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Biktarvy® (BIC/FTC/TAF) Use in Adults Aged ≥50 Years

This document is in response to your request for information regarding the use of Biktarvy® (bictegravir/emtricitabine/tenofovir alafenamide [BIC/FTC/TAF]) in adults aged ≥50 years. This response was developed according to principles of evidence-based medicine and contains data from Gilead clinical trials and real-world studies (N≥350).

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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]

Clinical trials in VS participants (Trials 4449, 1844, and 1878) included 111 subjects aged ≥65 years who received BIC/FTC/TAF, including 86 participants from an open-label, single-arm trial of subjects aged ≥65 years who were switched from their previous ARV regimen to BIC/FTC/TAF. Of the total number of BIC/FTC/TAF-treated patients in these trials, 100 (90%) were 65 to 74 years of age, and 11 (10%) were 75 to 84 years of age. No overall differences in safety or effectiveness were observed between elderly participants and adults between 18 and <65 years of age, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

The pharmacokinetics of BIC, FTC, and TAF have not been fully evaluated in the elderly (≥65 years of age). Population pharmacokinetics analysis of HIV-infected participants in phase 3 trials of BIC/FTC/TAF showed that age did not have a clinically relevant effect on exposures of BIC and TAF up to 74 years of age.

Clinical Studies: BIC/FTC/TAF Use in Adults Aged ≥50 Years

In several clinical studies that included PWH who initiated or switched to BIC/FTC/TAF, high rates of virologic suppression (HIV-1 RNA <50 c/mL) were observed at various time points (Weeks 24, 48, 72, 96, or 240) in participants aged ≥50 years. Overall, there were low rates of discontinuation due to AEs, with no BIC/FTC/TAF-related discontinuations due to renal, bone, or hepatic AEs.[2-5]

Real-World Data: BIC/FTC/TAF Use in Adults Aged ≥50 Years

In one prospective and three retrospective studies, overall virologic suppression rates with BIC/FTC/TAF were high (92.6–96%) at various time points (Weeks 24, 48, or 96) among PWH aged ≥50 years. In studies that reported safety outcomes, rates of AEs and treatment discontinuations due to AEs varied by study, and eGFR decreases or no changes from BL were reported.[6-10]

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Clinical Studies: BIC/FTC/TAF Use in Adults Aged ≥50 Years

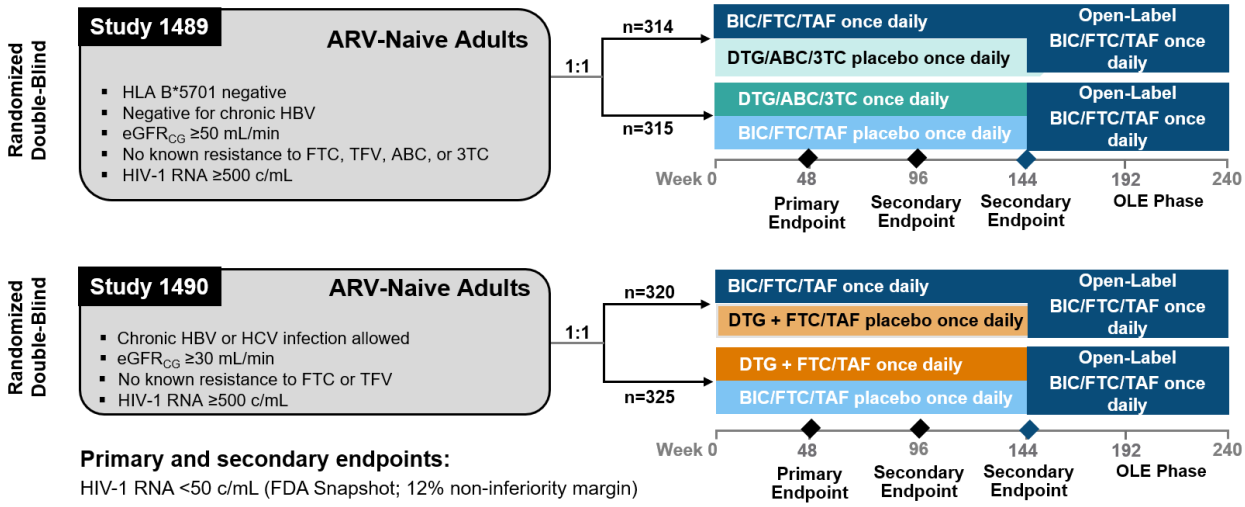
Pooled Analysis of Six Phase 3 Clinical Trials

