SOLAR: Long-Acting Cabotegravir and Rilpivirine Administered Every 2 Months versus Daily Oral Bictegravir/Emtricitabine/Tenofovir Alafenamide

Summary

- SOLAR (**S**witch **O**nto **L**ong-**A**cting **R**egimen) is a Phase 3b, randomized, open-label, active-controlled, multicenter, parallel-group, non-inferiority study to assess the antiviral activity and safety of long-acting cabotegravir + rilpivirine (CAB + RPV LA) administered every 2 months (Q2M) compared with daily oral bictegravir/emtricitabine/tenofovir alafenamide (BIC/FTC/TAF).[1]
    - At Month 12, CAB + RPV LA Q2M was non-inferior to daily oral BIC/FTC/TAF (HIV-1 RNA ≥ 50 copies/mL 1% vs. < 1%, respectively, adjusted treatment difference, 0.7%) (mITT-E population). Non-inferiority was also met in the ITT-E and Per Protocol populations.
    - Confirmed virologic failures (mITT-E) occurred in 2 participants treated with CAB + RPV LA compared to zero participants on BIC/FTC/TAF. One additional CVF occurred in the ITT-E population.
- Participants in the CAB + RPV LA arm had a higher rate of drug-related adverse events (AEs) compared to continuation of oral BIC/FTC/TAF (20% vs. < 1%, respectively).[1]
- Injection site reactions (ISRs) were comparable to prior clinical experience in occurrence and severity.[1]
    - 98% of ISRs were Grades 1 or 2.
    - Discontinuations due to ISRs occurred in 2% of participants.

SOLAR: STUDY DESIGN

SOLAR (Study 213500) is a Phase 3b, randomized, open-label, active-controlled, multicenter, parallel-group, non-inferiority study designed to assess the antiviral activity and safety of CAB + RPV LA administered Q2M compared with oral BIC/FTC/TAF.[1] Adult HIV-1 infected participants must have been on an uninterrupted stable regimen of BIC/FTC/TAF with an undetectable HIV-1 viral load for ≥ 6 months prior to and at screening.

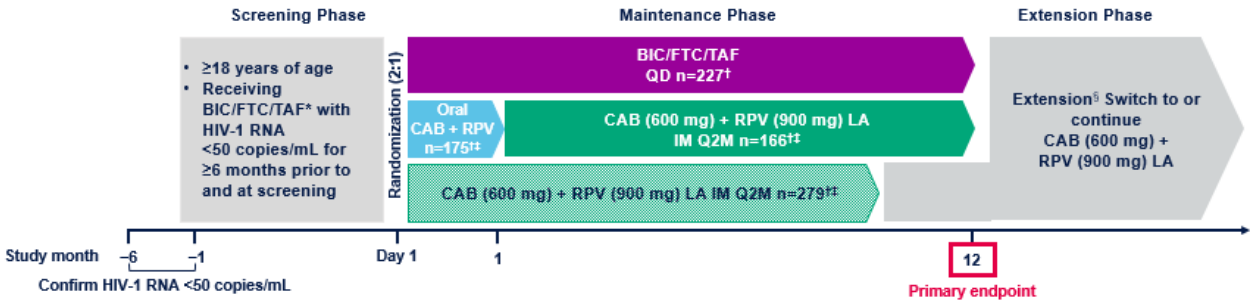
Participants were randomized 2:1 to either switch to CAB + RPV LA or continue BIC/FTC/TAF through 12 months.[1] An optional oral lead-in (OLI) was allowed for participants randomized to the LA arm; the decision to use the OLI was determined by the study participant following informed consent discussions with the investigator. See Figure 1.

The primary endpoint was the proportion of participants with HIV-1 RNA ≥ 50 copies/mL per FDA Snapshot algorithm at Month 12 (OLI and BIC/FTC/TAF)/Month 11 (direct-to-injection, DTI) (ITT-E population).[1] The mITT-E population (all ITT-E participants, excluding all participants [n = 11] from a single site due to critical protocol violations and GCP non-compliance) served as the pre-specified primary population for the efficacy analysis.

The study continued with an Extension Phase after Month 12.[1] In the Extension Phase, eligible participants (HIV-1 RNA < 50 copies/mL at Month 12) were given an option to continue CAB + RPV LA Q2M

(participants randomized to CAB + RPV LA in the Maintenance Phase) or start CAB + RPV LA Q2M (participants randomized to oral BIC/FTC/TAF therapy in the Maintenance Phase).

