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Biktarvy® (BIC/FTC/TAF) Comparison With CAB + RPV IM Q2M

This document is in response to your request for information regarding the efficacy and safety of Biktarvy® (bictegravir/emtricitabine/tenofovir alafenamide [BIC/FTC/TAF]) compared with cabotegravir and rilpivirine intramuscular injections once every 2 months (CAB + RPV IM Q2M) in people with HIV-1 (PWH).

This document summarizes information from studies that were not sponsored by Gilead Sciences, Inc. For additional information regarding each study, please refer to its respective sponsor.

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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

Clinical Data on BIC/FTC/TAF vs CAB + RPV IM Q2M

The SOLAR study was a phase 3b, randomized, open-label study that compared the efficacy and safety of CAB + RPV IM Q2M with BIC/FTC/TAF in VS PWH.[1]

- At Month 12, CAB + RPV IM Q2M showed noninferior efficacy compared with BIC/FTC/TAF, with <1% of participants (1/223) receiving BIC/FTC/TAF and 1% of participants (5/447) receiving CAB + RPV IM Q2M demonstrating HIV-1 RNA ≥50 c/mL in the mITT-E population.[1]
- No participants receiving BIC/FTC/TAF had CVF or treatment-emergent resistance. Three participants receiving CAB + RPV IM Q2M had CVF, 2 of whom had both INSTI and RPV (NNRTI) treatment-emergent resistance.[1]
- Through Months 11 to 12, 1% of participants (2/227) receiving BIC/FTC/TAF and 72% of participants (327/454) receiving CAB + RPV IM Q2M experienced any TRAEs.[1]
- In a subanalysis, OLI CAB + RPV IM Q2M demonstrated comparable efficacy to BIC/FTC/TAF at Month 12. The most frequently reported TRAEs with OLI CAB + RPV IM Q2M were diarrhea (2%) and headache (1%); weight gain and abnormal hepatic function (n=1 each) were the most common TRAEs in participants treated with BIC/FTC/TAF. Overall, 8 (5%) participants discontinued OLI CAB + RPV IM Q2M due to TRAEs, whereas no participants discontinued due to TRAEs in the BIC/FTC/TAF arm.[2]

Real-World Data on BIC/FTC/TAF vs CAB + RPV IM Q2M

In a study in VS PWH treated with BIC/FTC/TAF (n=2699) or CAB + RPV IM Q2M (n=4090) using data from the US OPERA cohort, more participants treated with CAB + RPV IM Q2M (76%) maintained virologic suppression compared with participants treated with BIC/FTC/TAF (68%). Odds of CVF were similar between treatment groups

(BIC/FTC/TAF, 1% and CAB + RPV IM Q2M, 2%; aOR, 0.72; 95% CI: 0.46–1.11). Safety data were not reported.[3]

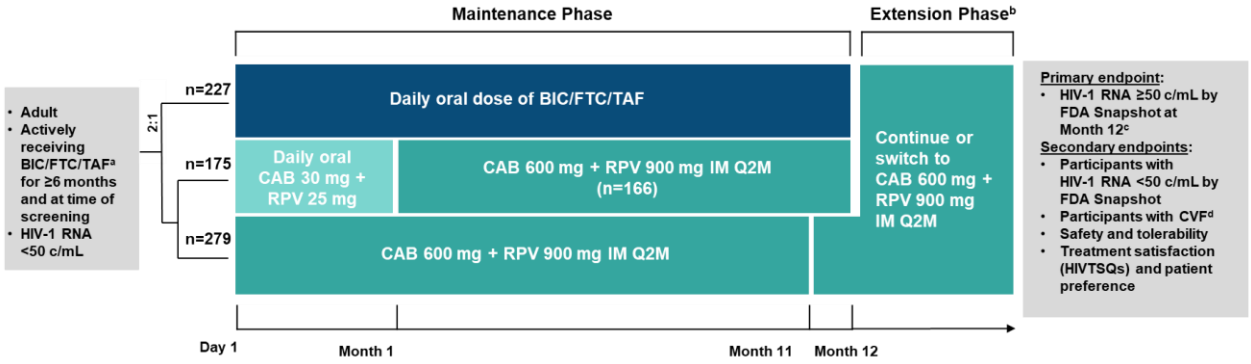
Clinical Data on BIC/FTC/TAF vs CAB + RPV IM Q2M

