Patient-Reported Outcomes After 12 Months of Maintenance Therapy With CAB + RPV LA Compared With BIC/FTC/TAF in the Phase 3b SOLAR Study

TUPEB06

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Key Takeaways

- **SOLAR (NCT04542070) is a Phase 3b, randomized, active-controlled study comparing outcomes for participants switching to cabotegravir + rilpivirine long-acting (CAB + RPV LA) dosed every 2 months (Q2M) vs. continuing daily oral bictegravir/emtricitabine/tenofovir alafenamide (BIC/FTC/TAF) over 12 months, including patient-reported outcome (PRO) assessments.**
- **Despite being virally suppressed and reporting high satisfaction with oral therapy at baseline, nearly half of participants reported psychosocial challenges related to their prior daily oral treatment, including either a fear of disclosure, adherence anxiety, or a daily reminder of their HIV status.**
- **Switching to CAB + RPV LA Q2M improved treatment satisfaction significantly vs. continuing BIC/FTC/TAF over 12 months, with most participants preferring LA therapy over daily oral therapy.**
- **Despite a similar proportion reporting psychosocial challenges at baseline between arms, a lower proportion of participants in the CAB + RPV LA Q2M arm reported psychosocial challenges at Month 12 compared with participants receiving BIC/FTC/TAF, including either a fear of disclosure, adherence anxiety, or a daily reminder of their HIV status.**
- **For participants reporting at least one psychosocial challenge at baseline, statistically and clinically significant improvements in treatment satisfaction were observed after switching to CAB + RPV LA Q2M vs. continuing BIC/FTC/TAF.**

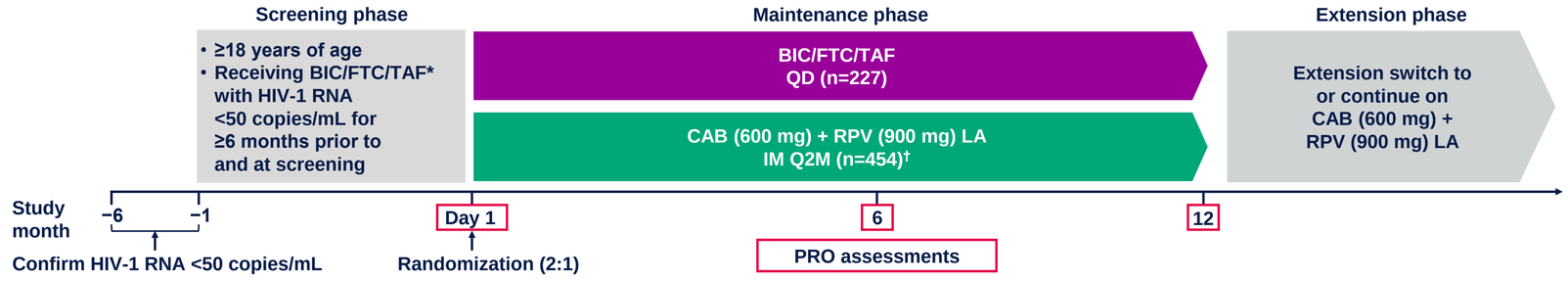
Background

- Despite the success of daily oral antiretroviral therapy, a commitment to lifelong daily pill taking can present several inherent psychosocial challenges and a treatment burden for people living with HIV (PLHIV).[1,2]
- CAB + RPV LA, administered monthly or Q2M, is the first complete LA regimen recommended by treatment guidelines for the maintenance of HIV-1 virologic suppression in PLWH.[3–5]
- Treatment guidelines recognize the potential of CAB + RPV LA to improve individual quality of life for PLWH by helping to alleviate privacy and stigma concerns, as well as improving convenience.[3–5]
- SOLAR (NCT04542070) is a Phase 3b, randomized, active-controlled study that demonstrated noninferior efficacy of switching to CAB + RPV LA Q2M vs. continuing daily oral BIC/FTC/TAF over 12 months.[6]
- Here, we report PROs through 12 months from the SOLAR study.