Figure 1. SOLAR Study Design[2]



*A single prior INI regimen is allowed if BIC/FTC/TAF is a second-line regimen 6 months prior to screening. Any prior change in regimen, defined as a change of a single drug or multiple drugs simultaneously, must have occurred due to tolerability/safety, access to medications, or convenience/simplification, and must not have been done for treatment failure (HIV-1 RNA ≥ 400 copies/mL).

†n values are based on the safety population.

‡Participants randomized to the LA arm were offered an optional OLI; the decision was determined by the participants following informed consent discussions with the investigator.

§The extension phase continued study treatment until CAB LA and RPV LA are either locally approved and commercially available, the participant no longer derives clinical benefit, the participant meets a protocol-defined reason for discontinuation, or until development of either CAB LA or RPV LA is terminated. Visits continued to occur Q2M.

BIC/FTC/TAF = bictegravir/emtricitabine/tenofovir alafenamide; CAB + RPV LA = long-acting cabotegravir plus rilpivirine; IM = intramuscular; INI = integrase inhibitor; OD = once daily; OLI = oral lead-in; Q2M = every 2 months.

RESULTS

At Baseline (mITT-E population), 447 participants were randomized to switch to CAB + RPV LA (OLI, n = 173; DTI, n = 274) and 223 participants were randomized to continue daily oral BIC/FTC/TAF.[1]

Baseline Demographic Characteristics

Demographic characteristics were similar between treatment groups.[1] Among study participants, 12 transgender females, 1 transgender male, and 1 gender non-conforming individual were included. See Table 1.

Table 1. Select Baseline Characteristics from SOLAR (mITT-E population)[1]

Characteristic	CAB + RPV LA Q2M (N = 447)	BIC/FTC/TAF (N = 223)
Median age, years (range)	37 (18-74)	37 (18-66)
≥ 50	86 (19)	42 (19)
Female (sex at birth), n (%)	77 (17)	41 (18)
Race, n (%)		
Black	95 (21)	49 (22)
White	307 (69)	156 (70)
Asian	23 (5)	11 (5)
Other[a]	22 (5)	7 (3)
BMI (kg/m^2), median (IQR)	26.0 (23.2–29.4)	25.4 (23.4–29.6)

[a]Other race participants: American Indian or Alaska Native, n = 14 (CAB + RPV LA Q2M) and n = 2 (BIC/FTC/TAF); Native Hawaiian or other Pacific Islander, n = 1 (BIC/FTC/TAF); multiple, n = 8 (CAB + RPV LA Q2M) and n = 4 (BIC/FTC/TAF).

BIC/FTC/TAF = bictegravir/emtricitabine/tenofovir alafenamide; BMI = body mass index; CAB + RPV LA = long-acting cabotegravir + rilpivirine; IQR = interquartile range

Overall, 47% of participants on BIC/FTC/TAF at baseline (n = 315/670) reported experiencing at least one of the following psychosocial challenges either "always" or "often": "worried about people unintentionally discovering their HIV status", "worried about forgetting to take their HIV medication", or "felt that taking their HIV medication was an uncomfortable reminder of their HIV status."[1]

Efficacy

At Month 12, non-inferior efficacy of CAB + RPV LA vs BIC/FTC/TAF was demonstrated for the proportion with HIV-1 RNA ≥ 50 copies/mL.[1] The upper bound of 95% confidence interval (CI) for the adjusted treatment difference between CAB + RPV LA Q2M and BIC/FTC/TAF was less than the pre-defined non-inferiority margin of 4%. Among participants with no virologic data, the incidence of AEs leading to withdrawal was low, and discontinuations for other reasons were similar between the CAB + RPV LA and BIC/FTC/TAF groups. See Table 2.