Switch Onto Long-Acting Regimen (SOLAR) Study

Study design and demographics[1]

A ViiV-sponsored, phase 3b, randomized, open-label, multicenter, active-control, non-inferiority study evaluated the safety and efficacy of CAB + RPV compared with BIC/FTC/TAF in PWH who were VS. Participants with an undetectable HIV-1 RNA (<50 c/mL) who had been on BIC/FTC/TAF as a first or second regimen for ≥6 months were randomly assigned in a 2:1 ratio to continue daily oral BIC/FTC/TAF or switch to CAB + RPV for 12 months. Participants who were assigned to receive CAB + RPV were able to choose to either start with a 1-month OLI or with SWI. Key exclusion criteria included any history of non-INSTI regimen and known or suspected presence of RAMs to any component BIC/FTC/TAF or CAB + RPV.

Figure 1. SOLAR: Study Design[1]



[a]One prior INSTI-containing regimen was allowed if BIC/FTC/TAF was a second-line regimen >6 months prior to screening. Change in regimen must have been for safety/tolerability or reasons unrelated to treatment failure.
[b]Extension phase continued until CAB + RPV IM Q2M were either commercially available or locally approved, the participant no longer showed clinical benefit, or for other protocol-defined reasons.
[c]Based on the mITT-E population, which excluded 11 participants due to study site non-compliance with protocol entry criteria.
[d]Defined as two consecutive assays of HIV-1 RNA ≥200 c/mL.

Table 1. SOLAR: Select Baseline Demographics and Disease Characteristics (mITT-E Population)[1]

Key Demographics and Characteristics	BIC/FTC/TAF (n=223)	CAB + RPV IM Q2M (n=447)
Age, median (range), years	37 (18–66)	37 (18–74)
≥50 years, n (%)	42 (19)	86 (19)
Female sex at birth,[a] n (%)	41 (18)	77 (17)

Key Demographics and Characteristics		BIC/FTC/TAF (n=223)	CAB + RPV IM Q2M (n=447)
Race, n (%)	White	156 (70)	307 (69)
	Black	49 (22)	95 (21)
	Asian	11 (5)	23 (5)
	Other	7 (3)	22 (5)
BMI, median (IQR), kg/m^2		25.4 (23.4–29.6)	26 (23.3–29.4)
Duration on previous ART, median, years		2.47	2.58
CD4 count, median (IQR), cells/mcL		640 (459–846)	649 (477–850)
CD4 count category, n (%)	<350 cells/mcL	28 (13)	54 (12)
	350 to <500 cells/mcL	35 (16)	74 (17)
	≥500 cells/mcL	159 (71)	319 (71)

[a]Twelve transgender female participants, 1 transgender male participant, and 1 gender non-conforming participant were included.

Efficacy results

A total of 681 participants underwent randomization, and 670 participants were included in the mITT-E analyses. At Months 11 to 12, rates of virologic suppression demonstrated noninferior efficacy of CAB + RPV IM Q2M compared with BIC/FTC/TAF. From baseline to Months 11 to 12, the median change in CD4 count was +20 and +39 cells/mcL in the BIC/FTC/TAF and CAB + RPV IM Q2M groups, respectively.[1]

Table 2. SOLAR: Efficacy Outcomes at Months 11 to 12 (mITT-E Population)[1]

Efficacy Outcome, n (%)	BIC/FTC/TAF (n=223)	CAB + RPV IM Q2M (n=447)
HIV-1 RNA <50 c/mL	207 (93)	403 (90)
HIV-1 RNA ≥50 c/mL	1 (<1)	5 (1)
No data on virologic status	15 (7)	39 (9)