Methods

Figure 1. SOLAR Study Design

Phase 3b, randomized, open-label, active-controlled, multicenter, parallel-group, noninferiority study

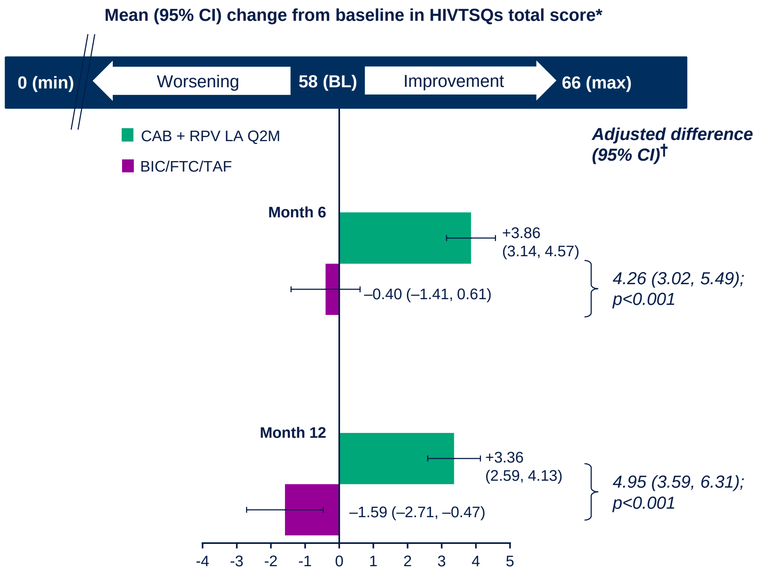


*A single prior INI regimen was allowed if BIC/FTC/TAF was a second-line regimen 6 months prior to screening. Any prior change in regimen, defined as a change of a single drug or multiple drugs simultaneously, must have occurred due to tolerability/safety, access to medications, or convenience/simplification, and must not have been done for treatment failure (HIV-1 RNA ≥400 copies/mL). †Participants randomized to the LA arm were offered an optional OLI, with participant decision following discussion with the investigator. Participants receiving CAB + RPV LA starting with injections (without an OLI) were assessed at Month 1/Month 5/Month 11, whereas participants receiving CAB + RPV LA with an OLI were assessed at Month 2/Month 6/Month 12. Time points for both arms are referred to as Month 2, Month 6, and Month 12 throughout, respectively.
IM, intramuscular; INI, integrase inhibitor; LA, long-acting; OLI, oral lead-in; PRO, patient-reported outcome; Q2M, every 2 months; QD, once daily.

- Among 687 participants randomized (2:1; n=6 not dosed), 454 switched to CAB + RPV LA Q2M (starting with injections or oral lead-in) and 227 continued BIC/FTC/TAF (**Figure 1**).
- Outcomes assessed: Treatment satisfaction (HIV Treatment Satisfaction Questionnaire status version [HIVTSQs]),[8] acceptability of injections (Perception of Injection [PIN] questionnaire), treatment preference (preference questionnaire [single question]), and participants' psychosocial outcomes (three-item questionnaire).

Results

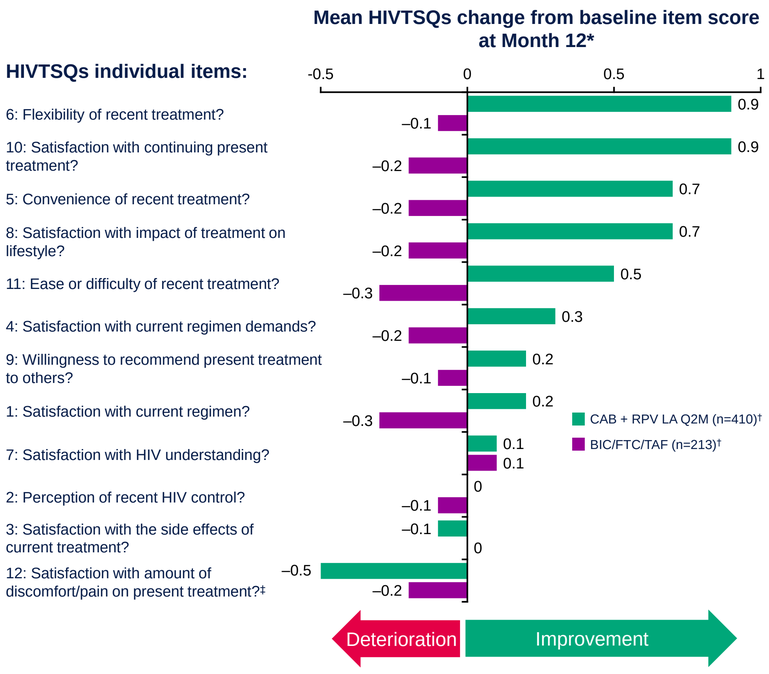
Figure 2. Change in Total Treatment Satisfaction (HIVTSQs)