Studies in ARV-naive participants

Study design and demographics

Data from two randomized, double-blind, active-controlled, non-inferiority phase 3 studies in ARV-naive participants (Studies 1489 and 1490) that evaluated the efficacy and safety of BIC/FTC/TAF were pooled in post hoc analyses to compare results in participants aged ≥50 years with those of participants aged <50 years (Figure 1).[2]

Figure 1. Studies 1489 and 1490: Study Designs[2,11,12]



Abbreviations: HLA=human leukocyte antigen; OLE=open-label extension; TFV=tenofovir.

Table 1. Studies 1489 and 1490: BL Demographics and Disease Characteristics[2]

Key Demographics and Characteristics		Aged ≥50 Years (n=96)	Aged <50 Years (n=538)
Age, median (Q1, Q3), years		55 (52, 60)	30 (25, 37)
Male sex at birth, n (%)		81 (84.4)	484 (90)
Region, n (%)	US	56 (58.3)	365 (67.8)
	Outside US	40 (41.7)	173 (32.2)
Race, n (%)	White	59 (61.5)	304 (56.5)
	Black	30 (31.3)	181 (33.7)
	Other[a]	4 (4.2)[b]	36 (6.7)[b]
Hispanic or Latinx ethnicity, n (%)		11 (11.5)	144 (26.9)[b]
HIV-1 RNA >100,000 c/mL, n (%)		23 (24)	96 (17.8)
CD4 count, median (IQR), cells/mcL		436 (235–601)	442 (299–590)

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Key Demographics and Characteristics		Aged ≥50 Years (n=96)	Aged <50 Years (n=538)
Medical history, n (%)	Hypertension	46 (47.9)	52 (9.7)
	Hyperlipidemia	39 (40.6)	48 (8.9)
	Diabetes mellitus	16 (16.7)	22 (4.1)
	Cardiovascular disease	6 (6.3)	8 (1.5)

[a]Included American Indican or Alaska Native, Asian, Native Hawaiian or Pacific Islander, and other.
[b]Data were missing for 1 participant.

Efficacy results at Week 240[2]

At Week 240, rates of virologic suppression (HIV-1 RNA <50 c/mL) were high in both age groups and did not differ significantly between groups (Table 2).

Table 2. Studies 1489 and 1490: Rates of Virologic Suppression at Week 240[2]

HIV-1 RNA <50 c/mL, n/N (%)	Aged ≥50 Years	Aged <50 Years	*P*-Value
M=E analysis	67/68 (98.5)	359/364 (98.6)	0.9139
M=F analysis	67/96 (69.8)	359/538 (66.7)	0.5

Abbreviation: M=F=missing=failure.

Significantly more participants aged ≥50 years had ≥95% adherence than those <50 years (82.8% vs 66.3%, respectively; *P*=0.002). From BL to Week 240, CD4 cell counts increased in both age groups, with a mean ± SD increase of 291±221.3 cells/mcL in participants aged ≥50 years and 347±238.2 cells/mcL in participants aged <50 years (LSMD [range], -58 [-120 to 4]; *P*=0.07).

Safety results through Week 240

Through Week 240, rates of TEAEs were similar between age groups (Table 3).[2]

Table 3. Studies 1489 and 1490: Safety Results Through Week 240[2]

Safety Parameters, n (%)	Aged ≥50 Years (n=96)	Aged <50 Years (n=538)
Any TEAEs	90 (93.8)	514 (95.5)
Any Grade 3 or 4 TEAEs	30 (31.3)	102 (19)
Any serious TEAEs	33 (34.4)	103 (19.1)
Study drug-related TEAEs	25 (26)	153 (28.4)
Study drug-related Grade 3 or 4 TEAEs	4 (4.2)[a]	5 (0.9)[b]
Study drug-related serious TEAEs	2 (2.1)[c]	3 (0.6)[d]
Discontinuations due to TEAEs	4 (4.2)[e]	6 (1.1)[f]
Deaths	6 (6.3)[g]	2 (0.4)[h]