From baseline through Month 12, viral blips were reported in 4% of participants in both the BIC/FTC/TAF group (n/N=9/223) and the CAB + RPV IM Q2M group (n/N=19/447); of the participants with viral blips, 11% (1/9) and 5% (1/19), respectively, had HIV-1 RNA ≥50 c/mL at Month 12. Neither of the 2 participants in the mITT-E population who received CAB + RPV IM Q2M and developed CVF had viral blips through Month 12.[4]

Resistance analysis through 12 months[1,5]

No participant who received BIC/FTC/TAF met the CVF criterion for resistance analysis. Two participants who received CAB + RPV IM Q2M in the mITT-E population had on-treatment RAMs. One participant who developed on-treatment RPV (NNRTI) and INSTI RAMs at CVF later resuppressed during long-term follow-up on DRV/c, FTC, and TAF (Participant 1, Table 3). The second participant who developed RPV and INSTI RAMs at CVF also achieved viral resuppression on BIC/FTC/TAF followed by DRV/c, FTC, and TAF (Participant 2, Table 3).

A third participant from the ITT-E population who received CAB + RPV IM Q2M also met the CVF criterion and had RPV RAMs in the genotype at failure (Participant 3, Table 3), but it is unknown if these were present at baseline since the retrospective assessment of peripheral blood mononuclear cells was not successful. This participant later achieved viral resuppression on BIC/FTC/TAF.

The 3 participants who received CAB + RPV IM Q2M with CVF did not have late injections outside of the dosing window (+7 days). The participants' plasma drug concentrations were

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above the respective protein-adjusted 90% inhibitory concentration (CAB, 0.166 mcg/mL; RPV, 12 ng/mL) and phase 3 benchmarks (CAB, 0.65 mcg/mL; RPV, 17.3 ng/mL) at SVF timepoints.

Table 3. SOLAR: Participants With CVF Who Received CAB + RPV IM Q2M[1,5]

Participant (Population)	SVF Timepoint, Months	HIV-1 RNA at SVF/CVF, c/mL	RAMs at Baseline	RAMs at CVF	Phenotypic Sensitivity to RPV/CAB at SVF, FC
1 (mITT-E)	6	1327/ 1409	None	RPV: M230L INSTI: Q148R	3.2/3.1
2 (mITT-E)	11	6348/ 419	INSTI: G140G/R	RPV: K101E INSTI: G118R	1.9/8.4
3 (ITT-E)	3	3797/ 928	Assay failed	RPV: E138E/K + Y181Y/C	4.2/analysis failed

Abbreviation: FC=fold change.

Safety results[1,5]

Through Month 12, 1% of participants (2/227) who received BIC/FTC/TAF experienced any TRAE, compared with 72% (327/454) in the CAB + RPV IM Q2M group. AEs, excluding ISRs, are summarized in Table 4. A summary of ISRs reported by participants who received CAB + RPV IM (SWI and OLI groups) is shown in Table 5.

Table 4. SOLAR: AEs, Excluding ISRs, Through Month 12 (ITT Population)[1,5]

AEs, n (%)		BIC/FTC/TAF (n=227)	CAB + RPV IM Q2M (n=454)
Any AE		172 (76)	349 (77)
TRAEs		2 (<1)	90 (20)
AEs that led to withdrawal		2 (<1)	15 (3)
TRAEs that led to withdrawal		0	9 (2)[a]
Any Grade ≥3 AEs		26 (11)	42 (9)
Grade ≥3 TRAEs		0	7 (2)
Any SAEs		15 (7)	21 (5)
Treatment-related SAEs		0	3 (<1)[b]
Common AEs (≥10%)	COVID-19 infection	39 (17)	74 (16)
	Headache	12 (5)	49 (11)

[a]During the OLI period (each, n=1): limb discomfort/paresthesia/dysesthesia, dizziness, fatigue, deafness/ear congestion/fatigue, participant-reported blood pressure fluctuation, and diarrhea/joint stiffness; during the IM injection period (each, n=1): myocardial infarction, increase in ALT, and fatigue/pyrexia.
[b]Increase in ALT (n=2) and acute myocardial infarction (n=1).

