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

Summary

- The proportion of participants with HIV-1 RNA blips was similar between the long-acting cabotegravir plus rilpivirine (CAB + RPV LA) every-other-month (Q2M) and monthly (Q1M) groups through Week 152 in ATLAS-2M and between the CAB + RPV LA Q1M and oral abacavir/dolutegravir/lamivudine (ABC/DTG/3TC) groups through Week 96 in FLAIR. The presence of HIV-1 RNA blips was not associated with confirmed virologic failure (CVF).[1]
- A retrospective cohort study evaluated frequency of blips and persistent low-level viremia in 144 patients living with HIV after switching treatment to CAB + RPV LA for at least 3 months. Viral loads of < 20 copies/mL, < 50 copies/mL, and < 200 copies/mL were maintained in 58.7%, 81.9%, and 97.2% of patients, respectively. A viral load of ≥200 copies/mL occurred in 4 patients post-switch: 3 of these resuppressed and 1 had CVF.[2]
- Important Safety Information can be found in the Prescribing Information and also at Our HIV Medicines.

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FLAIR AND ATLAS-2M EXPLORATORY ANAYSIS

For further information on the ATLAS-2M study, please click here.

For further information on the FLAIR study, please click here.

An exploratory analysis analyzed plasma HIV-1 RNA samples from participants 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 (PWH) receiving either CAB + RPV LA Q2M, CAB + RPV LA injections once monthly, or daily oral ABC/DTG/3TC.[1]

CVF was defined as 2 consecutive HIV-1 RNA ≥200 copies/mL. HIV-1 RNA blips were defined as single HIV-1 RNA values between 50 to <200 copies/mL with adjacent values <50 c/mL.[1]

The proportion of participants with at least 1 HIV-1 blip was similar between the Q2M IM and Q1M groups in ATLAS-2M at 152 weeks and between the CAB + RPV LA once monthly and the ABC/DTG/3TC groups in FLAIR at 96 weeks.[1] The proportion of patients with HIV-1 RNA < 50 copies/mL were similar between treatment groups, regardless of whether participants had blips.

In the ATLAS-2M Q2M and Q1M groups, 11/522 (2%) and 2/523 (<1%) participants met CVF criteria through Week 152, respectively. In FLAIR, 4/283 (1%) participants in the Q1M group and 4/283 (1%) in the ABC/DTG/3TC group met CVF criteria through Week 96. See Table 1.

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

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-other-month dosing; Q1M, monthly dosing.

[a]Defined as HIV-1 RNA values between 50 to <200 c/mL and adjacent HIV-1 RNA values <50 c/mL; [b]Defined as 2 consecutive HIV-1 RNA ≥200 c/mL; [c]Participant met CVF criteria at Week 24.

SAN DIEGO CLINIC

A retrospective cohort study was performed among adult people living with HIV receiving care at the University of California San Diego Owen Clinic to evaluate real-world predictors of viremia and the frequency of blips and low-level viremia after switching to CAB + RPV LA.[2] Electronic medical records identified 144 participants with a mean follow-up after switching to CAB + RPV LA of 278 days. Pre- and post-switch viral load trends were categorized into 4 categories:

- Blip (≥ 1 viral load 20-199 copies/mL followed by the next viral load < 20 copies/mL)
- Persistent low-level viremia (≥ 2 consecutive viral loads 20-199 copies/mL)
- High viral load (≥ 1 viral load ≥ 200 copies/mL)
- Continuously suppressed (all viral loads < 20 copies/mL)

After switching to CAB + RPV LA, 59.7%, 81.9%, and 97.2% maintained all viral loads of < 20 copies/mL, < 50 copies/mL, and < 200 copies/mL, respectively. A viral load increase to ≥ 200 copies/mL occurred in 4 patients who switched to CAB + RPV LA; three of these re-suppressed without intervention and one developed virologic failure.

A multivariable regression model analysis showed that participants with persistent low-level viremia prior to switching had at least one viral load of ≥ 20 copies/mL post-switch [OR 3.55 (1.54-8.66), *P*=0.005]. When analyzed using a viral load cut-off of 50 copies/mL for all outcomes, persistent low-level viremia continued to be a significant predictor of having a post-switch HIV viral load >50 copies/mL.

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. Kenney S, Patel N, Hill L. Predictors of Post-Switch Viremia in Patients on Injectable Cabotegravir/Rilpivirine. Presented at the 30th Conference on Retroviruses and Opportunistic Infections (CROI), February 19-22, 2023, Seattle, Washington. Poster 516.