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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>100).

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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 subjects (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 participants 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 subjects 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 subjects 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: Use in Adults Aged ≥50 Years

In several prospective 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, 144, or 240) in those 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.[2-8]

Real-World Data: 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 baseline were reported.[9-12]

Clinical Studies: Use in Adults Aged ≥50 Years

Pooled Analysis of ARV-Naive Adults Aged ≥50 Years

Study design and demographics

Data from two randomized, double-blind, active-controlled, noninferiority phase 3 studies in ARV-naive participants that evaluated the efficacy and safety of BIC/FTC/TAF with DTG-containing regimens were pooled in post hoc analyses to compare results through Week 144 and Week 240 in participants aged ≥50 years vs <50 years (Figure 1).[2,3]

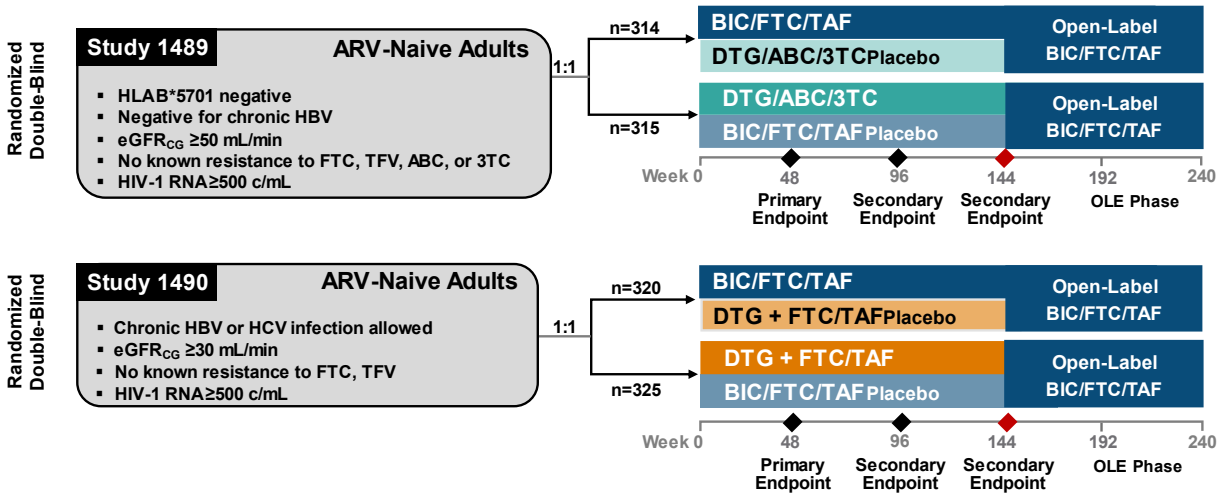

Figure 1. Studies 1489 and 1490: Study Designs[3]

Abbreviation: HLA=human leukocyte antigen.

Table 1. Studies 1489 and 1490: Baseline Demographics and Disease Characteristics[2,3]

Key Demographics and Characteristics	Aged ≥50 Years (n=196)			Aged <50 Years (n=1078)		
	BIC/FTC/TAF (n=96)	DTG/ABC/3TC (n=41)	DTG + FTC/TAF (n=59)	BIC/FTC/TAF (n=538)	DTG/ABC/3TC (n=274)	DTG + FTC/TAF (n=266)
Age, median (range), years	55 (50–71)	54 (50–68)	54 (50–77)	30 (18–49)	30 (18–49)	31 (18–49)
Male, %	84	73	86	90	92	89
Black or African descent, %	32	27	20	34	37	33
Hispanic/Latinx, %	11	15	20	27	22	26
HIV-1 RNA, median (IQR), $\log_{10}$ copies/mL	4.48 (4–4.93)	4.27 (3.74–5.01)	4.45 (3.90–4.92)	4.41 (4–4.86)	4.53 (4.06–4.85)	4.45 (4.04–4.83)
CD4 count, median (IQR), cells/mcL	436 (235–601)	534 (291–741)	405 (229–610)	442 (299–590)	444 (331–599)	447 (314–597)
$eGFR_{CG}$, median (IQR), mL/min	99 (83.7–114)	101.9 (83.2–130.5)	104 (84.2–121.8)	126.4 (108.6–146.8)	125.1 (109.9–146.4)	124.9 (106.1–151.5)

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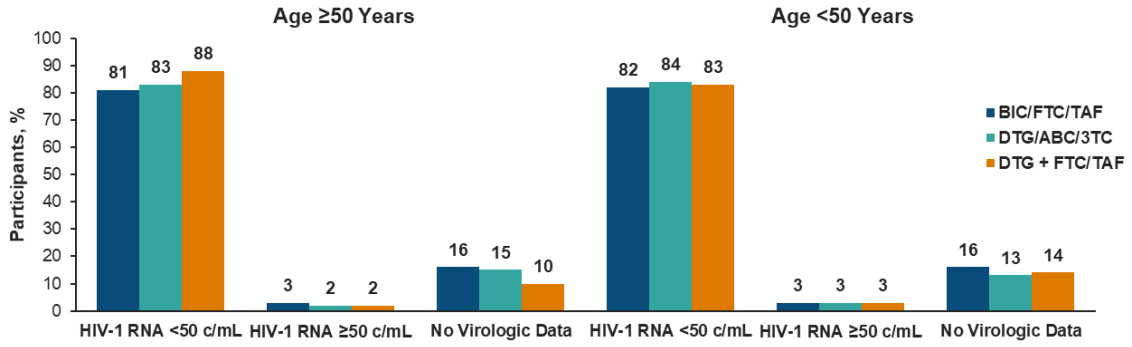
Efficacy results at Week 144[2]

Overall, BIC/FTC/TAF was noninferior to either DTG-containing regimen at the Week 48 primary endpoint and at Week 144. There were no significant differences in efficacy outcomes at Week 144 between treatment arms in participants aged ≥50 years (BIC/FTC/TAF vs DTG/ABC/3TC, *P*=0.73; BIC/FTC/TAF vs DTG + FTC/TAF, *P*=0.24) or in participants aged <50 (BIC/FTC/TAF vs DTG/ABC/3TC, *P*=0.34; BIC/FTC/TAF vs DTG + FTC/TAF, *P*=0.8; Figure 2) by FDA Snapshot analysis.

Figure 2. Studies 1489 and 1490: Efficacy Outcomes at Week 144[2]



Safety results through Week 144[2]

In the BIC/FTC/TAF arm, AEs were comparable between participants aged ≥50 years and those aged <50 years, with low rates of discontinuation due to AEs (Table 2).

Table 2. Studies 1489 and 1490: Safety Results Through Week 144[2]

Safety Result, %	Aged ≥50 Years			Aged <50 Years		
	BIC/FTC/TAF (n=96)	DTG/ABC/3TC (n=41)	DTG + FTC/TAF (n=59)	BIC/FTC/TAF (n=538)	DTG/ABC/3TC (n=274)	DTG + FTC/TAF (n=266)
TRAEs, all grades, ≥5% in any group						
Diarrhea	4	10	3	5	3	3
Nausea	5	7	2	4	19	6
Headache	4	0	0	5	6	4
Flatulence	2	0	5	<1	<1	2
Hypercholesterolemia	2	0	5	<1	0	0
AEs leading to discontinuation	2	5	7	1	1	1

Abbreviation: TRAE=treatment-related AE.