Table 5. SOLAR: ISRs in CAB + RPV IM Q2M Groups (ITT-E Population)[5a]

Event		SWI CAB + RPV IM Q2M (n=279)	OLI CAB + RPV IM Q2M (n=175)
Injections, n		3742	2228
ISR events,[a] n		1181	734
ISR symptom	Pain, n (% of injections)	887 (24)	507 (23)
	Discomfort, n (% of injections)	65 (2)	56 (3)
	Nodule, n (% of injections)	56 (2)	28 (1)
	Grade 3,[b] n (% of ISR events)	10 (<1)	19 (3)
Duration of ISR, median (IQR), days		3 (2–5)	3 (2–5)

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Event	SWI CAB + RPV IM Q2M (n=279)	OLI CAB + RPV IM Q2M (n=175)
Participants who withdrew secondary to injection-related reasons,[c] n (% of participants with injections)	8 (3)	3 (2)

[a]One injection could be associated with multiple ISRs. Data on grading was missing for 1 ISR in the SWI group.
[b]No Grade 4 or 5 ISRs were reported.
[c]Included 1 participant who discontinued due to ISR AEs, 1 participant who withdrew from the study secondary to injection intolerability, and 1 participant who was excluded from the primary analysis of the mITT-E population for unknown reasons.

Weight change[6]

At Month 12, the median (IQR) weight change was +0.05 (-2.3 to +1.95) kg in the BIC/FTC/TAF group and -0.4 (-2.95 to +2.1) kg in the CAB + RPV IM Q2M group. By Month 12, a total of 4% of participants (9/213) in the BIC/FTC/TAF group and 3% of participants (11/408) in the CAB + RPV IM Q2M group experienced a weight increase of ≥10%. Changes in BMI with BIC/FTC/TAF and CAB + RPV IM Q2M remained numerically similar, and there were no clinically relevant changes in the proportion of participants with metabolic syndrome or insulin resistance from baseline through Month 12 in either treatment group.

Treatment satisfaction[7]

The mean adjusted baseline HIVTSQs score was 58.38 for the BIC/FTC/TAF group and 57.88 for the CAB + RPV IM Q2M group. From baseline to Month 6, there was a -0.4 (95% CI: -1.41 to +0.61) change in score for the BIC/FTC/TAF group and a +3.86 (95% CI: 3.14–4.57) change in score for the CAB + RPV IM Q2M group, with an adjusted difference of 4.26 (95% CI: 3.02–5.49; *P*<0.001). From Month 6 to Month 12, there was a -1.59 (95% CI: -2.71 to -0.47) change in score for the BIC/FTC/TAF group and a +3.36 (95% CI: 2.59–4.13) change in score for the CAB + RPV IM Q2M group, with an adjusted difference of 4.95 (95% CI: 3.59–6.31; *P*<0.001). Changes from baseline to Month 12 in HIVTSQs scores reflected greater patient satisfaction in the CAB + RPV IM Q2M group than in the BIC/FTC/TAF group.

Subanalysis in participants with OLI CAB + RPV IM Q2M[2]

A prespecified descriptive analysis evaluated 12-month efficacy, safety, and patient-reported outcomes in participants who received OLI CAB + RPV IM Q2M (CAB 30 mg + RPV 25 mg once daily), compared with participants who received BIC/FTC/TAF. Of the 402 participants included, 175 received OLI CAB + RPV IM Q2M, and 227 received BIC/FTC/TAF. Two participants in the OLI CAB + RPV IM Q2M arm and 4 in the BIC/FTC/TAF arm were excluded from the mITT-E analysis. The study was not powered for statistical comparisons between treatments; therefore, all endpoints were analyzed descriptively.

Efficacy

OLI CAB + RPV IM Q2M demonstrated comparable efficacy to BIC/FTC/TAF at Month 12 (Table 6). One participant receiving OLI CAB + RPV IM Q2M met the CVF criterion through Month 12, with an HIV-1 RNA of 1327 c/mL at Month 6 at SVF, followed by an HIV-1 RNA of 1409 c/mL at the subsequent confirmatory visit.

