WEIGHT AND LIPID CHANGES IN PHASE 3 CABOTEGRAVIR AND RILPIVIRINE LONG-ACTING TRIALS

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Background:
Long-acting (LA) cabotegravir (CAB), an integrase strand transfer inhibitor (INSTI), and rilpivirine (RPV), a non-nucleoside reverse transcriptase inhibitor, constitute a highly effective 2-drug regimen administered intramuscularly monthly or every 2 months for the maintenance of virologic suppression. Weight and lipid changes over 48 weeks in virologically suppressed adults receiving CAB+RPV LA in Phase 3/3b clinical trials are presented.

Methods:
Data from CAB+RPV LA–naive participants randomized to CAB+RPV LA every 4 weeks (Q4W), 8 weeks (Q8W), or oral comparator antiretroviral therapy (CAR) were pooled from ATLAS, FLAIR, and ATLAS-2M studies. Changes in weight, body mass index (BMI), and lipids from baseline to Week 48 were analyzed.

Results:
Baseline demographic characteristics and weight were similar across treatment groups. Median weight change from baseline to Week 48 was 1.20, 1.25, and 1.00 kg in Q4W, Q8W, and CAR groups, respectively. Weight increase ≥10% occurred in 8%, 5%, and 7% of participants in Q4W, Q8W, and CAR groups, respectively. Median BMI change was 0.40, 0.42, and 0.35 kg/m^2 in Q4W, Q8W, and CAR groups, respectively. An upward shift from normal BMI category occurred in 13.4%, 14.6%, and 13.8% of participants in Q4W, Q8W, and CAR groups, respectively; 3.9% (Q4W), 4.1% (Q8W), and 4.7% (CAR) developed clinical obesity (BMI >30 kg/m^2). No clinically significant changes in triglycerides; total, high-density lipoprotein (HDL), and low-density lipoprotein cholesterol; or total cholesterol/HDL ratios were found across treatment groups.

Conclusion:
In this pooled analysis, changes in weight and lipid parameters over 48 weeks were modest and similar, respectively, in participants receiving CAB+RPV LA Q4W or Q8W compared to CAR. Since INSTI-associated weight changes recently emerged, weight data collection across the CAB development program was not standardized at sites and limited metabolic data were collected. Future and on-going studies will

further characterize potential INSTI-associated weight gain and metabolic perturbations.

Disclosure of Interest Statement:
P Patel, R D'Amico, E Elliot, JW Polli, J van Wyk, M Bosse, V Vannappagari, and L Gray are employees of ViiV Healthcare and may own stock in GlaxoSmithKline. S Thiagarajah, S Wu, and O Upadhyay are employees of and may own stock in GlaxoSmithKline. R Van Solingen-Ristea is an employee of Janssen Research and Development and may own stock in Johnson & Johnson. C Orkin has received lecture fees, fees for advisory boards, travel bursaries, and research grants to her institution from ViiV Healthcare, Gilead, Merck, and Janssen. ET Overton has received research support to his institution and has served as a consultant for Gilead, Merck, Theratechnologies, and ViiV Healthcare. S Swindells has received grants from ViiV Healthcare.