There were no discontinuations due to renal AEs in the BIC/FTC/TAF or DTG + FTC/TAF groups; there was 1 discontinuation due to renal failure in the DTG/ABC/3TC group that was not considered related to study drug. Changes from baseline in $eGFR_{CG}$ occurred early and were stable through Week 144 (median change from baseline ranged from -9 to -12 mL/min across treatment groups and age subgroups), which was consistent with the inhibition of tubular creatinine secretion via organic cation transporter-2 by DTG and BIC.

In Study 1489, changes from baseline in BMD at Week 144 were comparable between the BIC/FTC/TAF and DTG/ABC/3TC treatment groups in adults aged ≥50 years (hip: -0.46% vs -1.13%; spine: +1.29% vs -0.51%, respectively).

There were no statistically significant differences between BIC/FTC/TAF and either comparator in median weight change at Week 144 in adults aged ≥50 years (BIC/FTC/TAF +4.3 kg, DTG/ABC/3TC +4.7 kg, DTG + FTC/TAF +3.4 kg). The differences in lipid changes from baseline to Week 144 in adults aged ≥50 years were not clinically significant between BIC/FTC/TAF and comparators (Table 3). The proportion of participants initiating lipid-modifying agents during the study was numerically similar across treatment groups.

Table 3. Studies 1489 and 1490: Lipid Safety Results Through Week 144[2]

Fasting Baseline/Week 144, median	Aged ≥50 Years			Aged <50 Years		
	BIC/FTC/TAF (n=96)	DTG/ABC/3TC (n=41)	DTG + FTC/TAF (n=59)	BIC/FTC/TAF (n=538)	DTG/ABC/3TC (n=274)	DTG + FTC/TAF (n=266)
TC, mg/dL	177/182	178/192	171/177	154/170[a]	156/165	157/169
LDL, mg/dL	116/132	122/134	112/124	96/119[a]	97/112	96/115
HDL, mg/dL	42/47	42/49	43/50[a]	42/46	43/49	43/47
TG, mg/dL	109/110	122/134	104/110	93/96	92/92	92/92
TC:HDL	3.8/4.1	3.8/4.3	3.7/4.0	3.6/3.7[a]	3.3/3.6	3.5/3.6

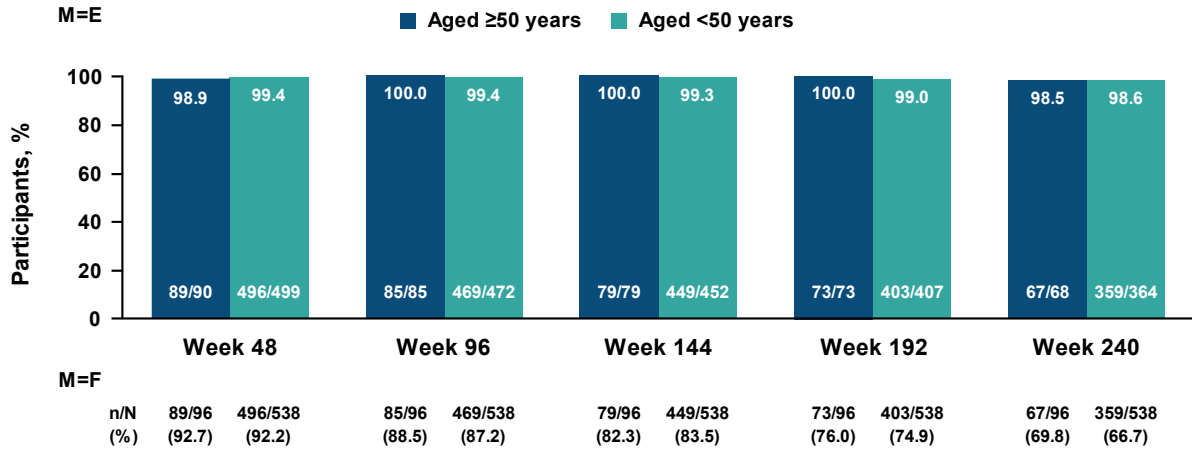
[a]*P*<0.005 for the change from baseline to Week 144 for BIC/FTC/TAF vs DTG/ABC/3TC or DTG + FTC/TAF.

Studies 1489 and 1490: Week 240 BIC/FTC/TAF pooled analysis[3]

Efficacy results at Week 240

The virologic suppression rates with BIC/FTC/TAF were high in in participants aged ≥50 years and <50 years (Figure 3). The increase in CD4 cell count from baseline to Week 240 was similar in both groups (mean [SD] change from baseline: +291 [221] and +347 [238] cells/mcL, respectively; *P*=0.07). No treatment-emergent resistance to BIC/FTC/TAF was reported through Week 240.

Figure 3. Studies 1489 and 1490: HIV-1 RNA <50 c/mL Through Week 240[3]



Safety results through Week 240

Through Week 240, study drug-related AEs reported in ≥5% participants (aged ≥50 vs <50 years, respectively) were nausea (5% vs 4%), headache (4% vs 5%), and diarrhea (4% vs 5%). Rates of study drug discontinuation due to AEs were overall low, but higher in participants aged ≥50 years (Table 4).

Table 4. Studies 1489 and 1490: Safety Results Through Week 240[3]

Safety Parameters, n (%)	Aged ≥50 Years (n=96)	Aged <50 Years (n=538)
Any AE	90 (94)	514 (96)
Study drug-related AE	25 (26)	153 (28)
Any Grade 3 or 4 AE	30 (31)	102 (19)
Study drug-related Grade 3 or 4 AE	4 (4)	5 (<1)
Any SAE	33 (34)	103 (19)
Discontinuation due to AE	4 (4)[a]	6 (1)[b]

[a]Cardiac arrest, chest pain, COVID-19, and obesity (n=1 each).
[b]Abdominal distention, dyspepsia, toxicity due to various agents, intervertebral discitis, tension headache (each, n=1).

The mean changes from baseline in hip and spine BMD were reported to be minimal and 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) in Study 1489. According to the study authors, changes in $eGFR_{CG}$ and metabolic parameters were not clinically significant, except for changes in body weight in those who were underweight or who had cachexia at baseline (Table 5). Overall, a larger percentage of participants aged ≥50 years than those aged <50 years received lipid-modifying agents at baseline (22% vs 2%, respectively) and initiated use through Week 240 (21% and 5%, respectively). Rates of treatment-emergent diabetes (5% vs 2%) and hypertension (20% vs 12%) were also numerically higher in those aged ≥50 years vs <50 years.

