DURABLE SUPPRESSION 2 YEARS AFTER SWITCH TO DOLUTEGRAVIR + RILPIVIRINE 2-DRUG REGIMEN: SWORD 1&2 STUDIES

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Background:
Reducing long-term cumulative toxicity is important for individuals infected with human immunodeficiency virus (HIV). Treatments that reduce long-term cumulative antiretroviral exposure using 2-drug regimens (2DRs) are of interest. At 48 weeks (wk), efficacy of dolutegravir (DTG) plus rilpivirine (RPV) as a 2DR for maintaining virologic suppression was noninferior to 3-drug regimens (3DRs).

Methods:
Two identical, open-label, phase III noninferiority studies (SWORD 1&2) evaluated the efficacy and safety of switching from a current antiretroviral regimen (CAR) to once-daily DTG+RPV in HIV-1-infected adults with HIV-1 ribonucleic acid <50 c/mL (viral load [VL] <50 c/mL) for ≥6 months and with no history of virologic failure. Participants were randomized 1:1 to switch to DTG+RPV (early-switch) or continue CAR. Those randomized to CAR with confirmed suppression at Wk48 switched to DTG+RPV at Wk52 (late-switch). Secondary endpoints included VL<50 c/mL at Wk100 (snapshot algorithm) for intention-to-treat–exposed population and safety evaluations.

Results:
1024 participants were randomized and exposed (DTG+RPV, 513; CAR, 511). At Wk100 (early-switch group), 456 (89%) had VL <50 c/mL; a low rate of snapshot virologic nonresponse was observed (3%); 6 (1.2%) met Confirmed Virologic Withdrawal (CVW) criterion. The early-switch group demonstrated a stable safety profile consistent with each component; 34 (7%) experienced adverse events leading to withdrawal. At Wk100 (late-switch group), 444 (93%) had VL <50 c/mL; 2 (<1%) met CVW criterion. At Wk48, the safety profile was comparable in both groups. One participant with RPV resistance at CVW (early-switch group, Wk100) had pre-existing non-nucleoside reverse transcriptase inhibitor mutations at baseline. None developed integrase strand transfer inhibitor resistance.

Conclusion:
Once-daily DTG+RPV durably maintained HIV suppression through Wk100 after switching from a 3DR in virologically suppressed, HIV-1-infected adults. The safety profile of DTG+RPV was consistent with each component. DTG+RPV offers

reduction in cumulative antiretroviral exposure without increasing the risk of virologic failure.

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