Table 6. SOLAR Subanalysis: Virologic Response at Month 12 (mITT-E Population)[2]

Efficacy Outcome, n (%)	BIC/FTC/TAF (n=223)	OLI CAB + RPV IM Q2M (n=173)
HIV-1 RNA <50 c/mL	207 (93)	151 (87)
HIV-1 RNA ≥50 c/mL	1 (<1)	2 (1)
No data on virologic status	15 (7)[a]	20 (12)[b]

[a]Participants in this group had no data available at Month 12 due to withdrawal (n=9), LTFU (n=2), or death, protocol deviation, or physician decision (n=1 each); 1 participant remained on study with missing data.
[b]Participants in this group had no data available at Month 12 due to discontinuing from AEs (n=10), withdrawal (n=4), LTFU (n=3), or protocol deviation and physician decision (n=1 each); 1 participant remained on study with missing data.

Safety

AEs in the BIC/FTC/TAF and OLI CAB + RPV IM Q2M groups are summarized below (Table 7). Weight gain and abnormal hepatic function (n=1 each) were the most common TRAEs in participants treated with BIC/FTC/TAF. Two participants withdrew BIC/FTC/TAF due to brain injury and encephalopathy (n=1) and tuberculosis (n=1) that were not deemed treatment related.

Table 7. SOLAR Subanalysis: AEs (Excluding ISRs) Through Month 12 (ITT Population)[2]

AEs	BIC/FTC/TAF (n=227)	OLI CAB + RPV IM Q2M (n=175)
Participants with ≥1 AE, n (%)	172 (76)	155 (89)
Maximum AE severity Grade 1–2, n/N (%)	146/172 (85)	125/155 (81)
SAEs, n (%)	15 (7)[a]	11 (6)[b]
Withdrawal due to TRAEs, n (%)	0	8 (5)

[a]No SAEs were considered treatment related.
[b]Three SAEs were considered treatment related.

Treatment satisfaction

In the OLI CAB + RPV IM Q2M arm, mean ± SD absolute HIVTSQs total scores increased from 58.2 (7.9) at baseline to 60.5 (10.4) at Month 6 and 61.6 (7.1) at Month 12. Absolute HIVTSQs total scores decreased in the BIC/FTC/TAF arm over the same period (mean [SD]: baseline: 58.4 [8.2]; Month 6: 57.8 [9.3]; Month 12: 56.7 [10]).

At Month 13, 142 participants (64%) originally assigned to BIC/FTC/TAF switched to CAB + RPV IM Q2M; 45 of those participants (32%) chose an OLI. Among these participants, the most common reasons for switching to CAB + RPV IM Q2M were interest in new HIV treatments (31%), less worry about forgetting daily medication (22%), and greater convenience (16%).

Real-World Data on BIC/FTC/TAF vs CAB + RPV IM Q2M

US OPERA Cohort

A real-world analysis of prospectively collected data from the US OPERA cohort evaluated the virologic effectiveness of switching to CAB + RPV IM Q2M or CAB + RPV IM Q2M in treatment-experienced PWH who were VS (HIV-1 RNA <50 c/mL). Overall, 2699 participants who received BIC/FTC/TAF and 4090 who received CAB + RPV IM Q2M were included in the analysis (Table 8).