Table 5. Studies 1489 and 1490: Change From Baseline in Renal and Metabolic Parameters at Week 240[3]

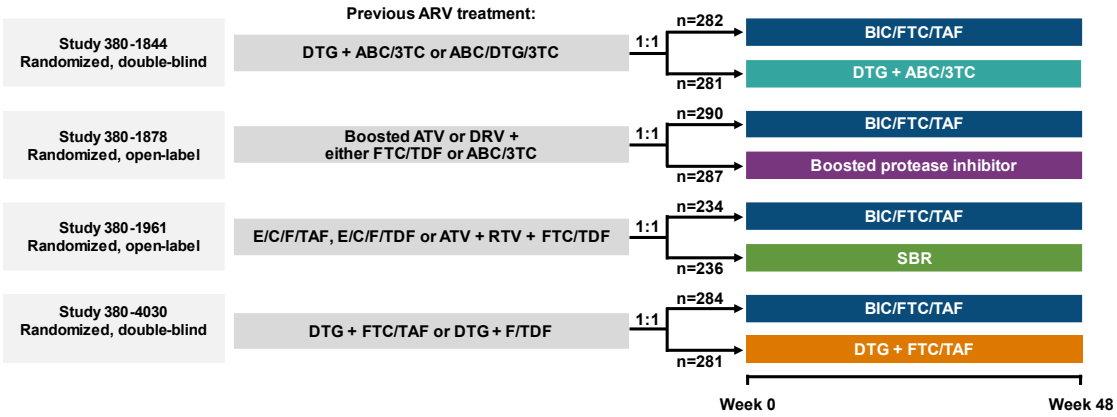
	Aged ≥50 Years		Aged <50 Years		*P*-Value
	n	Median (Q1,Q3)	n	Median (Q1,Q3)	
$eGFR_{CG}$, mL/min	67	-10.5 (-19.6, 2.4)	363	-7.7 (-19.4, 3.0)	0.30
Body weight, kg	68	4.8 (0.7, 10.2)	363	6.4 (2.4, 12.0)	0.09
TC:HDL ratio	65	-0.3 (-0.9, 0.4)	345	0.1 (-0.4, 0.6)	0.0044

Pooled Analysis of VS Adults Aged ≥50 Years[4]

Study design and demographics[4]

Data from four phase 3, randomized, multicenter trials of VS adults who switched to BIC/FTC/TAF were pooled in a post hoc analysis to assess efficacy and safety outcomes in PWH aged ≥50 years and <50 years (Figure 4). Comorbidities such as diabetes, cardiovascular disease, hyperlipidemia, and hypertension were more frequent in participants aged ≥50 years (Table 6). Use of comedications during the study was also more frequent in those aged ≥50 years vs <50 years, including specific non-ARV medications such as lipid-modifying agents (41% vs 12%), renin-angiotensin system agents (28% vs 12%), antithrombotic agents (20% vs 5%), and beta-blocking agents (15% vs 5%).

Figure 4. Studies 1844, 1878, 1961, and 4030: Study Designs[4]



Abbreviation: SBR=stay on baseline regimen.

Table 6. Studies 1844, 1878, 1961, and 4030: Baseline Demographics and Disease Characteristics[4]

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)
Region, n (%)	US	327 (73)	294 (46)
	Ex-US	123 (27)	346 (54)
Race, n (%)	White	291 (65)	369 (58)
	Black	131 (29)	166 (26)
	Other[a]	27 (6)	104 (16)
Hispanic or Latino ethnicity, n (%)		72 (16)	131 (21)
HIV-1 RNA <50 c/mL, n (%)		441 (98)	632 (99)
CD4 count, median (Q1, Q3), cells/mcL		640 (486, 852)	691 (523, 887)
Medical history, n (%)	Diabetes	38 (8)	30 (5)
	Hyperlipidemia	149 (33)	96 (15)
	Hypertension	114 (25)	83 (13)
Concomitant use of ≥1 non-ARV medication during the study, n (%)		431 (96)	590 (92)

[a]Includes American Indian or Alaska Native, Asian, Native Hawaiian, or Pacific Islander, and other.

Efficacy results at Week 48[4]

At Week 48, rates of VS and virologic failure were numerically similar in both age groups (Table 7). Overall, 84% of participants aged ≥50 years and 85% of participants aged <50 years reported ≥95% adherence through Week 48.

Table 7. Studies 1844, 1878, 1961, and 4030: Virologic Outcomes at Week 48 (FDA Snapshot Analysis)[4]

Outcome, n (%)	Aged ≥50 Years (n=450)	Aged <50 Years (n=640)
HIV-1 RNA <50 c/mL	421 (93.6)	599 (93.6)
HIV-1 RNA ≥50 c/mL	25 (5.6)	32 (5)
No virologic data	4 (0.9)	9 (1.4)

Safety results through Week 48[4]

Through Week 48, study drug-related AEs reported in ≥2% participants (aged ≥50 vs <50 years, respectively) were headache (3% vs 2%), diarrhea (2% vs 1%), and constipation (2% and <1%). Overall rates of study drug discontinuation due to AEs were low in both groups (Table 8).

Table 8. Studies 1844, 1878, 1961, and 4030: Safety Results Through Week 48[4]

Safety Parameters, n (%)	Aged ≥50 Years (n=450)	Aged <50 Years (n=640)
Any AE	354 (79)	494 (77)
Study drug-related AE	58 (13)	80 (13)
Any Grade 3 or 4 AE	33 (7)	30 (5)
Study drug-related Grade 3 or 4 AE	3 (1)	4 (1)
Any SAE	39 (9)	30 (5)
Discontinuation due to AE	8 (2)[a]	6 (1)[b]

[a]Fatigue (n=2), vomiting, device-related infection, headache, cerebrovascular accident, abnormal dreams, agitation, nightmare, and hyperhydrosis (each, n=1).
[b]Dyspepsia, headache, abnormal dreams, schizophrenia, suicidal ideation, and rash (each, n=1).

In Study 1844, the mean changes from baseline in hip and spine BMD changes 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 9). More participants aged ≥50 years initiated lipid-modifying agents through Week 48 (5%) compared with those aged <50 years (1%). Rates of treatment-emergent diabetes (1% vs 1%) and hypertension (4% vs 3%) were similar in participants aged ≥50 years vs <50 years.

Table 9. Studies 1844, 1878, 1961, and 4030: Change From Baseline in Renal and Metabolic Parameters Through Week 48[4]

	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	-1.0 (-9.6, 8.4)	0.92
Body weight, kg	429	1.5 (-0.8, 3.8)	609	1.8 (-0.4, 4.0)	0.29
TC:HDL ratio	412	-0.1 (-0.5, 0.4)	593	0.0 (-0.4, 0.3)	0.0044

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

Study design and demographics[5]

A 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 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 virologic failure. The co-primary endpoints at Week 48 were the proportion of participants with HIV-1 RNA ≥50 c/mL via FDA Snapshot analysis (ITT population; non-inferiority margin, 4%) and the mean percent change in lumbar spine BMD from baseline in a subset of participants (BIC/FTC/TAF, n=143; CAR, n=153).

Baseline demographics and characteristics in the BIC/FTC/TAF and CAR groups included the following: median age of 64 and 63 years, respectively; 48% and 55% females; median of 9.5 years on ART in each group; and 94% and 96% currently receiving a TDF-based regimen.