*HIVTSQs: 12-item status version;[7] range per item is 0–6, where 0 = "very dissatisfied" and 6 = "very satisfied." Total score = sum of items 1–11, item 12 is presented separately.
†Based on a mixed model for repeated measures with visit as the repeated factor, including the following variables: treatment, visit, treatment x visit, maintenance baseline score, sex at birth (male, female), baseline body mass index (<30, ≥30 kg/m^2), age (<50, ≥50 years), and race (White, non-White). Baseline: CAB + RPV LA, n= 466; BIC/FTC/TAF, n=222; Month 6: CAB + RPV LA, n=436; BIC/FTC/TAF, n=220; Month 12: CAB + RPV LA, n=410; BIC/FTC/TAF, n=213.
BL, baseline; CI, confidence interval; HIVTSQs, HIV Treatment Satisfaction Questionnaire status version; LA, long-acting; Q2M, every 2 months.

- At baseline, mean (standard deviation [SD]) scores were 57.88 (7.91) and 58.38 (8.23) for the CAB + RPV LA arm and BIC/FTC/TAF arm, respectively.
- At both Month 6 and Month 12, mean (95% CI) adjusted HIVTSQs total scores improved significantly from baseline for LA vs. BIC/FTC/TAF participants (**Figure 2**), meeting the threshold for minimum clinically important difference (distribution-based approach: mean difference between arms >½ SD at baseline).[8]

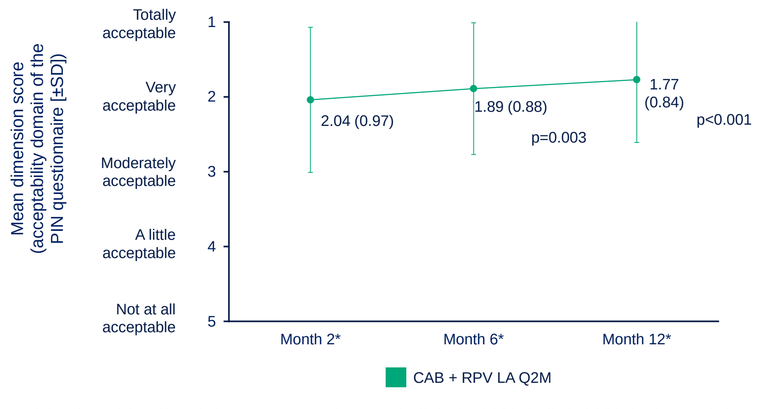
Figure 3. Change in Individual Item Scores (HIVTSQs)



*HIVTSQs: 12-item status version;[7] range per item is 0–6, where 0 = "very dissatisfied" and 6 = "very satisfied."
†"Satisfaction with impact of treatment on lifestyle" and "Willingness to recommend present treatment to others": CAB + RPV LA Q2M, n=408; BIC/FTC/TAF, n=212. "Satisfaction with continuing present treatment," "Satisfaction with amount of discomfort/pain," and "Ease or difficulty of recent treatment": CAB + RPV LA Q2M, n=409; BIC/FTC/TAF, n=212.
‡Not included in HIVTSQs total scores.
HIVTSQs, HIV Treatment Satisfaction Questionnaire status version; LA, long-acting; Q2M, every 2 months.

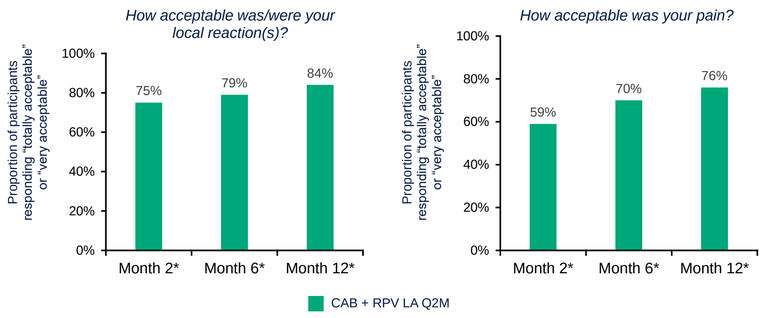
- At Month 12, treatment satisfaction had improved from baseline in nine of the 12 individual items for LA participants, with the greatest improvements observed for items concerning treatment flexibility, satisfaction, and convenience.
- There was a notable decrease from baseline in satisfaction with amount of discomfort/pain on present treatment for LA participants.
- Mean individual item scores did not show improvement for BIC/FTC/TAF participants at Month 12, except for the item concerning HIV understanding (**Figure 3**).

