SAFETY AND EFFICACY OF CABOTEGRAVIR + RILPIVIRINE LONG-ACTING WITH AND WITHOUT ORAL LEAD-IN: FLAIR WEEK 124 RESULTS

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Background:
FLAIR (NCT02938520), a Phase 3, randomised, open-label study, established noninferiority of switching virologically suppressed participants after a cabotegravir (CAB) + rilpivirine (RPV) oral lead-in (OLI) from daily oral dolutegravir/abacavir/lamivudine current antiretroviral therapy (CAR) to monthly CAB+RPV long-acting (LA) over two years. Here, we describe Extension-Phase results of switching CAR participants to LA therapy with or without OLI.

Methods:
Antiretroviral therapy–naive participants achieving virologic suppression (HIV-1 RNA <50 copies/mL) with CAR during the 20-week Induction Phase were randomised (1:1) to continue CAR or switch to LA therapy (n=283 per arm). Participants received a once-daily CAB+RPV OLI for ≥4 weeks before receiving monthly injectable CAB+RPV LA. At Week (W) 100, CAR participants could switch to LA therapy (Extension-Switch population), directly (Direct-to-Inject [DTI] arm) or with a 4-week OLI (OLI arm), or withdraw. W124 endpoints for the Extension-Switch population included plasma HIV-1 RNA ≥50 copies/mL and <50 copies/mL, confirmed virologic failure (CVF; two consecutive HIV-1 RNA ≥200 copies/mL), safety and tolerability.

Results:
Participants who transitioned to CAB+RPV LA entered the DTI (n=111) or OLI arms (n=121). At W124, one participant (<1%) in each arm had HIV-1 RNA ≥50 copies/mL. Participants maintained virologic suppression in the DTI (99%) and OLI (93%) arms. One participant in the DTI arm developed CVF at W112. Adverse events (AEs) leading to withdrawal were infrequent. One Grade 4 drug-related AE occurred in the DTI arm (mixed cellularity Hodgkin's lymphoma). Number of participants experiencing serious AEs was comparable between arms. Overall, CAB+RPV LA was well tolerated; injection site reactions were the most common AE (most classified as mild/moderate).

Conclusion:
Switching directly to LA therapy without OLI demonstrated similar safety and tolerability to treatment including OLI. Similar efficacy was observed across arms at W124, suggesting that CAB+RPV LA, with or without OLI, is a well-tolerated and effective maintenance therapy.

Disclosure of Interest Statement:
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