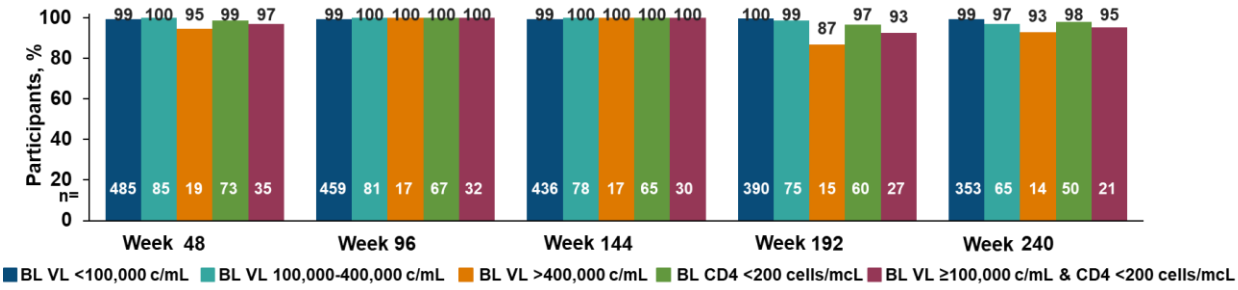
	BL VL <100,000 c/mL (n=515)	BL VL 100,000–400,000 c/mL (n=99)	BL VL >400,000 c/mL (n=20)	BL CD4 ≥200 cells/mcL (n=554)	BL CD4 <200 cells/mcL (n=80)	BL VL ≥100,000 c/mL and CD4 <200 cells/mcL (n=39)
Age, median (range), years	32 (18–71)	33 (18–71)	35 (23–68)	31 (18–71)	36 (22–64)	36 (22–64)
Female at birth, n (%)	64 (12)	5 (5)	0	59 (11)	10 (13)	1 (3)

		BL VL <100,000 c/mL (n=515)	BL VL 100,000–400,000 c/mL (n=99)	BL VL >400,000 c/mL (n=20)	BL CD4 ≥200 cells/mcL (n=554)	BL CD4 <200 cells/mcL (n=80)	BL VL ≥100,000 c/mL and CD4 <200 cells/mcL (n=39)
Race and ethnicity, n (%)	Black/African descent	169 (33)	35 (36)	7 (35)	174 (32)	37 (47)	18 (47)
	Hispanic/Latinx	137 (27)	17 (17)	1 (5)	139 (25)	16 (20)	4 (10)
Body weight, median (Q1, Q3), kg		77.5 (68.2, 89.2)	74.8 (66.7, 84.8)	73.9 (64.9, 83.3)	77.2 (68.2, 88)	71.5 (64.5, 84.7)	71.9 (63.5, 85.3)
BMI, median (Q1, Q3), kg/m^2		25.3 (22.4, 29)	24 (21.7, 26.9)	23.8 (22.5, 29)	25.2 (22.4, 28.8)	24.1 (21.2, 26.5)	24 (21.2, 25.9)
Asymptomatic HIV, n (%)		481 (93)	79 (80)	12 (60)	532 (96)	40 (50)	16 (41)
$eGFR_{CG}$, median (Q1, Q3), mL/min		122 (105, 144)	122 (102, 144)	124 (100, 135)	123 (105, 144)	118 (95, 136)	122 (95, 142)

Efficacy results through Week 240

High rates of virologic suppression were maintained through Week 240, including in participants with a VL >400,000 c/mL at BL (M=E; Figure 4). Of those who had a VL >400,000 c/mL at BL and a VL measurement at Week 240, 1 participant had a VL >50 c/mL (133 c/mL) at Week 240.

Figure 4. Pooled Analysis of Studies 1489 and 1490: HIV-1 RNA <50 c/mL Through Week 240 According to Baseline Stratification Subgroups (M=E Analysis)[9]



Of the 80 participants with a CD4 count <200 cells/mcL at BL, 3 continued to have a CD4 count <200 cells/mcL (183, 180, and 111 cells/mcL) at Week 240. Two of the 3 participants had a VL >400,000 c/mL (499,000 and 476,000 c/mL) at BL, but each attained virologic suppression by Week 4 and remained suppressed through Week 240.