Table 2. Summary of Study Outcomes at Month 12/11 (Maintenance Phase) - FDA Snapshot Analysis (mITT-E Population)[1]

Outcomes	CAB + RPV LA Q2M (N = 447) n (%)	BIC/FTC/TAF (N = 223) n (%)
HIV-1 RNA ≥ 50 copies/mL	**5 (1)**	**1 (< 1)**
Adjusted Treatment Difference [% (95% CI)]	0.7 (-0.7, 2.0)	
Data in window not below 50 copies/mL	3 (< 1)	1 (< 1)
Discontinued for lack of efficacy	1 (< 1)	0
Discontinued for other reason while not below 50 copies/mL	1 (< 1)	0
HIV-1 RNA < 50 copies/mL	**403 (90)**	**207 (93)**
Adjusted Treatment Difference [% (95% CI)]	-2.7 (-7.0, 1.7)	
No virologic data	39 (9)	15 (7)
Discontinued study due to AE or death	13 (3)[a]	1 (< 1)[b]
Discontinued study for other reasons	24 (5)[c]	13 (6)[d]
On study but missing data in window	2 (< 1)	1 (< 1)

[a] Injection site pain, n = 2; acute myocardial infarction, n = 1; dysesthesia/limb discomfort/paraesthesia/peripheral swelling, n = 1; dizziness, n = 1; fatigue, n = 1; deafness/ear congestion/fatigue, n = 1; blood pressure fluctuation (participant reported)/depression, n = 1; alanine aminotransferase increase, n = 1; diarrhoea/joint stiffness, n = 1; acute hepatitis B, n = 1; fatigue/pyrexia, n = 1, injection site discharge, n = 1; [b] Participant had a fatal serious adverse event of brain injury/encephalopathy, n = 1; [c] Withdrawal by participant, n = 12; lost to follow-up, n = 6; protocol deviation, n = 5; investigator decision, n = 1; [d] Physician decision (pregnancy), n = 1; withdrawal by participant, n = 9; protocol deviation, n = 1; lost to follow-up, n = 2.

BIC/FTC/TAF = bictegravir/emtricitabine/tenofovir alafenamide; CAB + RPV LA = long-acting cabotegravir and rilpivirine; CI = confidence interval; mITT-E = modified intent-to-treat exposed; Q2M = every 2 months

In the mITT-E population at Month 12, CAB + RPV LA demonstrated noninferior efficacy compared with BIC/FTC/TAF for the proportion of participants with virologic non-response (HIV-1 RNA ≥ 50 copies/mL, 1% vs. < 1%, respectively; adjusted treatment difference [95% CI], 0.7% [-0.7, 2.0]).[1] Noninferior efficacy

was also demonstrated for the proportion of participants with virologic success (HIV-1 RNA < 50 copies/mL 90% vs 93%, respectively; adjusted treatment difference [95% CI], -2.7% [-7.0, 1.7]).

In the ITT-E population at Month 12, 89% and 93% of participants receiving CAB + RPV LA and BIC/FTC/TAF, respectively, demonstrated virologic success (HIV-1 RNA < 50 copies/mL; adjusted treatment difference [95% CI], -3.5% [−7.9, 0.9]).[1] Virologic non-response was observed in 1% and < 1% of participants receiving CAB + RPV LA and BIC/FTC/TAF, respectively (HIV-1 RNA ≥ 50 copies/mL; adjusted treatment difference [95% CI], 0.9% [−0.5, 2.2]).

In the per protocol population at Month 12, 91% and 93% of participants receiving CAB + RPV LA and BIC/FTC/TAF, respectively, demonstrated virologic success (HIV-1 RNA < 50 copies/mL; adjusted treatment difference [95% CI], −2.1% [−6.4, 2.2]).[1] Less than 1% of participants in each arm demonstrated virologic non-response (HIV ≥ 50 copies/mL; adjusted treatment difference [95% CI], 0.5% [-0.8, 1.7]).

Confirmed Virologic Failures

Confirmed virologic failure (CVF) was defined by two consecutive plasma HIV-1 RNA levels ≥ 200 copies/mL after prior suppression to < 200 copies/mL.[1] Through Month 12 in the mITT-E Population, 2 (0.4%) participants receiving CAB + RPV LA in the mITT-E population met the CVF criterion. One additional participant receiving CAB + RPV LA in the ITT-E population met CVF criterion through Month 12. See Table 3.