Results at Week 48[5]

At Week 48, virologic suppression rates (HIV-1 RNA <50 c/mL) in the BIC/FTC/TAF and CAR groups were 95.8% and 96.2%, respectively. No virologic data were available for 2.3% and 1.1% of participants in the BIC/FTC/TAF and CAR groups, respectively.
Five participants (1.9%) in the BIC/FTC/TAF group and 7 participants (2.7%) in the CAR group had HIV-1 RNA ≥50 c/mL; the between-group difference for these data met the threshold for non-inferiority (difference, -0.8%; 95% CI: -3.4 to 1.8). No participants underwent drug resistance testing (HIV-1 RNA levels were <500 c/mL).

The mean (SD) percent change in lumbar spine BMD from baseline to Week 48 was significantly greater in the BIC/FTC/TAF group than in the CAR group: +2.17% (5.23) vs +0.61% (5.44; difference: 1.56%; 95% CI: 0.32–2.79; *P*=0.014).

No treatment-related SAEs occurred, and Grade 3/4 AEs were reported in 3.1% and 2.3% of participants in the BIC/FTC/TAF and CAR groups, respectively.

Results at Week 96[6]

At Week 96, virologic suppression was achieved by 92.3% in the BIC/FTC/TAF group and 94.2% in the CAR group, and no virologic data were available for 5% and 3.1% of participants, respectively. 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).

The mean (SD) change in lumbar spine BMD from baseline to Week 96 was +3.98% (6.1) in the BIC/FTC/TAF group and +2.29% (6.02) in the CAR group (difference, 1.7; 95% CI: 0.25–3.14; *P*=0.021).

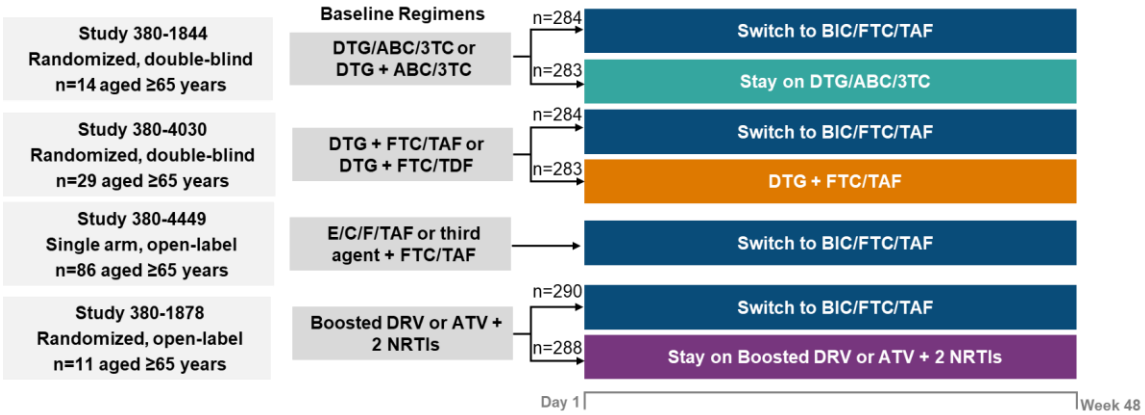
No treatment-related SAEs were reported in either group. One participant (0.4%) in the BIC/FTC/TAF group discontinued due to TB, and 30 participants (11.5%) in the CAR group discontinued due to declining kidney function. The change in CrCl from baseline to Week 96 was 1.7% in the BIC/FTC/TAF group and -3.5% in the CAR group. The change in weight from baseline to Week 96 was 0% in the BIC/FTC/TAF group and -2.6% in the CAR group; a weight gain of >5% was reported in 13.4% and 6.4%, respectively. In the BIC/FTC/TAF group, incident hypertension and incident dyslipidemia were reported in 60/166 participants (51.7%) and 69/207 (33.3%), respectively; rates in the CAR group were 46/100 (49.1%) and 58/218 (26.6%).

Pooled Analysis of VS Adults Aged ≥65 Years[7]

Study design and demographics

Data from four clinical trial in VS adults were pooled in a post hoc analysis to evaluate the efficacy and safety of BIC/FTC/TAF in participants aged ≥65 years through Week 48 (Figure 5).

Figure 5. Studies 1844, 4030, 4449, and 1878: Study Designs[7]



Note: Current analysis evaluated only those participants who received BIC/FTC/TAF.

Table 10. Studies 1844, 4030, 4449, and 1878: Baseline Demographics and Disease Characteristics[7]

Key Demographics and Characteristics		BIC/FTC/TAF (N=140)
Age, median (range), years		68 (65–80)
Female, n (%)		19 (14)
Race, n/N (%)	White	121/137 (88)
	Black	16/137 (12)
Weight, median (range), kg		79 (49–131)
$eGFR_{CG}$, median (range), mL/min		74 (38–130)
HIV-1 RNA <50 c/mL at baseline, n (%)		136 (97)
CD4 count, median (range), cells/mm^3		629 (132–1471)
Baseline regimen: INSTI (67%), n (%)	E/C/F/TAF	79 (56)
	DTG/ABC/3TC	14 (10)
	E/C/F/TDF	1 (0.7)
Baseline regimen: PI (29%),[a] n (%)	ATV/b + ABC/3TC	25 (18)
	DRV/b + ABC/3TC	6 (4.3)
	ATV/b + FTC/TDF	5 (3.6)
	DRV/b + FTC/TDF	4 (2.9)
Baseline regimen: NNRTI (4%), n (%)	RPV/FTC/TDF	4 (2.9)
	EFV/FTC/TDF	1 (0.7)
	NVP + FTC/TDF	1 (0.7)
Medical history at baseline, n (%)	Hyperlipidemia	83 (59)
	Hypertension	77 (55)
	Cardiovascular disease	34 (24)
	Diabetes mellitus	31 (22)

[a]The "/b" represents the PI being boosted by RTV or COBI.

Efficacy results at Week 48

Virologic suppression (HIV-1 RNA <50 c/mL) at Week 48 was maintained in 92% of the 140 participants aged ≥65 years using FDA Snapshot analysis. No participant had virologic failure (HIV-1 RNA ≥50 c/mL). Eleven participants (8%) had no virologic data at Week 48, but all were undetectable after Week 48. No development of resistance was reported. At Week 48, the median (IQR) change in CD4 count was 13 (-54 to 98) cells/mm^3.

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Safety results through Week 48

BIC/FTC/TAF was reported to be well tolerated in VS participants ≥65 years of age through Week 48 (Table 11). There were no renal, bone, or hepatic AEs that led to discontinuation.

Table 11. Studies 1844, 4030, 4449, and 1878: Safety Results Through Week 48[7]

Safety Parameter, n (%)	BIC/FTC/TAF (N=140)
Any Grade 2–4 study drug-related AE	2 (1.4)
Any Grade 3 or 4 laboratory abnormality	14 (10)
Any study drug-related SAE	0
AEs that led to study drug discontinuation	4 (2.9)[a]

[a]Included abdominal discomfort (Grade 2, drug-related), alcohol withdrawal, benzodiazepine withdrawal, and device-related infection.