Safety results through Week 240

The most frequently reported study drug-related AEs were nausea, headache, and diarrhea; no study drug-related SAEs or study drug-related AEs that led to drug discontinuation were reported by participants with a VL >100,000 c/mL with or without a low CD4 count at BL. None of the 5 cases of immune reconstitution inflammatory syndrome occurred among participants who had a high VL at BL; each occurred within the first 48 weeks of the study in participants who had a VL <100,000 c/mL at BL, and all resolved with treatment.

At Week 240, participants who had a VL ≥100,000 c/mL at BL had significantly greater median changes in weight from BL than those who had a VL <100,000 c/mL (9.9 kg vs 5.6 kg; *P*<0.001). Participants who had BL CD4 count <200 cells/mcL experienced significantly greater weight change from BL to Week 48 than participants with CD4

≥200 cells/mcL (+8.3 kg vs 2.7 kg, respectively; *P*<0.001).The median actual weights at Week 240 were comparable across subgroups, despite BL values that were significantly lower in the VL ≥100,000 c/mL subgroup than in the VL <100,000 c/mL subgroup (72.8 kg vs 77.8 kg; *P*<0.01) and significantly lower in the CD4 <200 cells/mcL subgroup than in the CD4 ≥200 cells/mcL subgroup (71.2 kg vs 77 kg; *P*<0.05).

OLE: delayed switch pooled analysis through Week 240 (96 weeks into the OLE)

Demographics and disposition according to initial DTG-based regimen[11]

Demographics and disease characteristics at the beginning of the OLE phase for participants who were initially randomly assigned to receive a DTG-based regimen (DTG/ABC/3TC or DTG + FTC/TAF) during the DB phase are shown in Table 9. Of the 315 participants initially assigned to receive DTG/ABC/3TC during the DB phase, 254 began treatment with BIC/FTC/TAF in the OLE phase, and 221 completed Week 240 assessments. Of the 325 participants initially assigned to receive DTG + FTC/TAF during the DB phase, 265 began treatment with BIC/FTC/TAF in the OLE phase, and 236 completed Week 240 assessments. Both subgroups of participants had a median duration of exposure to BIC/FTC/TAF of 96 weeks.

Table 9. Pooled Analysis of Studies 1489 and 1490: Baseline Demographics and Disease Characteristics of OLE Participants Who Initially Received DTG-Based Regimens[11]

Key Demographics and Characteristics		DTG/ABC/3TC→ BIC/FTC/TAF (n=254)	DTG + FTC/TAF→ BIC/FTC/TAF (n=265)
Age, median (Q1, Q3), years		36 (30, 45)	38 (30, 48)
Female sex at birth, n (%)		29 (11.4)	26 (9.8)
Race or ethnicity,[a] n (%)	White	144 (56.7)	160 (60.4)
	Black	94 (37)	80 (30.2)
	Asian	8 (3.1)	7 (2.6)
	Other	8 (3.1)	18 (6.8)
	Hispanic/Latinx	54 (21.3)	73 (27.5)
HIV-1 RNA	Median (Q1, Q3), log_{10} c/mL	1.28 (1.28, 1.28)	1.28 (1.28, 1.28)
	<50 c/mL, n (%)	245 (96.5)	263 (99.2)
	50 to <200 c/mL, n (%)	3 (1.2)	1 (0.4)
	≥200 c/mL, n (%)	6 (2.4)	1 (0.4)
CD4 cell count	Median (Q1, Q3), cells/mcL[3]	766 (599, 1023)	730 (550, 958)
	≥50 to <200 cells/mcL, n (%)	0	3 (1.1)
	≥200 to <500 cells/mcL, n (%)	40 (15.7)	46 (17.4)
	≥500 cells/mcL, n (%)	214 (84.3)	216 (81.5)
Body weight, median (Q1, Q3), kg		83 (72.6, 94.3)	81.7 (71, 96)
$eGFR_{CG}$, median (Q1, Q3), mL/min		115.6 (98.5, 137.6)	111 (95.1, 134.8)

[a]Ethnicity data were missing for 1 participant in the DTG/ABC/3TC→BIC/FTC/TAF group.
Note: Missing values were excluded from calculations of percentages.

