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LONG-ACTING CABOTEGRAVIR + RILPIVIRINE AS MAINTENANCE THERAPY: ATLAS WEEK 48 RESULTS

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Background:
ATLAS, a phase 3, open-label, multicenter study, was designed to establish whether switching to monthly long-acting (LA) Cabotegravir (CAB) + Rilpivirine (RPV) LA is noninferior to continuing current 3-drug oral ART in adults with virologically suppressed HIV-1 infection.

Methods:
Eligible participants had HIV-1 RNA <50 c/mL for ≥6 months without virologic failure on oral regimens comprising 2 NRTI + 1 INSTI, NNRTI, or PI. Participants were randomly assigned (1:1) to continue current ART (CART arm) or switch to the LA arm. The LA arm participants received oral CAB 30mg + RPV 25mg once daily for 4 weeks for safety monitoring, then single 3 mL loading doses of CAB LA 600mg (200 mg/mL) and RPV LA 900mg (300 mg/mL) by IM injection, followed by 2 mL IM injections every 4 ± 1 weeks of CAB LA 400mg and RPV LA 600mg. The primary endpoint was HIV-1 RNA ≥50 c/mL at W48, using the FDA snapshot algorithm with a 6% noninferiority margin.

Results:
616 participants initiated treatment (308/arm; ITT-E). Median age was 42 yrs (26% ≥50 yrs); 33% were female and 68% white. Baseline regimens included 2 NRTI + 1 NNRTI (50%), INSTI (33%), or PI (17%). At W48, 5 participants (1.6%) in the LA arm and 3 (1.0%) in the CART arm had HIV-1 RNA ≥50 c/mL, meeting noninferiority criteria for the primary endpoint (Table). Similarly, the LA arm was noninferior to CART for the key secondary endpoint of HIV-1 RNA <50 c/mL (93% vs 95%). Three LA and 4 CART participants had confirmed virologic failure (CVF, HIV-1 RNA ≥200 c/mL in consecutive samples). The LA CVFs included 1 with RAM E138A, 1 with E138A+V108I (both having E138A in baseline DNA), and 1 with RT-E138E/K and IN-N155H. The 4 CART CVFs included 1 each of RAMs M184I, M184V+G190S, M230M/I, and 1 with no RAMs. In the LA arm, 231 participants (75%) had injection site pain with 4 participants (1%) withdrawing for these events. Incidences of grade 3/4 and serious AEs were similar across the LA and CART arms; there was 1 death (CART arm). Of the 275 LA arm participants completing HIVTSQc at W48, 98% were more satisfied with CAB LA + RPV LA compared with their daily oral treatment at study entry.

Conclusion:
The regimen of monthly injections of CAB LA + RPV LA was noninferior to continued 3-drug oral ART at W48. The LA regimen was generally well tolerated, with low rates of serious AEs and drug- or injection-related withdrawals. Virologic failure was infrequent in both arms. Overall, these results support the therapeutic potential of once-monthly CAB LA + RPV LA.