[a]Abdominal pain, atypical chest pain, and elevated liver enzymes (each, n=1) and atrial flutter, dizziness, and acute pancreatitis (n=1).
[b]Abdominal distention, diarrhea, generalized tonic-clonic seizure, osteoporosis, and suicide attempt (each, n=1).
[c]Atrial flutter, acute pancreatitis, and dizziness (n=1) and chest pain (n=1).
[d]Generalized tonic-clonic seizure, spontaneous abortion, and suicide attempt (each, n=1).
[e]Cardiac arrest, chest pain, COVID, and obesity (each, n=1).
[f]Abdominal distention, dyspepsia, toxicity due to various agents, intervertebral discitis, and tension headache (each, n=1).
[g]Cardiac arrest (n=2), hypertensive heart disease with congestive heart failure, poorly differentiated gastric adenocarcinoma, COVID, and drug toxicity (each, n=1).
[h]Hemorrhagic hypovolemia (self-inflicted) and unknown cause (each, n=1).

The mean changes from BL in hip and spine BMD were reported to be minimal and were similar between participants aged ≥50 years vs >50 years at Week 240 (hip, 0.3% vs -0.4%; spine, 1.3% vs -0.9%, respectively). Rates of treatment-emergent diabetes (5.1% vs 1.7%)

and hypertension (19.6% vs 12.5%) were also numerically higher in those aged ≥50 years than in those aged <50 years.[2]

According to a multivariate linear regression analysis, the estimated mean (95% CI) difference in weight between participants aged <50 years and ≥50 years at Week 240 was 2.4 (-0.1 to 5) kg (*P*=0.061). Age <50 years vs ≥50 years was not a risk factor associated with a ≥10% weight gain at Week 240 (odds ratio, 1.79; 95% CI: 0.99–3.25; *P*=0.055).[13,14]

Table 4. Studies 1489 and 1490: Change in Renal and Metabolic Parameters From BL to Week 240[2]

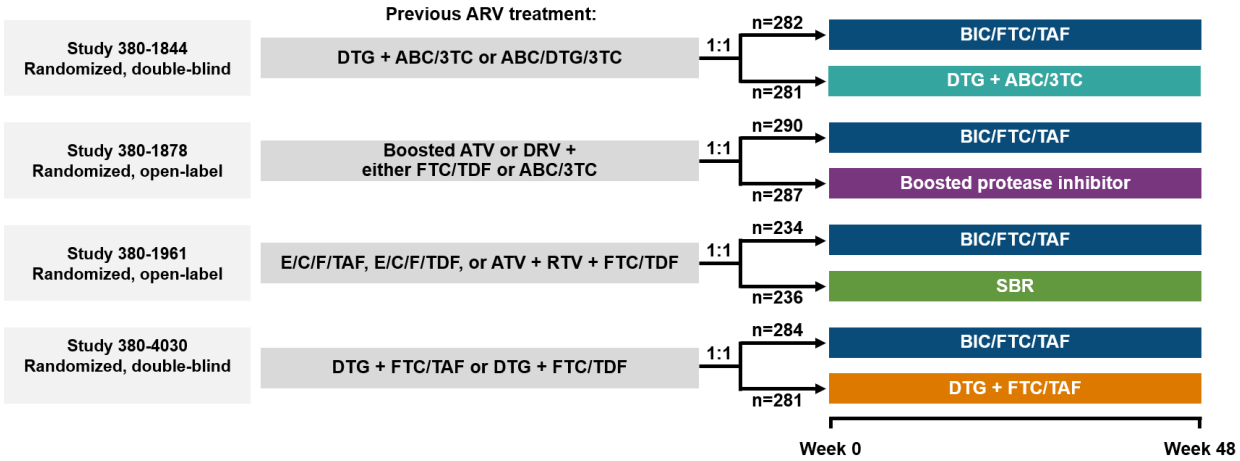
	Aged ≥50 Years		Aged <50 Years		*P*-Value
	n	Median (Q1, Q3)	n	Median (Q1, Q3)	
$eGFR_{CG}$, mL/min	67	-10.5 (-19.6, 2.4)	363	-7.7 (-19.4, 3)	0.3003
Body weight, kg	68	4.8 (0.7, 10.2)	363	6.4 (2.4, 12)	0.087
TC:HDL ratio	65	-0.3 (-0.9, 0.4)	345	0.1 (-0.4, 0.6)	0.0044

Studies in VS participants

Study design and demographics

Data from four phase 3, randomized trials of VS adults who switched to BIC/FTC/TAF (Studies 1844, 1878, 1961, and 4030) were pooled in a post hoc analysis to assess efficacy and safety outcomes in PWH aged ≥50 years and <50 years (Figure 2). Comorbidities such as diabetes, cardiovascular disease, hyperlipidemia, and hypertension were more frequent in participants aged ≥50 years (Table 5).[2]

Figure 2. Studies 1844, 1878, 1961, and 4030: Study Designs[2,11,15]



Abbreviations: ATV=atazanavir; DRV=darunavir; RTV=ritonavir; SBR=stay on BL regimen.