Table 3. Summary of Participants Randomized to CAB + RPV LA with Confirmed Virologic Failures at Month 12[1]

Patient	Sex, Country, BMI at baseline, Subtype	RAMs at Baseline		Viral Load at SVF/CVF (copies/ mL)	RAMs at SVF Fold-Change		Comment
Participants with CVF in the mITT-E Population							
1	Male, Italy, 21.5 kg/m^2, Subtype B	RPV	none	SVF Month 6: 1327	RPV	M230L RPV FC = 3.2	Received BIC/FTC/TAF prior to enrollment; resuppressed on D/C/F/TAF following long-term follow-up
		INSTI	none	CVF Retest: 1409	INSTI	Q148R CAB FC = 3.1	
2	Male, Spain, 22.9 kg/m^2, Subtype AE	RPV	None	SVF Month 11: 6348	RVP	K101E RPV FC = 1.9	Received ABC/3TC/DTG and BIC/FTC/FAF prior to enrollment; resuppressed on BIC/FTC/TAF and D/C/F/TAF during long-term follow-up
		INSTI	G140G/R	CVF Retest: 419	INSTI	G118R CAB FC = 8.4	
Participant with CVF in the ITT-E Population							
3[a]	Male, USA, 30.5 kg/m^2, Subtype failed; HIV subtype C at Month 3	RPV	Assay Failed	SVF Month 3: 3797	RPV	E138E/K, Y181Y/C RPV FC = 4.2	Excluded due to protocol deviation
		INSTI	Assay Failed	CVF Retest: 928	INSTI	Assay Failed	

[a] Prior to enrolling in the study, the participant had received prohibited prior ART with at least three prior INSTI regimens; they re-suppressed on BIC/FTC/TAF during long-term follow-up. This participant was excluded from the mITT-E population due to significant and persistent non-compliance to protocol entry requirements at the study site.

ABC/3TC/DTG = abacavir/lamivudine/dolutegravir; ART = antiretroviral therapy; BIC/FTC/TAF = bictegravir/emtricitabine/tenofovir; BMI = body mass index; CVF = confirmed virologic failure; D/C/F/TAF = darunavir/cobicistat/emtricitabine/tenofovir alafenamide; FC = fold change; INSTI = integrase inhibitor; RAM = resistance-associated mutation; RPV = rilpivirine; SVF = suspected virologic failure

Efficacy by Subgroup Analysis

A *post hoc* analysis was conducted to determine outcomes by subgroup: sex at birth (male and female), age (< 35, 35–< 50, ≥ 50 years), body mass index (BMI; < 30 and ≥ 30 kg/m^2), race (White, Black, Asian, Other), and ethnicity (Hispanic or LatinX).[3] Rates of virologic suppression (HIV-1 RNA < 50 copies/mL at Month 12 by snapshot analysis) among patients who received CAB + RPV LA ranged from 86-100% across subgroups; rates of non-response (HIV-1 RNA ≥ 50 copies/mL) ranged from 0-2%. Overall, 2/422 patients (< 1%) had CVF: both were male, < 35 years old, White, and had a BMI < 30 kg/m^2.

Safety

Excluding ISRs, AEs and serious AEs were similar between groups; however, non-ISR drug-related AEs were also reported more frequently for CAB + RPV LA group (90 [20%] participants) compared with the BIC/FTC/TAF group (2 [< 1%] participants).[1] This is consistent with reported findings from prior switch studies where a higher incidence of drug related AEs are reported for participants switching to a new regimen compared to those remaining on their current regimen. See Table 4.

Table 4. Safety Summary, Excluding Injection Site Reactions – Maintenance Phase[1]

Parameter, n (%)	CAB + RPV LA Q2M (N = 454) n (%)	BIC/FTC/TAF (N = 227) n (%)
Any AE (excluding ISR)	349 (77)	172 (76)
Drug-related AEs	90 (20)	2 (< 1)
Any Grade 3-5 AE	42 (9)	26 (11)
Drug-related	7 (2)	0
Leading to Withdrawal	25 (6)	2 (< 1)
Drug-related	9 (2)[a]	0
Any SAE	21 (5)	15 (7)
Drug-related	4 (1)[b]	0

[a] OLI period: dysesthesia/limb discomfort/paresthesia/peripheral swelling, n = 1; dizziness, n = 1; fatigue, n = 1; deafness/ear congestion/fatigue, n = 1; blood pressure fluctuation (participant reported)/depression, n = 1; diarrhea/joint stiffness, n = 1; Injection period: myocardial infarction, n = 1; alanine aminotransferase increase, n = 1; fatigue/pyrexia, n = 1; injection site pain, n = 7; injection site pain or swelling, n = 1; injection site pain/nodule, n =1; injection site discharge, n = 1; [b] Increased alanine aminotransferase, n = 2; acute myocardial infarction, n = 1; injection site pain, n = 1.