At baseline, the median weight was 79 kg; the median (IQR) weight change through Week 48 was 1 (-0.9 to 3) kg.

There was a median change in $eGFR_{CG}$ from baseline to Week 12 of -2.9 mL/min, which remained stable through Week 48 (-2.7 mL/min change from baseline). There was a 14.5% decrease in median RBP:Cr and a 26.4% increase in median urine β2m:Cr. There were no reports of proximal tubulopathy.

There were modest improvements in fasting lipid parameters (Table 12). At baseline, 43% of participants (n=60) were on lipid-modifying medications, and 4% of participants (n=6) initiated lipid-modifying medication during the study.

Table 12. Studies 1844, 4030, 4449, and 1878: Median Changes From Baseline in Fasting Lipids at Week 48 (n=129)[7]

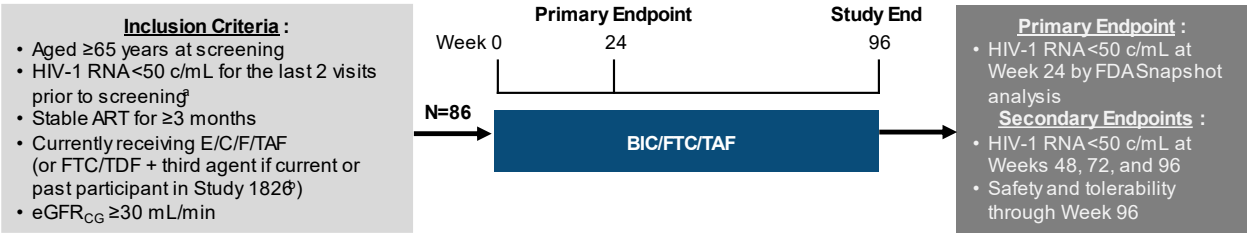
	TC, mg/dL	LDL, mg/dL	HDL, mg/dL	TG, mg/dL	TC:HDL
Baseline	186	112	51	127	3.8
Median change from baseline	-7	-2	0	-15	-0.1

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 6).[8]

Figure 6. Study 4449: Study Design[8,13]



[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.

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Table 13. Study 4449: Baseline Demographics and Disease Characteristics[8]

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 baseline, n (%)		84 (98)
CD4 count, median (IQR), cells/mm^3		676 (515–829)
$eGFR_{CG}$, median (IQR), mL/min		76 (65–88)
Weight, median (IQR), kg		78 (69–87)
Baseline regimen, n (%)	E/C/F/TAF	79 (92)
	RPV/FTC/TDF	4 (5)
	Other[b]	3 (4)

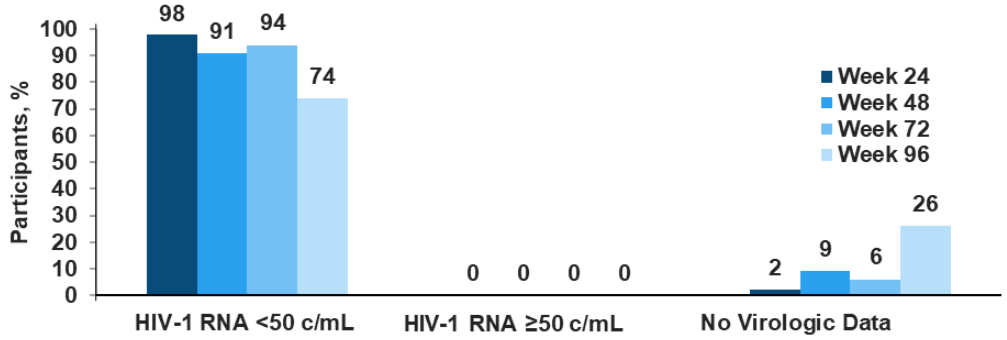
[a]Three participants did not disclose their race.
[b]Other baseline regimens included EFV/FTC/TDF (n=1), E/C/F/TDF (n=1), and NVP + FTC/TDF (n=1).

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 7).[8,14] 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 baseline in CD4 count was -3 (-59 to 91) cells/mm^3 at Week 96 (n=59).[13]

Through Week 96, no participants met the criteria for resistance testing and no treatment-emergent resistance was observed. Participants with pre-existing resistance maintained suppression through Week 96.[8]

Figure 7. Study 4449: Efficacy Outcomes Through Week 96[8,14]



Safety results through Week 96

Most treatment-emergent AEs were Grade 1 or 2 (Table 14). None of the SAEs (10.5%) were considered related to study drug. There were no discontinuations due to renal, bone, or hepatic AEs.[8]

Table 14. Study 4449: Summary of Safety Results Through Week 96[8]

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, weight gain, irritability and sleep disorder; not attributed to study drug: drug withdrawal syndrome and alcohol withdrawal syndrome.

The median (IQR) change in weight from baseline to Week 96 was 0 (-2.3 to 2) kg. At Week 96, RBP:Cr decreased by a median of 16.4% (baseline, 139.3 mcg/g), and β2m:Cr increased by a median of 18.7% (baseline, 72 mcg/g).[8,13] Median change in $eGFR_{CG}$ from baseline to Week 48 was -6.0 mL/min and remained stable through Week 96.[8,14] Changes in metabolic parameters (Table 15) were deemed by study authors to be clinically irrelevant.[8]

Table 15. Study 4449: Changes in Fasting Lipids at Week 96 (n=56)[8]

Lipid Parameter	Baseline	Median Change from Baseline	*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

Real-World Data: Use in Adults Aged ≥50 Years

Belgian Real-World Study

Study design and demographics[9]

An observational, multicenter, retrospective cohort study evaluated the effectiveness, durability, and tolerability of BIC/FTC/TAF in adult PWH (N=2001). The primary outcome was the proportion of patients with HIV-1 RNA <50 c/mL at Weeks 24 and 48 of BIC/FTC/TAF treatment (on-treatment analysis); secondary endpoints at Week 48 included the following: rate of protocol-defined loss of virologic suppression (ie, 2 consecutive HIV-1 RNA of >200 c/mL after prior virologic suppression) and assessment of RAMs at time of virologic suppression loss; proportion of patients with viral blips (HIV-1 RNA of 50–200 c/mL) after prior virologic suppression; safety and tolerability; change in weight and the rates of 5% to 10% or >10% increase in weight; and change in CD4 cell count and CD4/CD8 ratio.

Most patients were male (65%), 41% were aged ≥50 years, and 80% were treatment-experienced, with a median (IQR) time on ART of 6 (0.9–12.3) years. Previous regimens included E/C/F/TAF (19.9%), DTG + FTC/TAF (12%), EFV/FTC/TAF (4.6%), DRV/COBI/FTC/TAF (4%), and DTG + FTC/TDF (2.9%). At baseline (time of BIC/FTC/TAF start), 68.1% had an HIV-1 RNA <50 c/mL, and the median (IQR) CD4 cell count was 567 (367–793) cells/mcL.