Table 5. Studies 1844, 1878, 1961, and 4030: BL Demographics and Disease Characteristics[2]

Key Demographics and Characteristics		Aged ≥50 Years (n=450)	Aged <50 Years (n=640)
Age, median (Q1, Q3), years		56 (52, 60)	39 (33, 45)
Male sex at birth, n (%)		342 (76)	393 (61.4)
Region, n (%)	US	327 (72.7)	294 (45.9)
	Outside US	123 (27.3)	346 (54.1)

Key Demographics and Characteristics		Aged ≥50 Years (n=450)	Aged <50 Years (n=640)
Race, n (%)	White	291 (64.7)	369 (57.7)
	Black	131 (29.1)	166 (25.9)
	Other[a]	17 (3.8)[b]	38 (5.9)[b]
Hispanic or Latinx ethnicity, n (%)		72 (16)[b]	131 (20.5)[c]
HIV-1 RNA <50 c/mL, n (%)		441 (98)	632 (98.8)
CD4 count, median (IQR), cells/mcL		640 (486–852)	691 (523–887)
Medical history, n (%)	Hyperlipidemia	220 (48.9)	121 (18.9)
	Hypertension	182 (40.4)	111 (17.3)
	Diabetes mellitus	76 (16.9)	38 (5.9)
	Cardiovascular disease	50 (11.1)	15 (2.3)

[a]Included American Indian or Alaska Native, Asian, Native Hawaiian, or Pacific Islander, and other.
[b]Data were missing for 1 participant. [c]Data were missing for 2 participants.

Efficacy results at Week 48[2]

At Week 48, 93.6% of participants in both age groups maintained virologic suppression (HIV-1 RNA <50 c/mL) by FDA Snapshot analysis (Table 6).

Table 6. Studies 1844, 1878, 1961, and 4030: Virologic Outcomes at Week 48 (FDA Snapshot Analysis)[2]

Outcome, n (%)	Aged ≥50 Years (n=450)	Aged <50 Years (n=640)	*P*-Value
HIV-1 RNA <50 c/mL	421 (93.6)	599 (93.6)	1
HIV-1 RNA ≥50 c/mL	4 (0.9)	9 (1.4)	0.58

Overall, 83.7% of participants aged ≥50 years and 85.3% of participants aged <50 years reported ≥95% adherence through Week 48. From BL to Week 48, CD4 cell counts increased in both age groups, with a mean ± SD increase of 18±162.5 cells/mcL in participants aged ≥50 years and 4±174.9 cells/mcL in participants aged <50 years (LSMD [range], 15 [-7 to 36] cells/mcL; *P*=0.18).

Safety results through Week 48[2]

Through Week 48, rates of TEAEs were similar between age groups (Table 7).

Table 7. Studies 1844, 1878, 1961, and 4030: Safety Results Through Week 48[2]

Safety Parameters, n (%)	Aged ≥50 Years (n=450)	Aged <50 Years (n=640)
Any TEAEs	354 (78.7)	494 (77.2)
Any Grade 3 or 4 TEAEs	33 (7.3)	30 (4.7)
Any serious TEAEs	39 (8.7)	30 (4.7)
Study drug-related TEAEs	58 (12.9)	80 (12.5)
Study drug-related Grade 3 or 4 TEAEs	3 (0.7)	4 (0.6)
Study drug-related serious TEAEs	1 (0.2)	1 (0.2)
Discontinuations due to TEAEs	8 (1.8)	6 (0.9)
Deaths	2 (0.4)	2 (0.3)

Mean changes in hip and spine BMD from BL to Week 48 were similar between participants aged ≥50 vs <50 years (hip, 0.2% vs 0.1%; spine, 0.5% vs 0.8%, respectively). Changes in $eGFR_{CG}$ and metabolic parameters were minimal in both groups (Table 8). More participants aged ≥50 years initiated lipid-modifying agents through Week 48 (5.3%) than did those aged <50 years (0.8%; *P*<0.0001). Rates of treatment-emergent diabetes (1.1% vs 1.3%) and

hypertension (5.2% vs 2.6%) were similar in participants aged ≥50 years vs <50 years (between groups, *P*>0.05 each).