AE = adverse event; BIC/FTC/TAF = bictegravir/emtricitabine/tenofovir; CAB + RPV LA = long-acting cabotegravir and rilpivirine; ISR = injection stie reaction; Q2M = every 2 months; SAE = serious adverse event

The most commonly reported drug-related AEs in the CAB + RPV LA arm were pyrexia (3%), headache (2%), fatigue (2%), and diarrhea (2%).[1] In the BIC/FTC/TAF arm, the two drug-related AEs reported were weight gain (< 1%) and abnormal hepatic function (< 1%). More participants in the CAB + RPV LA arm had AEs leading to withdrawal (6% vs. < 1%).

Injection Site Reactions

The median duration for ISRs was 3 days.[1] Most were Grade 1 or 2 (98%) and few participants discontinued due to injection-related reasons. See Table 5.

Table 5. Injection Site Reactions Summary (Event-Level) in the Maintenance Phase - 12 Month Analysis[2]

	Randomized to CAB + RPV LA Q2M		
	OLI (N = 175)[a] n (%)	**DTI (N = 279)[a] n (%)**	**Q2M Total (N = 454)[a] n (%)**
Number of injections, n	2228	3724	5952
ISR events, n[b]	734	1181	1915
Pain, n (% of injections)	507 (23)	887 (24)	1394 (23)
Discomfort, n (% of injections)	56 (3)	65 (2)	121 (2)
Nodule, n (% of injections)	28 (1)	56 (2)	84 (1)
Grade 3, n (% of ISR events)[c]	19 (3)	10 (< 1)	29 (2)
Median Duration (IQR), days	3 (2, 5)	3 (2, 5)	3 (2, 5)
Participant withdrawal due to injection-related reason, n (% of participants with injections)[d]	3 (2)	8 (3)	11 (2)

[a] Represents the number of participants who received an injection; [b] A single injection could result in one more ISR. Grading was missed in 1 ISR in the CAB + RPV LA DTI group; [c] There were no Grade 4 or Grade 5 ISRs. [d] Includes participants who discontinued due to ISR AEs, and an additional participant who withdrew from the study citing injection intolerability. This also includes one participant who was excluded from the primary analysis (mITT-E) population.
AE = adverse event; CAB = cabotegravir; DTI = direct to injection; IQR = interquartile range; ISR = injection site reaction; LA = long-acting; mITT-E = modified intention-to-treat exposed; OLI = oral lead-in; Q2M = every 2 months

Inflammatory Biomarkers

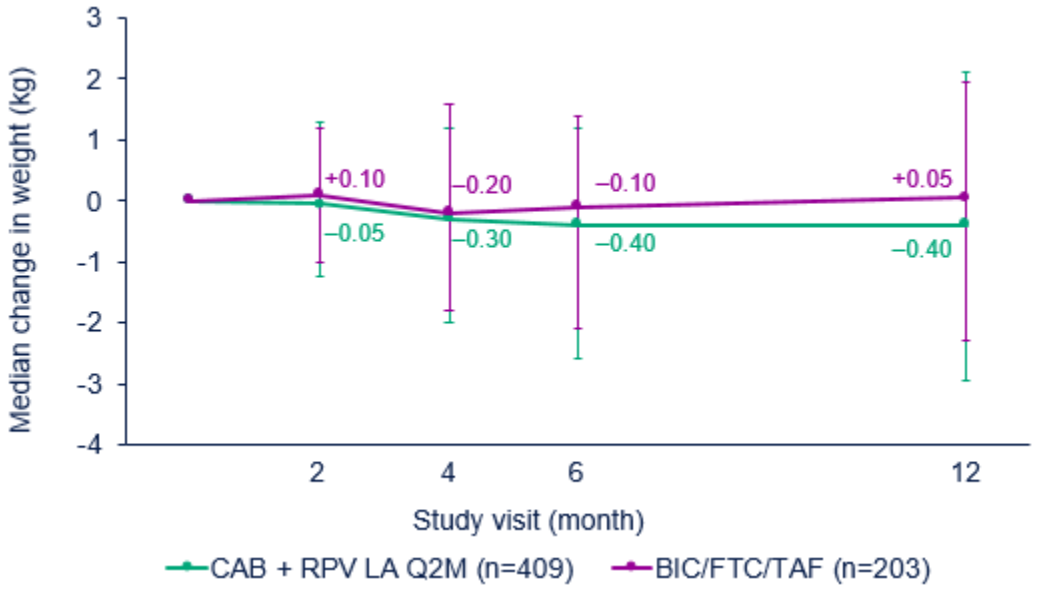
A *post hoc* analysis was conducted to determine changes in key inflammatory markers when switching to CAB + RPV LA over 12 months.[4] There were no significant differences between arms (both overall and by subgroup [sex, BMI, age]) in change from baseline for serum IL-6, C-reactive protein, D-dimer, CD4/CD8 ratio, or soluble CD14.

