

Long-Acting Cabotegravir Plus Rilpivirine: Low Level Viremia and Blips

Summary

- The proportion of patients with HIV-1 RNA blips was similar between the long-acting cabotegravir plus rilpivirine (CAB + RPV LA) every-2-month (Q2M) and every-1-month (Q1M) groups through Week 152 in ATLAS-2M, the CAB + RPV LA Q1M and oral abacavir/dolutegravir/lamivudine (ABC/DTG/3TC) groups through Week 96 in FLAIR, and the CAB + RPV LA Q2M and bictegravir/emtricitabine/tenofovir alafenamide (BIC/FTC/TAF) groups through Month 12 in SOLAR.^{1,2}
 - The presence of HIV-1 RNA blips was not associated with confirmed virologic failure (CVF).^{1,2}
- Important Safety Information can be found in the [Prescribing Information](#) and can also be accessed from [Our HIV Medicines](#).

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FLAIR AND ATLAS-2M EXPLORATORY ANALYSIS

For further information on the ATLAS-2M study, please click [here](#).

For further information on the FLAIR study, please click [here](#).

An exploratory study analyzed patient plasma HIV-1 RNA samples from baseline through Week 96 in the FLAIR study and from baseline through Week 152 in the ATLAS-2M study to compare low-level viremia in virologically suppressed people with HIV receiving either CAB + RPV LA Q2M, CAB + RPV LA Q1M, or daily oral ABC/DTG/3TC.¹

CVF was defined as 2 consecutive HIV-1 RNA \geq 200 copies/mL.¹ HIV-1 RNA blips were defined as single HIV-1 RNA value between 50 to < 200 copies/mL with adjacent values < 50 copies/mL.

The proportion of patients with at least 1 HIV-1 blip was similar between the Q2M and Q1M groups in ATLAS-2M at 152 weeks and between the CAB + RPV LA Q1M and the ABC/DTG/3TC groups in FLAIR at 96 weeks.¹ CVF among patients with blips was uncommon. See Table 1.

Table 1. Participants with Blips and/or CVF at Week 152 (ATLAS-2M) and Week 96 (FLAIR); ITT-E Populations¹

Parameter, n/N (%)	ATLAS-2M (Week 152)		FLAIR (Week 96)	
	Q2M	Q1M	Q1M	ABC/DTG/3TC
Participants with blips ^a	42/522 (8)	48/523 (9)	45/283 (16)	48/283 (17)
CVF ^b in participant with blips	1/42 (2) ^c	0/48	0/45	1/48 (2)

CVF = confirmed virologic failure; Q2M = every-2-month dosing; Q1M = monthly dosing.

^aDefined as HIV-1 RNA values between 50 to < 200 c/mL and adjacent HIV-1 RNA values < 50 c/mL; ^bDefined as 2 consecutive HIV-1 RNA \geq 200 c/mL; ^cParticipant met CVF criteria at Week 24.

SOLAR EXPLORATORY ANALYSIS

For further information on the SOLAR study, please click [here](#).

Patient plasma HIV-1 RNA samples were analyzed from baseline through Month 12 in the SOLAR study to assess HIV-1 RNA viral blips and the impact on CVF in patients switching to CAB + RPV LA vs continuing daily oral BIC/FTC/TAF.²

Overall, the proportion of patients with HIV-1 viral blips through Month 12 was 4% in both the CAB + RPV LA and BIC/FTC/TAF groups.² No patients who experienced a viral blip had CVF through Month 12. See Table 2.

Table 2. Participants with HIV-1 Blips and/or CVF²

Outcome at Month 12 (mITT-E), n (%)	CAB + RPV LA Q2M (OLI)	CAB + RPV LA Q2M (SWI)	BIC/FTC/TAF
Participants with HIV-1 blip ^a at any study visit	6/173 (3)	13/274 (5)	9/223 (4)
Participants with CVF ^b	1/173 (< 1)	1/274 (< 1)	0/223
With HIV-1 blip ^a	0/6	0/13	0/9
Without HIV-1 blip ^a	1/167 (< 1)	1/261 (< 1)	0/214

^aA single HIV-1 RNA value between 50 and <200 copies/mL with adjacent values <50 copies/mL; ^bTwo consecutive HIV-1 RNA values ≥200 copies/mL

BIC/FTC/TAF = bicitgravir/emtricitabine/tenofovir alafenamide; CAB + RPV LA = long-acting cabotegravir plus rilpivirine; CVF = confirmed virologic failure; mITT-E = modified intention-to-treat exposed; OLI = oral lead-in; Q2M = every 2 months; SWI = starting with injection.

Among patients with viral blips, 5% (1/19) in the CAB + RPV LA group and 11% (1/9) in the BIC/FTC/TAF group had HIV-1 RNA ≥ 50 copies/mL at Month 12.²

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Selection of references follows principles of evidence-based medicine and, therefore, references may not be all inclusive.



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REFERENCES

1. Latham C, et al. HIV-1 RNA blips, low-level viral replication and mean CD4+/CD8+ ratio during phase 3 cabotegravir + rilpivirine long-acting study (FLAIR) are similar to oral 3-drug therapy through Week 96. Presented at HIV Glasgow 2022, October 23-26, 2022, Glasgow, UK and virtually. Poster Presentation.
2. Latham C, et al. HIV-1 RNA Blips and Low-Level Viral Replication: SOLAR (CAB+RPV LA vs. BIC/FTC/TAF). Presented at the 31st Conference on Retroviruses and Opportunistic Infections (CROI), March 3-6, 2024, Denver, Colorado. Poster.