Table 8. Studies 1844, 1878, 1961, and 4030: Change in Renal and Metabolic Parameters From BL to Week 48[2]

	Aged ≥50 Years		Aged <50 Years		*P*-Value
	n	Median (Q1, Q3)	n	Median (Q1, Q3)	
$eGFR_{CG}$, mL/min	422	-0.9 (-8.1, 5.8)	603	-1 (-9.6, 8.4)	0.9223
Body weight, kg	429	1.5 (-0.8, 3.8)	609	1.8 (-0.4, 4)	0.2857
TC:HDL ratio	412	-0.1 (-0.5, 0.4)	593	0 (-0.4, 0.3)	0.933

BIC/FTC/TAF Study in African PWH Aged ≥60 Years

Study design and demographics[3]

A phase 3b, randomized, open-label, active-controlled, non-inferiority, 96-week study in Kenya compared the efficacy and safety of switching from a first-line regimen to BIC/FTC/TAF (n=260) vs continuing on the current ARV regimen (CAR group; n=260). Eligible participants were PWH aged ≥60 years who had HIV-1 RNA <50 c/mL for ≥12 weeks, had received an ARV regimen for ≥24 weeks, and had no prior history of VF. The co-primary endpoints were the proportion of participants with HIV-1 RNA ≥50 c/mL at Week 48 by FDA Snapshot analysis (non-inferiority margin, 4%) and the mean percent change in lumbar spine BMD from BL to Week 48 in a subset of participants (BIC/FTC/TAF, n=143; CAR, n=153). Secondary endpoints extended the primary analysis to Week 96 and were the proportion of participants with HIV-1 RNA ≥50 c/mL by FDA Snapshot analysis and the mean percent change in lumbar spine BMD from BL to Week 96.

BL demographics and characteristics in the BIC/FTC/TAF and CAR groups included the following: mean age of 64 years in both groups; female sex, 48% and 55%, respectively; median of 10 years on ART in each group; and 94% and 96% receiving DTG/TDF/3TC.

Results at Week 48[4]

At Week 48, 96.2% of participants in both treatment groups were VS (HIV-1 RNA <50 c/mL). No virologic data were available for 5 participants (1.9%) in the BIC/FTC/TAF group and 3 participants (1.2%) in the CAR group, and HIV-1 RNA ≥50 c/mL was reported in 5 participants (1.9%) and 7 participants (2.7%), respectively, meeting the threshold for non-inferiority (difference, -0.8%; 95% CI: -3.4 to 1.8; *P*<0.001). No participants met the criteria for resistance testing (HIV-1 RNA >500 c/mL).

After adjusting for BL BMI and sex, the mean ± SD percent change in lumbar spine BMD from BL to Week 48 was significantly greater in the BIC/FTC/TAF group than in the CAR group: +1.88±4.72% vs +0.42±5.51%; difference: 1.45%; 95% CI: 0.24–2.66%; *P*=0.019), and the mean ± SD percent change in femoral neck BMD was 0.84±7.1% and -1.71±8.46%, respectively (difference, 2.27%; 95% CI: 0.43–4.1%; *P*=0.016). Fractures were reported in 2 participants in the BIC/FTC/TAF group and 4 participants in the CAR group.

No treatment-related SAEs occurred in either group. Grade 3 or 4 AEs were reported in 16.9% and 14.2% of participants in the BIC/FTC/TAF and CAR groups, respectively, and led to zero discontinuations in the BIC/FTC/TAF group and 15 discontinuations (5.8%) in the CAR group. One participant in the BIC/FTC/TAF group discontinued due to the AE of tuberculosis.

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Results at Week 96[3]

At Week 96, virologic suppression was achieved by 92% in the BIC/FTC/TAF group and 83% in the CAR group (difference, 9.2%; 95% CI: 3.5–14.9%), meeting the non-inferiority criteria. Seven participants (2.7%) in each group had HIV-1 RNA ≥50 c/mL; the between-group difference for these data met the threshold for non-inferiority (difference, 0%; 95% CI: -2.8 to 2.8%; *P*=0.002); of these 14 participants, 12 cases of VF occurred before Week 48, and 2 cases occurred between Weeks 48 and 96; both occurred in the BIC/FTC/TAF group.