Table 8. US OPERA Cohort: Select Baseline Demographics and Disease Characteristics[3]

Key Demographics and Characteristics		BIC/FTC/TAF (n=2699)	CAB + RPV IM Q2M (n=4090)
Age, median (IQR), years		47 (36, 58)	38 (32, 49)
50–64 years, n (%)		961 (36)	807 (20)
≥65 years, n (%)		244 (9)	140 (3)
Female sex, n (%)		448 (17)	569 (14)
Black race,[a] n (%)		1112 (41)	1739 (42)
Hispanic or Latinx ethnicity,[b] n (%)		725 (27)	1372 (34)
Prior ART therapy, n (%)	INSTI	1847 (68)	3433 (84)
	NNRTI	382 (14)	242 (6)
	PI	310 (12)	153 (4)
	≥2 core agents	159 (6)	261 (6)
	Other	≤5	≤5
Duration on previous ART, median (IQR), months		41 (12, 70)	20 (9, 44)
CD4 count,[c] median (IQR), cells/mcL		694 (506, 914)	714 (532, 918)

Abbreviation: PI=protease inhibitor.
[a]Race data were missing for 322 participants.
[b]Ethnicity data were missing for 298 participants.
[c]CD4 cell counts were missing for 33 participants.

Effectiveness

Prior to first censoring (defined as treatment discontinuation, study end, LTFU, or death), the median (IQR) time on BIC/FTC/TAF was 22 months (14, 31), and the median (IQR) time on CAB + RPV IM Q2M was 15 months (8, 25). Among those with ≥1 follow-up HIV-1 RNA level available, more participants treated with CAB + RPV IM Q2M maintained virologic suppression compared with participants treated with BIC/FTC/TAF (Table 9).

Table 9. US OPERA Cohort: Maintenance of Virologic Suppression[3]

Efficacy Outcome, n (%)	BIC/FTC/TAF (n=2699)	CAB + RPV IM Q2M (n=4090)
All HIV-1 RNA <50 c/mL	1823 (68)	3112 (76)
Last HIV-1 RNA <50 c/mL	2239 (83)	3655 (89)

Among those with ≥1 follow-up HIV-1 RNA level available, the risk of CVF was lower with CAB + RPV IM Q2M than with BIC/FTC/TAF; however, after adjusting for baseline characteristics, the difference was not statistically significant (Table 10). Among participants with post-CVF HIV-1 RNA data available, 20/29 (69%) in the BIC/FTC/TAF group and

15/22 (68%) in the CAB + RPV LA Q2M group were resuppressed before study end, with a median (IQR) time to resuppression of 4 (3, 7) months and 2 (1, 3) months, respectively.

Table 10. US OPERA Cohort: CVF and Time to CVF[3]

CVF	BIC/FTC/TAF (n=2699)	CAB + RPV IM Q2M (n=4090)	aOR (95% CI)
CVF, n (%)	46 (2)	46 (1)	0.72 (0.46, 1.11)
Time to CVF, median (IQR), months	14 (9, 19)	8 (6, 15)	Reference

Abbreviation: aOR=adjusted odds ratio.

At study end, 2175 participants (81%) in the BIC/FTC/TAF group and 2997 participants (73%) in the CAB + RPV IM Q2M group remained on study treatment. Among participants who experienced CVF, fewer participants treated with BIC/FTC/TAF switched to a new regimen (n=13; 28%) compared with participants who received CAB + RPV IM Q2M (n=35; 76%).

Safety data were not reported.

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Abbreviations

AE=adverse event
aOR=adjusted odds ratio
ART=antiretroviral treatment
BIC=bictegravir
c/mL=copies/mL
CAB=cabotegravir
CD4=cluster of differentiation 4
CVF=confirmed virologic failure
DRV/c=darunavir/cobicistat
FTC=emtricitabine
HIVTSQs=HIV Treatment Satisfaction Questionnaire status version
IM=intramuscular
INSTI=integrase strand transfer inhibitors
ISR=injection site reaction
ITT-E=intent-to-treat exposed
LTFU=loss to follow-up
mITT-E=modified intent-to-treat exposed
NNRTI=non-nucleos(t)ide reverse transcriptase inhibitor
OLI=oral lead-in
PWH=people with HIV-1
Q2M=once every 2 months
RAM=resistance-associated mutation
RPV=rilpivirine
SAE=serious adverse event
SOLAR=Switch Onto Long-Acting Regimen
SVF=suspected virologic failure
SWI=start with injections
TAF=tenofovir alafenamide
TRAE=treatment-related adverse events
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.

Follow-Up

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