Figure 4A. Acceptability of Injection Site Reactions (ISRs) Through Month 12 (PIN Questionnaire)



*Month 2, n=434; Month 6, n=427; Month 12, n=411. PIN questionnaire was completed before Month 2 (injection 2), Month 6 (injection 4), and Month 12 (injection 7), and relates to ISRs experienced after injections 1, 3, and 6, respectively.
P values correspond to the Wilcoxon signed-rank test used to compare Month 6 and Month 12 scores with Month 2 scores.
P values are derived for "acceptance" only and not adjusted for multiple testing.
ISR, injection site reaction; LA, long-acting; PIN, Perception of Injection; Q2M, every 2 months; SD, standard deviation.

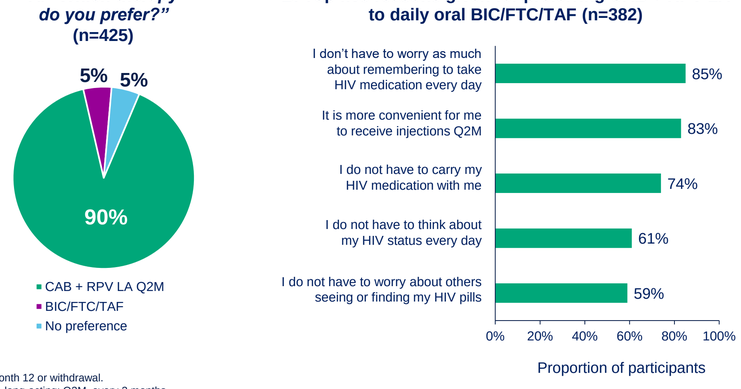
Figure 4B. Acceptability of ISRs Through Month 12 (Individual Acceptability Domain Items of the PIN Questionnaire)



*Month 2, n=434; Month 6, n=427; Month 12, n=411.
ISR, injection site reaction; LA, long-acting; PIN, Perception of Injection; Q2M, every 2 months.

- After receiving their first injection, participants in the CAB + RPV LA arm reported high acceptability of ISRs (Month 2; mean [SD], 2.04/5.00 [0.97]) in the PIN questionnaire.
- Statistically significant improvements at Month 6 (p=0.003) and Month 12 (p<0.001) were observed, indicating improved acceptability of ISRs over time, with 76% of participants rating pain as "totally" or "very acceptable" at Month 12 (**Figure 4A** and **4B**).

Figure 5. Treatment Preference (A) and Reason for Preference (B) for Participants Receiving CAB + RPV LA After a Year*



*Month 12 or withdrawal.
LA, long-acting; Q2M, every 2 months.

- At Month 12, CAB + RPV LA was preferred by 90% (n=382/425) of participants vs. previous daily oral therapy (5% [n=21/425]); 5% (n=22/425) reported no preference (**Figure 5A**).
- Supporting reasons for LA therapy preference included not having to worry about remembering to take HIV medicine, convenience, and not having to carry HIV medication (**Figure 5B**).
- Supporting reasons for participants preferring BIC/FTC/TAF (5% [n=21/425]) included aversion to injection (67% [n=14/21]), other reasons (38% [n=8/21]), the inconvenience of clinic appointments (33% [n=7/21]), convenience of oral therapy (29% [n=6/21]), and the reliability of oral medication to keep viral load undetectable (14% [n=3/21]).