Weight and Metabolic Changes

Changes in body weight, BMI category, waist and hip circumferences, waist-to-height ratio, waist-to-hip ratio, and the proportion of participants with insulin resistance or metabolic syndrome were assessed from baseline (Day 1) to Month 12.[5] The median (IQR) weight was 81.3 (70.7–91.8) in the CAB + RPV LA arm and 79.0 (69.4–91.7) in the BIC/FTC/TAF arm. In total, 59% (n = 401/681) of participants were in the overweight or obesity category at baseline. Nine percent of patients in each group were on lipid-lowering agents at baseline.

At Month 12, median (IQR) change in weight in the CAB + RPV LA group was -0.40 (-2.95, +2.10) kg and +0.05 (-2.30, +1.95) kg in the BIC/FTC/TAF group.[5] See Figure 2.

Figure 2. Median (IQR) Change in Weight Through Month 12[5]



Weight increase by ≥ 10% by Month 12 occurred in 3% (n = 11/454) of participants in the CAB + RPV LA arm vs. 4% (n = 9/227) in the BIC/FTC/TAF arm.[5] Overall, the proportion of individuals in BMI categories remained similar at Month 12. No participant shifted from normal to obesity or underweight to overweight. There were no clinically relevant changes from baseline to Month 12 in the median waist-to-height ratio (CAB + RPV LA, +0.000; BIC/FTC/TAF, +0.010) and median waist-to-hip ratio (CAB + RPV LA, +0.000; BIC/FTC/TAF, +0.010).

Three abnormal findings out of the following five qualified a person for metabolic syndrome: elevated waist circumference (females: ≥ 88 cm [≥ 35 in]; males: ≥ 102 cm [≥ 40 in]), elevated triglycerides (≥ 150 mg/dL [1.7 mmol/L]), reduced HDL-C (females: < 50 mg/dL [1.3 mmol/L]; males: < 40 mg/dL [1.0 mmol/L]), elevated blood pressure (meeting either or both criteria; systolic ≥ 130 and/or diastolic ≥ 85 mmHg), and elevated fasting glucose (≥ 100 mg/dL).[5] Insulin resistance was defined as Homeostasis Model of Assessment-Insulin Resistance (HOMA-IR) ≥ 2. There were no clinically relevant changes from baseline to Month 12 in the proportion of participants with metabolic syndrome or insulin resistance in either group. See Figures 3 and 4.

Figure 3. Metabolic Syndrome Through Month 12[5]