Results

The overall virologic suppression rates at Weeks 24 and 48 were 92% (n=1611) and 93.5% (n=1361), respectively, which were similar to the rates observed among patients aged ≥50 years at the same time points (92.6% [n=672] and 92.7% [n=576], respectively). At Week 48, 14 patients (0.7%) in the overall population experienced loss of virologic suppression. Among patients aged >50 years, 5 experienced loss of virologic suppression, and there were no reports of RAMs in this group. Four of these 5 patients were treatment-experienced, 2 were not VS at baseline, 2 experienced a viral blip, and 1 had RAMs at baseline.[9,15] The overall median (IQR) change from baseline at Week 48 in CD4 cell count and CD4/CD8 ratio was 50 (-50 to 172) cells/mcL and 0.1 (0–0.2), respectively; no analysis according to age was performed.[9]

In patients aged >50 years, the median (IQR) increase in weight from baseline at Week 48 was 1 (-1 to +4) kg, and 18% and 8.8% of patients gained 5% to 10% and >10% in weight from baseline, respectively; age >50 years was not associated with weight gain of >10% (*P*=0.16). There were 131 (6.5%) treatment discontinuations, with AEs (2.4%; most common of these AEs involved CNS/psychiatric toxicity and gastrointestinal toxicity, 0.4% each) and switch to a two-drug regimen (1.3%) being the most common reasons for discontinuation. No safety analyses were performed according to the age of the patient.[9]

RETROBIC Study[10]

Study design and demographics

A real-world, retrospective, multicenter study in Spain evaluated immunologic outcomes, effectiveness, and safety in VS PWH (N=1966) who switched to BIC/FTC/TAF. The primary endpoint was CD4 and CD8 cell counts and CD4/CD8 ratio at Weeks 48 and 96. Secondary endpoints included the proportion of patients with HIV-1 RNA <50 c/mL and <200 c/mL at Weeks 48 and 96 (on-treatment [discontinuation/M=E] and ITT populations [discontinuation/M=F]) and safety. The proportion of patients ≥60 years of age was 16.8% (n=330); age (≥60 years) was associated with a higher number of comorbidities (*P*<0.001). Of patients aged ≥60 years, 79.4% had comorbidities (33.3% and 18.2% had 1 and 2 comorbidities, respectively). Most patients (82.4%) had previously received a tenofovir-based ARV regimen; among those aged ≥60 years, 62.1% and 14.5% had previously received FTC/TAF and FTC/TDF, respectively.

Table 16. RETROBIC Study: Baseline Demographics and Disease Characteristics[10]

Key Demographics and Characteristics	Overall (N=1966)	≥60 Years (n=330)	<60 Years (n=1610)
Age, median (IQR), years	51 (42–57)	64 (61–69)	48.6 (40–54)[a]
Male, n (%)	1568 (79.7)	255 (77.3)	1292 (80.2)
Time since HIV diagnosis, median (IQR), years	18 (10–27)	26 (18–31)	16 (9–26)[a]
Previous AIDS diagnosis, n (%)	436 (22.2)	101 (30.6)	330 (20.5)[a]
CD4, median (IQR), cells/mm^3	694.2 (486–910.5)	623 (463.2–826.1)[a]	707.5 (493–940)[a]
CD4, median (IQR), %	35 (28.8–39.5)	35.3 (29–39.6)	35 (28.9–39.5)
CD8, median (IQR), cells/mm^3	854 (615.5–1083.6)	833 (582–983)[a]	856 (633–1105.5)[a]
CD4/CD8 ratio, median (IQR)	0.7 (0.5–0.8)	0.7 (0.5–0.8)	0.6 (0.5–0.8)

[a]*P*<0.05 for comparison between the age ≥60 years and <60 years groups.

Results

Among patients aged ≥60 years, CD4 cell counts increased significantly from baseline at Week 96, and CD8 cell counts decreased significantly from baseline to Week 48 (Table 17).

Table 17. RETROBIC Study: Changes From Baseline in Immune Cell Results[10]

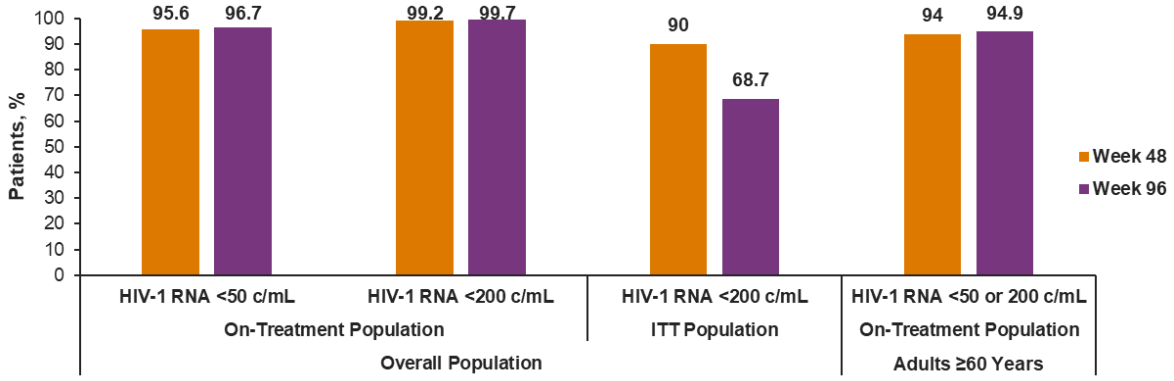
Δ vs BL, Median (IQR)	Overall (N=1966)		≥60 Years (n=330)		<60 Years (n=1610)	
	Week 48	Week 96	Week 48	Week 96	Week 48	Week 96
CD4, cells/mm^3	38.6 (-100.8 to 163)	38.5 (-134.8 to 220)	18 (-88 to 141)	40 (-122 to 232.5)[a]	42 (-105 to 171.1)	38 (-136.5 to 217)
CD4, %	0.9 (-2.4 to 4.2)	0.3 (-3.4 to 3.6)	0.5 (-3.3, 3.8)	0.1 (-4.3 to 3)	1 (-2 to 4.4)	0.3 (-3.2 to 3.8)
CD8, cells/mm^3	-25.5 (-241 to 143.5)	-22 (-238 to 183)	-60 (-286.5 to 121)[a]	-3 (-179 to 180)	-24 (-235 to 145)[a]	-28.5 (-242.2 to 183.2)

Δ vs BL, Median (IQR)	Overall (N=1966)		≥60 Years (n=330)		<60 Years (n=1610)	
	Week 48	Week 96	Week 48	Week 96	Week 48	Week 96
CD4/CD8 ratio	0 (0–0.1)	0 (-0.1 to 0.2)	0 (-0.1 to 0)[a]	-0.1 (-0.2 to -0.1)	0 (0–0.1)[a]	0.1 (0–0.2)

Abbreviations: Δ=change; BL=baseline.
[a]*P*<0.01 for comparison with BL value.

On-treatment analysis of effectiveness in patients aged ≥60 years revealed that 94% at Week 48 and 94.9% at Week 96 had HIV-1 RNA <50 c/mL or <200 c/mL (Figure 8). No significant differences in virological suppression rates according to age were found at either time point.