Efficacy results through Week 240[11]

During the OLE phase, both groups of participants who switched from DTG-containing regimens had high levels of virologic suppression through Week 240 using a M=E analysis, and viral suppression rates were similar to those in participants who were initially randomly assigned to the BIC/FTC/TAF group (Figure 5). In a missing=failure analysis, the rate of

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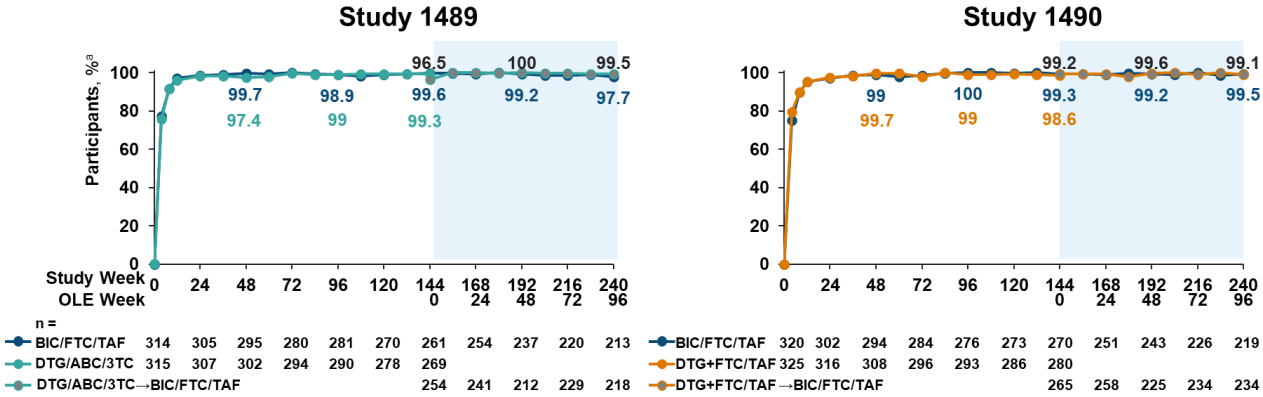
virologic suppression at Week 240 was 85.4% in the DTG/ABC/3TC→BIC/FTC/TAF group and 87.5% in the DTG + FTC/TAF→BIC/FTC/TAF group.

Figure 5. Pooled Analysis of Studies 1489 and 1490: HIV-1 RNA <50 c/mL Through Week 240 According to the DTG-Based Regimen Received During the DB Phase (M=E Analysis)[11]



Safety results through Week 240

Numerically similar rates of AEs and study drug-related AEs were reported by both groups during the OLE (Table 10). Reports of nausea and diarrhea were numerically lower after participants switched to BIC/FTC/TAF during the OLE phase. No drug-related Grade 4 AEs or SAEs were reported in either group. Overall, few AEs (0.4%; 2/519) led to discontinuation of the study drug.[11]

Table 10. Pooled Analysis of Studies 1489 and 1490: Safety Outcomes During the OLE Phase According to the DTG-Based Regimen Received During the DB Phase[11,17]

AEs		DTG/ABC/3TC→ BIC/FTC/TAF (n=254)	DTG + FTC/TAF→ BIC/FTC/TAF (n=265)
Any AE, n (%)		214 (84.3)	215 (81.1)
Drug-related AE, n (%)		13 (5.1)	8 (3)
Drug-related AEs in ≥2 participants in either group or overall, n (%)	Diarrhea	3 (1.2)	0
	Weight increased	2 (0.8)	1 (0.4)
	Headache	1 (0.4)	1 (0.4)
Grade 3 or 4 drug-related AE, n (%)		0	1 (0.4)[a]
Any SAE, n (%)		19 (7.5)	32 (12.1)
Drug-related SAE, n (%)		0	0
Drug-related AEs that led to DC of BIC/FTC/TAF, n (%)		2 (0.8)[b]	0
Death, n (%)		2 (0.8)[c]	3 (1.1)[d]
Any Grade 3 or 4 laboratory abnormality, n (%)		34 (13)	42 (16)