The mean ± SD percent change in lumbar spine BMD from BL to Week 96 was +3.57±5.39% in the BIC/FTC/TAF group and +1.76±5.79% in the CAR group (difference adjusted for sex and BMI, 1.63%; 95% CI: 0.28–2.98%; *P*=0.018), and the mean ± SD percent change in femoral neck BMD was 0.7±6.7% and -1.58±9.75%, respectively (adjusted difference, 1.95%; 95% CI: -0.09 to 3.99%; *P*=0.061).

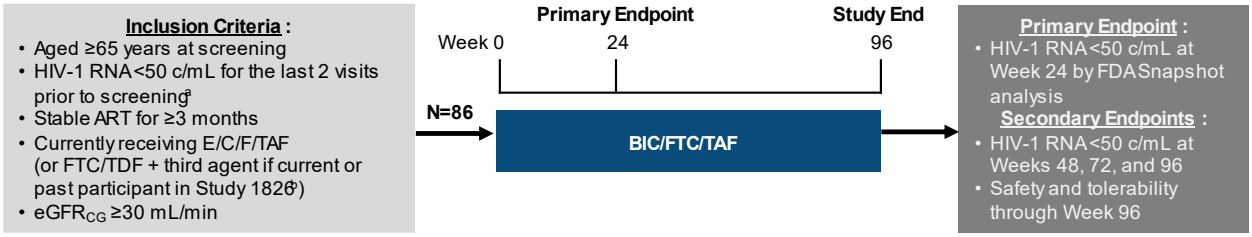
No treatment-related SAEs were reported in either group. One participant (0.4%) in the BIC/FTC/TAF group discontinued due to tuberculosis, and 30 participants (12%) in the CAR group discontinued due to declining kidney function (CrCl ≤50 mL/min). The median change in CrCl from BL to Week 96 was +1 mL/min in the BIC/FTC/TAF group and -3 mL/min in the CAR group. The change in weight from BL to Week 96 was 0 kg in the BIC/FTC/TAF group and -2 kg in the CAR group; a weight gain of ≥5% was reported in 13% and 6%, respectively. In the BIC/FTC/TAF group, incident hypertension and incident dyslipidemia were reported in 60/260 (23%) and 69/207 (33%) participants, respectively; rates in the CAR group were 46/260 (18%) and 58/218 (27%).

Study GS-US-380-4449

Study design and demographics

Study GS-US-380-4449 was a multicenter, open-label, single-arm, phase 3b study that evaluated the efficacy, safety, and tolerability of switching to BIC/FTC/TAF in VS PWH aged ≥65 years age (Figure 3).[5]

Figure 3. Study 4449: Study Design[5,16]



[a]Transient detectable viremic blips (HIV-1 RNA ≥50 c/mL and <400 c/mL) were acceptable.
[b]Study GS-US-292-1826 was an open-label, randomized, 48-week study that evaluated the efficacy and safety of switching from a TDF-based regimen to E/C/F/TAF in participants ≥60 years of age.

Table 9. Study 4449: BL Demographics and Disease Characteristics[5]

Key Demographics and Characteristics	BIC/FTC/TAF (N=86)
Age, median (IQR), years	69 (67–72)
Female, n (%)	11 (13)
Race, White/Black,[a] n (%)	82 (95)/1 (1)
HIV-1 RNA <50 c/mL at BL, n (%)	84 (98)
CD4 count, median (IQR), cells/mm^3	676 (515–829)

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Key Demographics and Characteristics		BIC/FTC/TAF (N=86)
$eGFR_{CG}$, median (IQR), mL/min		76 (65–88)
Weight, median (IQR), kg		78 (69–87)
BL regimen, n (%)	E/C/F/TAF	79 (92)
	RPV/FTC/TDF	4 (5)
	Other[b]	3 (4)

