ABSTRACT NO: 189 | SOLAR 12-MONTH EUROPEAN RESULTS: RANDOMIZED SWITCH TRIAL OF CAB+RPV LA VS. ORAL BIC/FTC/TAF

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Background: Cabotegravir+rilpivirine (CAB+RPV), the only complete long-acting (LA) regimen for maintaining HIV-1 suppression, may address daily oral therapy–associated challenges. We present Month (M) 12 post hoc analysis results for European participants from SOLAR, the first randomized (2:1) noninferiority study assessing switching virologically suppressed adults to CAB+RPV LA vs. continuing daily oral bictegravir/emtricitabine/tenofovir alafenamide (BIC/FTC/TAF).

Methods: The primary analysis ($n = 670$) was based on the modified intention-to-treat exposed (mITT-E) population ($n = 11$ from 1 site excluded for non-compliance) at M12. Endpoints included proportions with HIV-1 RNA ≥50 copies/mL (primary endpoint) and < 50 copies/mL, confirmed virologic failure (CVF; 2 consecutive HIV-1 RNA ≥200 copies/mL) incidence, safety and tolerability, and treatment satisfaction (HIV Treatment Satisfaction Questionnaire status version [HIVTSQs]).

Findings: Switching to CAB+RPV LA was noninferior to continuing BIC/FTC/TAF at M12. 303/670 participants (mITT-E) were from Europe; 67%($n = 203/303$) switched to LA; 33% ($n = 100/303$) con-tinued BIC/FTC/TAF. Baseline characteristics were sim-ilar between arms. At M12, 4 (2%) and 0 participants in the LA and BIC/FTC/TAF arms, respectively, had HIV-1 RNA ≥50 copies/mL (**Table**), of whom 2 had CVF (1%, $n = 2/203$). Adverse events (AEs), excluding injection site reactions, were similar between the LA (79% [$n = 160/203$]) and BIC/FTC/TAF arms (77%[$n = 77/100$]); 1% withdrew due to AEs in both arms (LA, $n = 3/203$; BIC/FTC/TAF, $n = 1/100$). Mean adjusted HIVTSQs scores improved significantly ($p < 0.001$) from baseline to M12 for LA (+3.64) vs. BIC/FTC/TAF participants (−2.19). **Interpretation:** Consistent with the overall SOLAR pop-ulatiowith treatment satisfaction improvements.

Table. Efficacy Outcomes in European Participants at Month 12* (mITT-E)†

Outcomes, n (%)	CAB+RPV LA Q2M (n=203)	BIC/FTC/TAF (n=100)
HIV-1 RNA <50 copies/mL (FDA Snapshot)	191 (94)	92 (92)
HIV-1 RNA ≥50 copies/mL (FDA Snapshot)	4 (2)‡	0
Data in window not below 50 copies/mL	2 (<1)	0
Discontinued for lack of efficacy	1 (<1)	0
Discontinued for other reason while not below 50 copies/mL	1 (<1)	0
No virologic data	8 (4)	8 (8)
Discontinued due to AE or death	4 (2)	0
Discontinued for other reason	3 (1)	7 (7)
On study but missing data in window	1 (<1)	1 (1)

*Assessed at Month 11 for participants in the LA arm starting with injections, and Month 12 for participants in the LA arm starting with an oral lead-in as well as participants in the BIC/FTC/TAF arm.
†No European participants were excluded from the ITT-E population.
‡Two participants had CVF and were classified as "discontinued for lack of efficacy" and "data in window not below 50 copies/mL." Neither had any of the three factors that, when found in combination, increase the risk of CVF (pre-existing RPV RAMs, HIV-1 subtype A6/A1, or BMI ≥30 kg/m^2). One participant had the INSTI RAM G140G/R at baseline, with RPV RAM K101E and INSTI RAM G1118R detected at failure. The second participant had no RPV or INSTI RAMs detected at baseline, with the RPV RAM M230L and INSTI RAM Q148R detected at failure.

AE, adverse event; BIC/FTC/TAF, bictegravir/emtricitabine/tenofovir alafenamide; BMI, body mass index; CAB, cabotegravir; CVF, confirmed virologic failure; FDA, U.S. Food and Drug Administration; INSTI, integrase strand transfer inhibitor; ITT-E, intention-to-treat exposed; LA, long-acting; mITT-E, modified intention-to-treat exposed; Q2M, every 2 months; RAM, resistance-associated mutation; RPV, rilpivirine.