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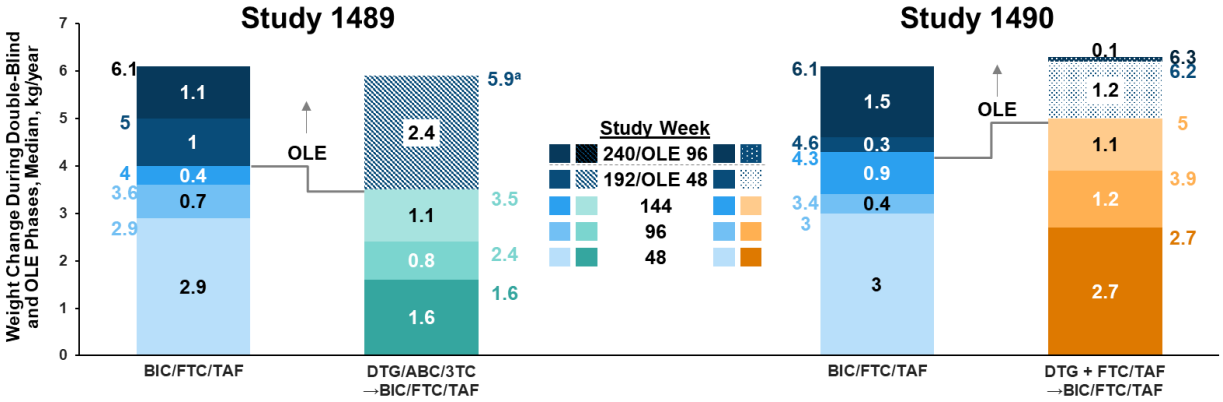
AEs		DTG/ABC/3TC→ BIC/FTC/TAF (n=254)	DTG + FTC/TAF→ BIC/FTC/TAF (n=265)
Grade 3 or 4 laboratory abnormalities that occurred in ≥2% of participants in either group, %	Increased creatine kinase	9 (4)	7 (3)
	Increased amylase	5 (2)[e]	4 (2)[e]
	Increased AST	5 (2)	2 (1)
	Increased triglycerides	4 (2)	1 (0)
	Glycosuria	3 (1)[f]	9 (3)[f]
	Increased fasting LDL	2 (1)	8 (3)
	Fasting hyperglycemia	2 (1)	6 (2)
	Increased ALT	2 (1)	4 (2)
	Non-fasting hyperglycemia	1 (1)	5 (3)

Abbreviation: DC=discontinuation.
[a]Participant experienced a Grade 3 worsening of diabetes without accompanying excessive weight gain on Day 1 after switching to BIC/FTC/TAF; it resolved within 15 weeks while on study drug.
[b]Obesity and weight gain (each, n=1).
[c]Deaths occurred due to seizures (n=1) and unknown cause (n=1) in a participant with known cardiovascular disease and risk factors.
[d]Deaths occurred due to unknown cause (n=2; 1 participant with known cardiovascular disease and risk factors and 1 participant with no known cardiovascular disease or risk factors) and malignant neoplasm of urinary bladder (n=1).
[e]Participants did not have clinical symptoms of pancreatitis.
[f]All cases of glycosuria occurred in participants with diabetes or concurrent hyperglycemia.

The median change in eGFR from start of OLE to Week 240 was +2 mL/min in the group that switched from DTG/ABC/3TC to BIC/FTC/TAF and +1.3 mL/min in the group that switched from DTG + FTC/TAF to BIC/FTC/TAF.[17] Participants initially assigned to receive DTG/ABC/3TC had significantly smaller median increases in weight at Week 144 (OLE BL) than those who received DTG + FTC/TAF (+3.5 vs +5 kg; *P*=0.025). During the OLE, participants who switched from DTG/ABC/3TC to BIC/FTC/TAF had greater median weight gain at Week 240 than those who initially received DTG + FTC/TAF (+2.4 vs +1.3 kg; *P*=0.007); however, cumulative weight changes were numerically similar across treatment groups (Figure 6).[11]

Figure 6. Pooled Analysis of Studies 1489 and 1490: Changes in Weight During the Study According to the DTG-Based Regimen Received During the DB Phase[11]



[a]This value represents the median cumulative change at Week 192; no changes in weight were observed from Week 192 to 240.
Note: The numbers within the bars represent the yearly weight changes (calculated as the median change from BL at the later time point minus the median change at the previous time point). The numbers to left and right of each bar indicate the median cumulative weight changes at each time point.