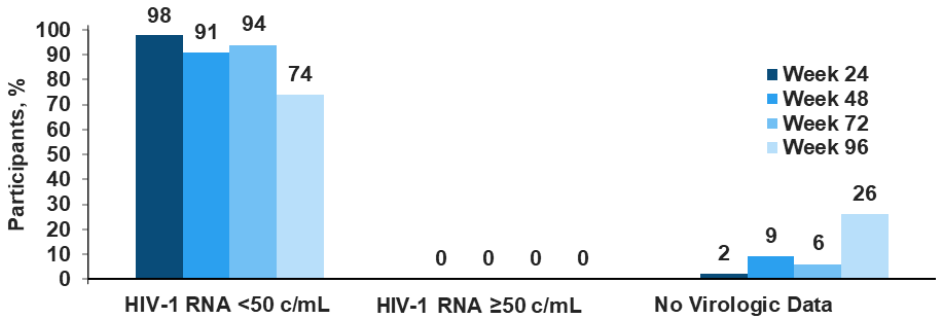
Abbreviations: EFV=efavirenz; NVP=nevirapine; RPV=rilpivirine.
[a]Three participants did not disclose their race.
[b]Other BL regimens included EFV/FTC/TDF (n=1), E/C/F/TDF (n=1), and NVP + FTC/TDF (n=1).

Efficacy results through Week 96

High rates of virologic suppression (HIV-1 RNA <50 c/mL) were maintained at the Week 24 primary endpoint (97.7%; 95% CI: 91.9–99.7) and at the secondary endpoints at Weeks 48 (90.7%), 72 (94.2%), and 96 (74.4%; Figure 4).[5,17] The number of missing virologic data at Week 96 (n=22) was largely due to the impact of the COVID-19 pandemic on study visits. The median (IQR) change from BL to Week 96 in CD4 count was -3 (-59 to 91) cells/mm^3 (n=59).[16]

Through Week 96, no participants met the criteria for resistance testing, and no treatment-emergent resistance was observed. Participants with pre-existing resistance maintained virologic suppression through Week 96.[5]

Figure 4. Study 4449: Efficacy Outcomes Through Week 96[5,17]



Safety results through Week 96

Most TEAEs were Grade 1 or 2 (Table 10). None of the SAEs (10.5%) were considered related to study drug. There were no discontinuations due to renal, bone, or hepatic AEs.[5]

Table 10. Study 4449: Summary of Safety Results Through Week 96[5]

Safety Parameters, n (%)	BIC/FTC/TAF (N=86)
Any Grade 3 or 4 AE	15 (17.4)
Study drug-related AE	11 (12.8)
AEs leading to study drug discontinuation	5 (5.8)[a]

[a]AEs attributed to study drug: abdominal discomfort, irritability, sleep disorder, and weight gain; not attributed to study drug: alcohol withdrawal syndrome and drug withdrawal syndrome .

The median (IQR) change in weight from BL to Week 96 was 0 (-2.3 to 2) kg. At Week 96, RBP:Cr decreased by a median of 16.4% (BL, 139.3 mcg/g), and β2M:Cr increased by a median of 18.7% (BL, 72 mcg/g).[5,16] Median change in $eGFR_{CG}$ from BL to Week 48 was -6 mL/min and remained stable through Week 96.[5,17] Changes in metabolic parameters (Table 11) were deemed by study authors to be clinically irrelevant.[5]

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Table 11. Study 4449: Changes in Fasting Lipids at Week 96 (n=56)[5]

Lipid Parameter	BL	Median Change From BL	*P*-Value
TC, mg/dL	191	-15	0.066
LDL, mg/dL	117	-10	0.069
HDL, mg/dL	51	-1	0.54
TG, mg/dL	131	-19	0.001
TC:HDL	3.9	-0.2	0.029

Abbreviation: TG=triglycerides.

Real-World Data: BIC/FTC/TAF Use in Adults Aged ≥50 Years

Key real-world studies are presented in Table 12. Data may not be all-inclusive.

Table 12. Summary of Real-World Studies in PWH Age ≥50 Years[6-9]