Figure 8. RETROBIC Study: Effectiveness in Overall Study Population (On-Treatment and ITT) and Adults ≥60 Years (On Treatment) at Weeks 48 and 96[10]



In the overall population, 50 patients (2.5%) experienced major AEs. AEs included CNS toxicity (n=15), gastrointestinal disturbances (n=9), and renal issues (n=6). Treatment was discontinued in 200 patients (10.2%); reasons included simplification to a two-drug regimen (3.8%), AEs (2.3%), loss to follow-up (2.1%), drug-drug interactions (1%), and virological failures (0.91%).

No significant changes in Cr or eGFR from baseline to Weeks 48 and 96 were observed in the overall population or either age subgroup. Among patients ≥60 years of age, TC levels decreased significantly from baseline to Week 48 (*P*<0.01), and LDL levels decreased significantly from baseline to Week 48. A significantly greater median (IQR) weight gain from baseline was also observed in the ≥60 years subgroup at Week 48 (1.5 [-1.3 to 3.6] kg) and Week 96 (3.1 [-0.5 to 6.7] kg) than in the <60 years subgroup (1.6 [-0.9 to 4.4] kg and 2.8 [-0.7 to 6.9] kg; *P*<0.01 for between-group comparisons at each time point).

BICSTaR Study: 24 Month Pooled Analysis[11]

An ongoing, prospective, multinational, observational cohort study evaluated 401 PWH aged ≥50 years with a high comorbidity burden at baseline who switched from another ART to BIC/FTC/TAF. Through 24 months of treatment, virologic effectiveness was maintained (96% had HIV-1 RNA <50 c/mL [M=E analysis]) and there were high rates of treatment persistence, with 90% of patients continuing to receive BIC/FTC/TAF. Cardiometabolic,

hepatic, and renal parameters remained stable, and BIC/FTC/TAF was generally well tolerated.

Retrospective Cohort Study in Adults Aged ≥50 Years[12]

Study design and demographics

A retrospective cohort study assessed the efficacy, safety, and tolerability of switching to BIC/FTC/TAF for 48 weeks in VS PWH aged ≥50 years. Key inclusion criteria included patients with HIV-1 RNA <50 c/mL within the year prior to switching to BIC/FTC/TAF and no history of primary INSTI treatment failure or INSTI resistance. For eligible patients, data were extracted from medical charts through Week 48 of treatment. The primary endpoint was the proportion of patients with plasma HIV-1 RNA <50 c/mL at Week 48. Secondary endpoints included subgroup analyses of virologic outcomes according to baseline regimen prior to switch at Week 48, change in CD4 cell count, and change in lipid levels from baseline through Week 48. Safety and tolerability assessments were conducted through Week 48.

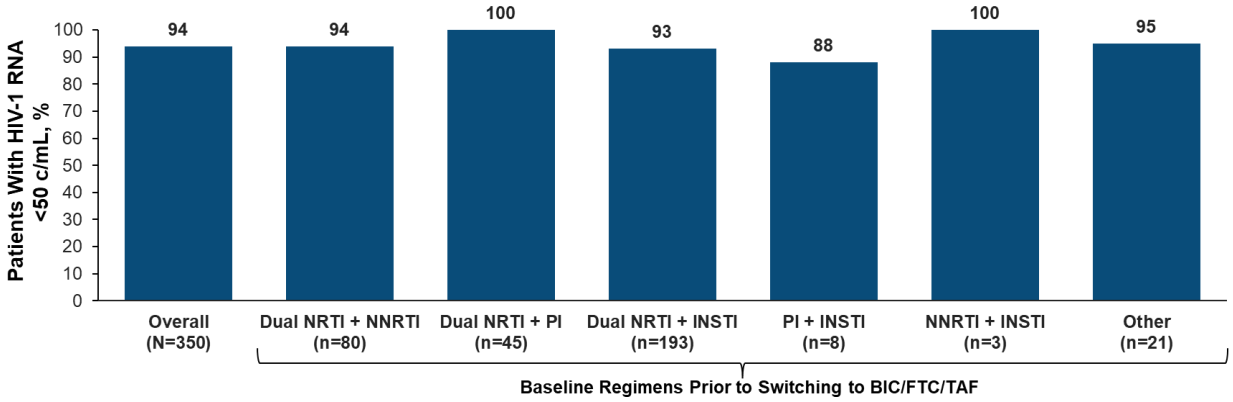
Table 18. Key Baseline Demographics and Disease Characteristics (Rolle et al)[12]

Key Demographics and Characteristics		BIC/FTC/TAF (N=350)
Age, median (range), years		57 (50–81)
Male, n (%)		281 (80)
Race/ethnicity, White/Black/Hispanic, n (%)		199 (57)/56 (16)/80 (23)
CD4 count, median (range), cells/mm^3		664 (58–2327)
Duration of HIV-1 infection, median (range), years		20 (1–40)
Duration of virologic suppression prior to switch, median (range), years		11 (0–27)
Number of ARV regimens prior to switch, median (range), n		4 (1–11)
Baseline regimen prior to switch, n (%)	Dual NRTI + INSTI	193 (55)
	Dual NRTI + NNRTI	80 (23)
	Dual NRTI + PI	45 (13)
	PI + INSTI	8 (2)
	NNRTI + INSTI	3 (1)
	Other	21 (6)

Efficacy results at Week 48

Virologic suppression (HIV-1 RNA <50 c/mL) was maintained in 94% of patients (330/350) at Week 48. In the subgroup analyses according to baseline regimen prior to switch, virologic suppression rates ranged from 88% to 100% (Figure 9). Virologic suppression was achieved by 88% of patients (23/26) with M184V/I mutations and by 91% of patients (70/77) without M184V/I mutations; similar virologic suppression rates were observed in patients with ≥1 NRTI RAMs (89%) vs those with no NRTI RAMs (91%). At Week 48, the median (95% CI) change in CD4 count from baseline was +7 (-9 to 29) cells/mm^3 (P=0.304).

Figure 9. Efficacy Outcomes at Week 48 (Rolle et al)[12]



Safety results through Week 48

A summary of the safety and tolerability data is presented in Table 19. Drug-related AEs were reported in 15% of patients, and the most common were fatigue (4%), weight gain (3%), and arthralgia (3%). The drug-related AEs that led to discontinuation of BIC/FTC/TAF included diarrhea (n=2), dizziness (n=2), arthralgia (n=2), Cr elevation (n=1), and abdominal pain (n=1). Grade 3 to 4 laboratory abnormalities were reported in 7% of patients and included hypertriglyceridemia (n=14), hyperglycemia (n=9), hypercholesterolemia (n=1), and transaminitis (n=1).

Table 19. Summary of Safety Results Through Week 48 (Rolle et al)[12]

Safety Parameters, n (%)	BIC/FTC/TAF (N=350)
Any drug-related AE	51 (15)
Any Grade 2–5 drug-related AE	16 (5)
Drug-related AE that led to discontinuation of BIC/FTC/TAF	8 (2)
Any Grade 3 or 4 laboratory abnormality	25 (7)
SAEs	0
Deaths	0

Significant improvements in lipid parameters were observed through Week 48 (Table 20). Fifty-one percent of patients (179/350) were on lipid-lowering therapy at baseline, 12% (42/350) initiated lipid-lowering therapy during the study, and 3% (11/350) discontinued lipid-lowering therapy during the study.