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During the OLE, minimal changes in lipid panel values were observed for each group (Table 11).[11,17]

Table 11. Pooled Analysis of Studies 1489 and 1490: Fasting Lipid Levels at Weeks 144 and 240 According to the DTG-Based Regimen Received During the DB Phase[11,17]

Lipid Parameters	DTG/ABC/3TC→ BIC/FTC/TAF (n=254)		DTG + FTC/TAF→ BIC/FTC/TAF (n=265)	
	Week 144	Week 240	Week 144	Week 240
TC, median, mmol/L	4.3	4.5	4.4	4.5
LDL, median, mmol/L	2.9	3	3.1	3
HDL, median, mmol/L	1.2	1.2	1.2	1.2
TG, median, mmol/L	1.1	1.1	1.1	1.2
TC:HDL ratio	3.3	3.5	3.5	3.7
Received lipid-lowering agents, %	8%	+2%	10%	+5%

Resistance results through Week 240[11]

Four participants met the criteria for resistance analysis (confirmed VL ≥200 c/mL or ≥200 c/mL at the last study visit, with no viral suppression to <50 c/mL during treatment), including 3 participants who were initially assigned to receive DTG/ABC/3TC and 1 who was initially assigned to receive DTG + FTC/TAF. No treatment-emergent resistance was detected.

Pooled 1489 and 1490 subanalysis: participants aged ≥50 years vs <50 years

A pooled analysis of data from Studies 1489 and 1490 was conducted, and subgroups of participants aged ≥50 vs <50 years were compared. There were no significant differences between groups in efficacy or general safety at Week 144. Most changes from BL in renal, bone, and lipid safety parameters were comparable between groups or were not considered clinically significant.[18]

PROs through Week 48[19,20]

PROs from the HIV-SI administered at BL and at Weeks 4, 12, and 48 were used to further characterize treatment tolerability. Treatment differences were assessed using logistic regression models (adjusted for age, sex, race, BL HIV-SI score, Veterans Aging Cohort Study Index, medical history of serious mental illness, and BL SF-36 physical and mental scores). Longitudinal modeling was also performed to show the prevalence of bothersome symptoms over time using generalized mixed models, including treatment, time, time-by-treatment interaction, and covariates in logistic regression models. Treatment differences were noted if the prevalence was statistically significantly different at ≥2 time points in the adjusted logistic regression model or at one time point in the adjusted logistic regression model and in the longitudinal model.

The initiation of BIC/FTC/TAF was associated with a lower prevalence of fatigue/loss of energy, dizziness/lightheadedness, nausea/vomiting, difficulty sleeping, and loss of appetite compared with DTG/ABC/3TC (each, $P<0.05$). No HIV-SI symptom favored DTG/ABC/3TC. The Pittsburgh Sleep Quality Index, SF-36, and Work Productivity and Activity Impairment tools were also administered at the same time points. No statistically significant differences between treatment groups were noted.

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Abbreviations

3TC=lamivudine
ABC=abacavir
AE=adverse event
ARV=antiretroviral
BIC=bictegravir
BL=baseline
BMD=bone mineral density
c/mL=copies per mL
CD4=cluster of differentiation 4
CG=Cockcroft-Gault
DB=double-blind
DTG=dolutegravir
ESRD=end-stage renal disease
FTC=emtricitabine
HIV-SI=HIV Symptom Index
INSTI=integrase strand transfer inhibitor
LTFU=lost to follow-up
M=E=missing=excluded
NRTI=nucleos(t)ide reverse transcriptase inhibitor
OLE=open-label extension
PRO=patient-reported outcome(s)
Q=quartile
RAM=resistance-associated mutation
SAE=serious adverse event
SF-36=36-Item Short Form Health Survey
TAF=tenofovir alafenamide
TC=total cholesterol
TFV=tenofovir
TG=triglyceride
URTI=upper respiratory tract infection
VL=viral load

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