Study Design	Study Population	Efficacy Results of PWH Aged ≥50 Years	Safety Results
Retrospective, multicenter, observational cohort study in Belgium (Nasreddine, 2023)[6]	2001 adult PWH who received BIC/FTC/TAF; 41% were aged ≥50 years, 80% were TE, and 68.1% were VS at BL	• At Wk 24, 92.6% (n=672) had VL <50 c/mL. • At Wk 48, 92.7% (n=576) had VL <50 c/mL. • Median (IQR) change from BL in CD4 count was 50 (-50 to 172) cells/mcL. • Five patients had loss of virologic suppression; no treatment-emergent RAMs were reported. At BL, 4/5 participants were TE, 2 were not VS, 2 experienced a viral blip, and 1 had BL RAMs.	• Overall, 131 patients (6.5%) discontinued treatment, mainly due to AEs (2.4%) or switch to a two-drug regimen (1.3%). • In patients aged >50 years, the median (IQR) increase in weight from BL at Wk 48 was 1 (-1 to +4) kg. • Age >50 years was not associated with weight gain of >10% (*P*=0.16).
RETROBIC study: retrospective, multicenter study in Spain (Troya, 2024)[7]	1966 VS PWH who switched to BIC/FTC/TAF; 16.8% (n=330) were aged ≥60 years	• CD4 counts increased from BL to Wk 96 (*P*<0.01). • CD8 counts decreased from BL to Wk 48 (*P*<0.01). • CD4/CD8 ratio improved from BL to Wk 48 (*P*<0.01). • VL <50 c/mL or <200 c/mL: 94% at Wk 48 and 94.9% at Wk 96.	• Overall, 50 patients (2.5%) had major AEs, and 200 patients (10.2%) discontinued treatment: switch to two-drug regimen (3.8%), AEs (2.3%), loss to follow-up (2.1%), drug-drug interaction (1%), and VF (0.91%). • Among patients ≥60 years of age, TC levels decreased significantly from BL to Week 48 (*P*<0.01), and LDL levels decreased from BL to Week 48.
REGAL cohort: a retrospective, multinational study (Fraysse, 2025)[10]	1144 VS PWH aged ≥50 years at time of BIC/FTC/TAF (n=551) or DTG/3TC (n=593) initiation	• From BL to 288 weeks of BIC/FTC/TAF treatment, there was 1 case (0.2%) of VF (incidence rate of VF per 100 PY, 0.7). • From BL to Wk 48, the median (IQR) change in CD4 count was 4 (-79 to 100) cells/mm^3. • Median CD4:CD8 ratio remained stable from BL to Wk 96.	• Of the patients who received BIC/FTC/TAF, 23 patients (4.2%) switched, changed, or discontinued treatment, and 10 patients (1.8%) were lost to follow-up. No deaths were reported. • Biomarkers of hepatic function remained stable through 96 weeks.

Study Design	Study Population	Efficacy Results of PWH Aged ≥50 Years	Safety Results
BICSTaR study: ongoing prospective, multinational, observational cohort study (Miralles, 2024)[8]	401 PWH aged ≥50 years with a high comorbidity burden at BL who switched to BIC/FTC/TAF	• Through 24 months of treatment, 96% had VL <50 c/mL (M=E analysis), and 90% continued to receive BIC/FTC/TAF.	• Cardiometabolic, hepatic, and renal parameters remained stable. • BIC/FTC/TAF was generally well tolerated.
Retrospective cohort study (Rolle, 2020)[9]	350 PWH aged ≥50 years who were VS within 1 year prior to switching to BIC/FTC/TAF	• At Wk 48, 94% (n/N=330/350) had VL <50 c/mL, including 88% (23/26) with BL M184V/I mutations and 89% with ≥1 NRTI RAMs. • CD4 counts were numerically higher at Wk 48 than at BL.	• Drug-related AEs were reported in 15%; most common were fatigue (4%), arthralgia (3%), and weight gain (3%). • Drug-related AEs led to discontinuation in 8 patients (2%). • Grade 3 to 4 laboratory abnormalities were reported in 25 patients (7%). • Significant improvements in lipid parameters were observed through Wk 48 (all *P*≤0.017).

Abbreviations: NRTI=nucleos(t)ide reverse transcriptase inhibitor; PY=patient years; RAM=resistance-associated mutation; VL=viral load.

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Abbreviations

β2M=β2 microglobulin
3TC=lamivudine
ABC=abacavir
AE=adverse event
ART=antiretroviral therapy
ARV=antiretroviral
BIC=bictegravir
BL=baseline
BMD=bone mineral density
c/mL=copies per mL
CAR=continue antiretroviral regimen
CD4/8=cluster of differentiation 4/8
CG=Cockcroft-Gault
DTG=dolutegravir
E/C/F=elvitegravir/ cobicistat/emtricitabine
FTC=emtricitabine
LSMD=least squares mean difference
M=E=missing=excluded
PWH=people with HIV
Q=quartile
RBP=retinol-binding protein
SAE=serious adverse event
TAF=tenofovir alafenamide
TC=total cholesterol
TDF=tenofovir disoproxil fumarate
TEAE=treatment-emergent adverse event
VF=virologic failure
VS=virologically suppressed

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.

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