Table 20. Lipid Safety Results Through Week 48 (Rolle 48)[12]

Lipid Parameters, Median, mg/dL	Baseline	Week 48	*P*-Value
TC	183.5	175.5	<0.001
LDL	106	96	<0.001
HDL	46	45	0.017
TG	139	123	<0.001

A median (range) weight increase from baseline of 1.2% (-12.6% to 35.8%) was observed at Week 48 (absolute median increase, 2.3 lb). Weight gain of ≥5% was reported in 19% of patients, and weight gain of ≥10% was reported in 5% of patients. Weight loss of ≥5% was reported in 7% of patients, and weight loss of ≥10% was reported in 2% of patients.

References

1. Enclosed, Gilead Sciences Inc. BIKTARVY® (bictegravir, emtricitabine, and tenofovir alafenamide) tablets, for oral use. US Prescribing Information. Foster City, CA.
2. Mills A, Gupta SK, Brinson C, et al. 144-Week Efficacy and Safety of B/F/TAF in Treatment-Naive Adults Age ≥50 Years [Presentation]. Paper presented at: Conference on Retroviruses and Opportunistic Infections (CROI); 08-11 March, 2020; Boston, MA.
3. Kityo CM, Gupta SK, Kumar PN, et al. Efficacy and Safety of B/F/TAF in Treatment-Naïve People With HIV Aged ≥ 50 Years: 5-Year Follow-Up From Two Phase 3 Studies [Poster P-547]. Paper presented at: IDWeek; October 16-19, 2024; Los Angeles, CA.
4. Kityo CM, Gupta SK, Kumar PN, et al. Efficacy and Safety of Bictegravir/Emtricitabine/Tenofovir Alafenamide in Virologically Suppressed People With HIV Aged ≥ 50 Years:48-Week Follow-Up From Four Phase 3 Studies [Poster 52]. Paper presented at: International Workshop on Aging & HIV; 24–25 October, 2024; Washington, DC.
5. Ombajo LA, Penner J, Nkuranga J, et al. A Randomized Trial Switching Adults ≥ 60 Years Old From First-Line ART to B/F/TAF: Week 48 Results [Poster 00643]. Paper presented at: Conference on Retroviruses and Opportunistic Infections (CROI); March 3-6, 2024; Denver, CO.
6. Ombajo LA, Penner J, Nkuranga J, et al. Switch of Virally Suppressed Adults ≥ 60 Years From First-Line ART to B/F/TAF: Week 96 Results [Poster 0660]. Paper presented at: Conference on Retroviruses and Opportunistic Infections (CROI); March 9-12, 2025; San Francisco, CA.
7. Ramgopal M, Maggiolo F, Ward D, et al. Pooled Analysis of 4 International Trials of Bictegravir/ Emtricitabine/ Tenofovir Alafenamide (B/F/TAF) in Adults Aged ≥ 65 Years Demonstrating Safety and Effocacy: Week 48 Results [Presentation]. Paper presented at: 23rd International AIDs conference (Virtual); July 06-10, 2020; Virtual.
8. Maggiolo F, Rizzardini G, Molina JM, et al. Bictegravir/emtricitabine/tenofovir alafenamide in older individuals with HIV: Results of a 96-week, phase 3b, open-label, switch trial in virologically suppressed people >/=65 years of age. *HIV Med.* 2022.
9. Nasreddine R, Florence E, Yombi JC, et al. Efficacy, durability, and tolerability of bictegravir/emtricitabine/tenofovir alafenamide for the treatment of HIV in a real-world setting in Belgium. *HIV Med.* 2023;24(8):914-924.
10. Troya J, Pousada G, Mican R, et al. Real-life data of immune recovery using bictegravir/emtricitabine/tenofovir alafenamide in virologically suppressed people living with HIV. Results at 48-96 weeks of RETROBIC Study. *J Antimicrob Chemother.* 2024;79(3):595-607.
11. Miralles C, van Welzen B, McConkey S, et al. Switching to B/F/TAF in a Real-World Cohort of Older People With HIV and a High Burden of Non–AIDS-Related Comorbidities [Poster TUPEB072]. Paper presented at: 25th International AIDS Conference; July 22-26, 2024; Munich, Germany.
12. Rolle CP, Nguyen V, Patel K, Cruz D, Hinestrosa F, DeJesus E. Efficacy, safety and tolerability of switching to bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF) in HIV-1 infected virologically-suppressed older adults in a real-world setting [Poster 897388]. Paper presented at: IDWeek Virtual; 21-25 October, 2020.
13. Maggiolo F, Rizzardini G, Molina JM, et al. Switching to bictegravir/emtricitabine/tenofovir alafenamide (B/F/TAF) in adults aged 65 years or older: Week 96 results from an international, phase 3b, open-label trial (GS-US-380-4449) [Presentation]. Paper presented at: 11th International AIDS Society (IAS) Conference on HIV Science Virtual; 18-21 July, 2021.
14. Maggiolo F, Rizzardini G, Molina JM, et al. Bictegravir/Emtricitabine/Tenofovir Alafenamide in Virologically Suppressed People with HIV Aged >/= 65 Years: Week 48 Results of a Phase 3b, Open-Label Trial. *Infect Dis Ther.* 2021;10(2):775-788.
15. Nasreddine R, Florence E, Yombi JC, et al. Efficacy, durability, and tolerability of bictegravir/emtricitabine/tenofovir alafenamide for the treatment of HIV in a real-world setting in Belgium [Supplement]. *HIV Med.* 2023;24(8):914-924.

Abbreviations

3TC=lamivudine
ABC=abacavir
AE=adverse event
ART=antiretroviral therapy
ARV=antiretroviral
ATV=atazanavir
β2m=β2 microglobulin
BIC=bictegravir
BMD=bone mineral density
c/mL=copies/mL
CAR=continue ART regimen
CD4/8=clusters of differentiation 4/8
CG=Cockcroft-Gault
CNS=central nervous system
COBI=cobicistat
DRV=darunavir
DTG=dolutegravir
E/C/F/TAF or TDF=elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide or tenofovir disoproxil fumarate
EFV=efavirenz
FTC=emtricitabine
INSTI=integrase strand transfer inhibitor
M=E=missing=excluded
M=F=missing=failure
NNRTI=non-nucleos(t)ide reverse transcriptase inhibitor
NRTI=nucleos(t)ide reverse transcriptase inhibitor
NVP=nevirapine
OLE=open-label extension
PI=protease inhibitor
PWH=people with HIV
Q=quartile
RAM=resistance-associated mutation
RBP=retinol-binding protein
RPV=rilpivirine
RTV=ritonavir
SAE=serious adverse event
TAF=tenofovir alafenamide
TC=total cholesterol
TDF=tenofovir disoproxil fumarate
TG=triglycerides
VS=virologically suppressed

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