Table 1. Psychosocial Outcomes at Baseline and Month 12

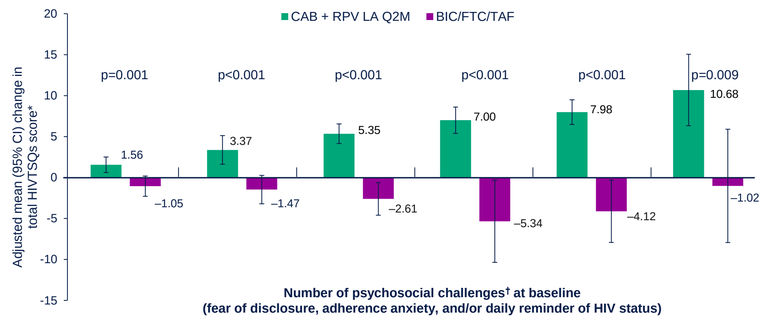
Psychosocial challenges, n (%)*	CAB + RPV LA Q2M		BIC/FTC/TAF	
	Baseline (n=447)	Month 12 (n=409)	Baseline (n=223)	Month 12 (n=214)
Any one psychosocial challenge	218 (49)	141 (34)	97 (43)	88 (41)
Fear of HIV status disclosure	109 (24)	59 (14)	52 (23)	46 (21)
Adherence anxiety	119 (27)	70 (17)	53 (24)	52 (24)
Daily reminder of HIV status	111 (25)	91 (22)	49 (22)	53 (25)

*Participants reporting "always" or "often" to psychosocial questions. LA, long-acting; Q2M, every 2 months.

- The proportion of participants reporting psychosocial challenges at study entry was similar across arms (LA, 49% [n=218/447]; BIC/FTC/TAF, 43% [n=97/223]).
- At Month 12, a lower proportion of participants in the CAB + RPV LA Q2M arm reported psychosocial challenges compared with participants receiving BIC/FTC/TAF (**Table 1**).
- Of those participants reporting psychosocial challenges at baseline,* a higher proportion of participants in the CAB + RPV LA Q2M arm reported improvements† across each of the three psychosocial questions compared with participants receiving BIC/FTC/TAF:
  - Fear of HIV status disclosure: LA, 74% (n=75/102); BIC/FTC/TAF, 44% (n=21/48).
  - Adherence anxiety: LA, 71% (n=79/112); BIC/FTC/TAF, 56% (n=28/50).
  - Daily reminder of HIV status: LA, 63% (n=67/107); BIC/FTC/TAF, 41% (n=19/46).

*Participants receiving CAB + RPV LA Q2M who scored "always"/"often" at baseline to psychosocial challenge questionnaires and had no missing data at Month 12.
†Moving from "always" at baseline to "sometimes"/"rarely"/"never"/"often" or "often" at baseline to "sometimes"/"rarely"/"never."

Figure 6. Change in Total Treatment Satisfaction (HIVTSQs) by Month 12 According to Psychosocial Challenges at Baseline



*HIVTSQs: 12-item status version;[7] range per item is 0–6, where 0 = "very dissatisfied" and 6 = "very satisfied." Total score = sum of items 1–11.
†Participants who scored "always"/"often" at baseline to psychosocial challenge questionnaires (fear of disclosure, adherence anxiety, and/or daily reminder of HIV status).
BL, baseline; CI, confidence interval; HIVTSQs, HIV Treatment Satisfaction Questionnaire status version; LA, long-acting; Q2M, every 2 months; SD, standard deviation.

- For participants who indicated at least one psychosocial challenge at baseline related to daily oral medication (47% of participants), there was a statistically and clinically significant improvement (distribution-based approach: mean difference between arms >½ SD at baseline)[8] in treatment satisfaction at Month 12 after switching to CAB + RPV LA vs. staying on BIC/FTC/TAF (**Figure 6**).

Conclusions

- Despite being virally suppressed and reporting high satisfaction with BIC/FTC/TAF, 47% of participants reported at least one psychosocial challenge at baseline; at Month 12, a lower proportion of participants in the CAB + RPV LA Q2M arm reported psychosocial challenges compared with participants receiving BIC/FTC/TAF.
- Treatment satisfaction improved from baseline for participants who switched to CAB + RPV LA Q2M vs. continuing BIC/FTC/TAF through Month 12, driven mainly by treatment flexibility, satisfaction, and convenience.
- Participants reporting at least one psychosocial challenge at baseline experienced statistically and clinically significant improvements in treatment satisfaction after switching to CAB + RPV LA Q2M vs. remaining on BIC/FTC/TAF.
- Participants receiving CAB + RPV LA Q2M reported high acceptability of ISRs at their first injection visit, with scores improving significantly at Month 6 and Month 12, consistent with observations across the Phase 3/3b program.[9–11]
- Most participants (90%) preferred LA therapy over daily oral therapy at Month 12, primarily due to the convenience of Q2M injections and the alleviation of adherence concerns.

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