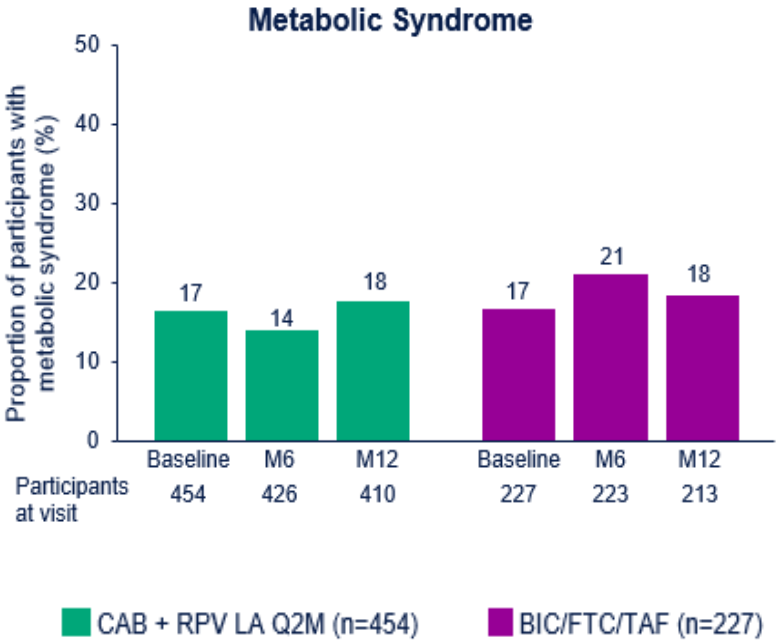
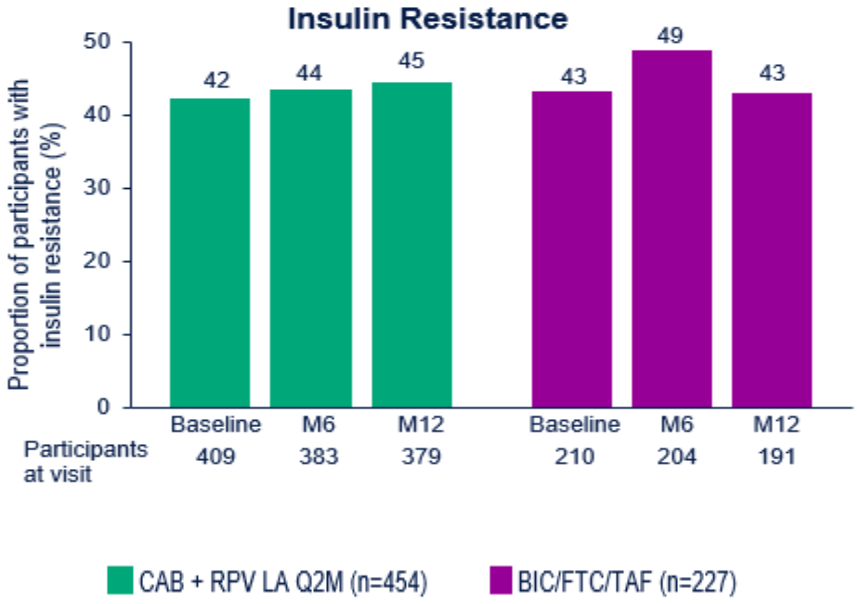


Figure 4. Insulin Resistance Through Month 12[5]



PATIENT REPORTED OUTCOMES

Preference

Participants in the CAB + RPV Q2M group, who had switched from the daily oral BIC/FTC/TAF regimen to CAB + RPV LA were asked to state their preference between the 2 therapies.[1] Of the 425 participants in the CAB + RPV LA Q2M group who responded to the questionnaire at Month 12 or at maintenance

withdrawal, the majority preferred CAB + RPV LA (90%) compared with those who preferred taking BIC/FTC/TAF (5%). Another 5% of participants reported no preference. The top reasons for preferring LA therapy included:

- not having to worry about taking HIV medicine every day (85%)
- more convenient to receive injections Q2M (83%)
- not having to carry HIV medications around (75%)
- not having to think about HIV status every day (61%)
- not having to worry about others seeing or finding HIV pills (59%)

Treatment Satisfaction

Mean adjusted HIVTSQs scores improved significantly from baseline for participants on CAB + RPV LA vs. BIC/FTC/TAF to Month 6 (adjusted difference [95% CI] 4.26 [3.02 to 5.49]; $P < 0.001$) and Month 12 (adjusted difference [95% CI] 4.95 [2.59 to 4.13]; $P < 0.001$).[1]

For further information on patient reported outcomes from the SOLAR study, please click here.

SOLAR SUB-STUDY

A post hoc analysis, outcomes for SOLAR participants in the north America (NA) region, comprising the United States (US) and Canada (CAN), were assessed.[6] Switching to CAB + RPV LA Q2M from BIC/FTC/TAF was efficacious for the maintenance of virologic suppression (At Month 12, the proportion of North American participants [mITT-E population] with HIV-1 RNA < 50 copies/mL was 88% (n = 189/216) in the LA arm vs. 94% (n = 102/109) in the BIC/FTC/TAF arm, consistent with results for the global population. The number of North American participants with adverse events was similar between the LA (74% [n = 164/223]) and BIC/FTC/TAF arms (73% [n = 83/113]), consistent with results for the global population.

This information is scientific and non-promotional in nature and is not intended for further distribution. Selection of references follows principles of evidence-based medicine and, therefore, references may not be all inclusive.

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