Conclusion. Hispanic/Latinx and Black participants who initiated/switched to TAF had significantly improved bone and renal parameters vs. TDF, with similar VS rates at W96. Efficacy and biomarkers were similar to the overall study population. These data in >2,400 Hispanic/Latinx and Black PLH demonstrate noninferior efficacy and safety advantages with TAF vs. TDF.

Table: Renal Urine Biomarkers and Bone Mineral Density Through Week 96

Treatment-Naive Participants									
	Hispanic/Latinx Participants			Black Participants			All Participants		
Biomarker, % Change at W96	TAF-Based (n=167)	TDF-Based (n=167)	p-value	TAF-Based (n=223)	TDF-Based (n=213)	p-value	TAF-Based (n=866)	TDF-Based (n=867)	p-value
RBP:Cr	21.6 (-16.3, 83.5)	68.3 (15.0, 171.2)	<0.001	19.6 (-17.2, 69.4)	55.8 (-3.3, 167.8)	<0.001	13.8 (-18.8, 66.1)	74.2 (10.4, 192.2)	<0.001
B2M:Cr	-28.4 (-52.3, 6.1)	29.3 (-21.4, 223.6)	<0.001	-34.0 (-62.4, 3.2)	2.8 (-48.8, 132.3)	<0.001	-32.1 (-61.0, 4.2)	33.5 (-27.8, 230.7)	<0.001
Spine BMD	-1.0 (-2.8, 1.1)	-2.1 (-4.5, 0.0)	0.003	-0.9 (-3.0, 1.8)	-2.5 (-4.7, -0.3)	<0.001	-0.9 (-3.1, 1.1)	-2.8 (-5.0, -0.5)	<0.001
Hip BMD	-1.0 (-2.5, 0.6)	-2.5 (-4.6, -0.2)	<0.001	-1.0 (-3.1, 0.7)	-3.4 (-5.7, -1.3)	<0.001	-0.9 (-2.8, 1.0)	-3.6 (-5.5, -1.2)	<0.001
Switch Participants									
	Hispanic/Latinx Participants			Black Participants			All Participants		
Biomarker, % Change at W96	TAF-Based (n=472)	TDF-Based (n=332)	p-value	TAF-Based (n=485)	TDF-Based (n=403)	p-value	TAF-Based (n=2291)	TDF-Based (n=1801)	p-value
RBP:Cr	11.6 (-36.8, 73.2)	51.7 (2.1, 118.0)	<0.001	11.0 (-21.6, 60.5)	56.4 (2.4, 169.8)	<0.001	-2.3 (-42.0, 46.7)	61.2 (6.3, 162.2)	<0.001
B2M:Cr	-15.4 (-68.7, 49.0)	42.2 (-15.9, 168.5)	<0.001	-3.2 (-48.6, 30.9)	32.7 (-25.8, 169.7)	<0.001	-25.8 (-71.1, 20.6)	53.0 (-21.9, 191.9)	<0.001
Spine BMD	1.7 (-0.5, 3.8)	-0.2 (-2.0, 2.3)	<0.001	2.2 (-0.1, 4.2)	0.0 (-2.0, 2.1)	<0.001	1.8 (-0.4, 4.1)	-0.1 (-2.3, 2.2)	<0.001
Hip BMD	1.7 (0.0, 3.4)	-0.3 (-1.6, 1.3)	<0.001	1.9 (0.4, 3.4)	-0.3 (-1.9, 1.4)	<0.001	1.8 (0.2, 3.4)	-0.5 (-2.1, 1.2)	<0.001

Data are presented as median (Q1, Q3); p-values were from Wilcoxon rank sum test (renal urine biomarkers) or ANOVA (BMD).

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319. SWORD 1 and 2: Switch from TDF Containing Regimen to DTG+RPV Maintains Bone Mineral Density and Decreases Bone Turnover Markers Over 148 Weeks

Lesley Kahl, BSc, Hons I, PhD[1]; Grace A McComsey, MD[2]; Monica Coronado Poggio, MD[3]; Sergio Lupo, MD, PhD[4]; Joss de Wet, MBChB, CCFP[5]; David A. Parks, MD[6]; Brian Wynne, MD[1]; Martin Gartland, PhD[1]; Kostas Angelis, PhD[7]; Alicia Aylott, MSc[7]; Michael Cupo, PhD[8]; Kati Vandermeulen, MSc[9]; Jean A. van Wyk, MB, ChB[1] and Kimberly Smith, MD[1]; [1]ViiV Healthcare, Brentford, UK; [2]University Hospitals of Cleveland and Case Western Reserve University, Cleveland, Ohio; [3]Hospital Universitario La Paz, Madrid, Spain; [4]CAICI Institute, Rosario, Santa Fe, Argentina; [5]University of British Columbia Canada, Vancouver, BC, Canada; [6]Central West Healthcare, St. Louis, Missouri; [7]GlaxoSmithKline, London, UK; [8]GlaxoSmithKline, Collegeville, Pennsylvania; [9]Janssen R&D, Beerse, Antwerpen, Belgium

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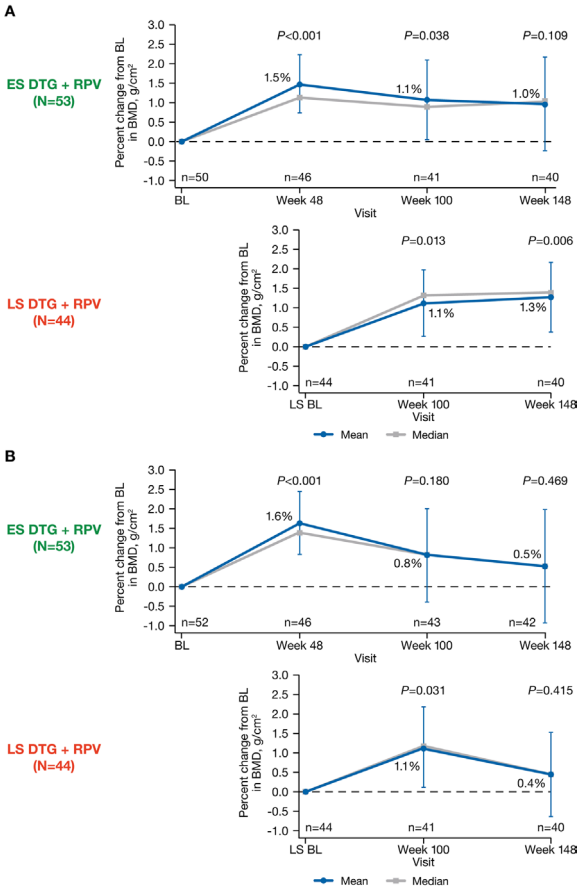
Background. HIV infection and antiretroviral therapy (ART), particularly tenofovir (TDF), is associated with loss of bone mineral density (BMD). The SWORD studies demonstrated noninferiority of the 2-drug regimen (2DR) dolutegravir (DTG) + rilpivirine (RPV) to continuing current triple-therapy ART (CAR) at 48 weeks and continued viral suppression on DTG+RPV through Week 148. A substudy of SWORD 1 and 2 evaluated a change in BMD by DEXA for those participants who switched from triple ART containing TDF to DTG+RPV. The primary analysis reported at 48 weeks showed a significant increase in total hip and lumbar spine BMD and a significant decrease in bone turnover markers in patients receiving DTG+RPV compared with CAR. Here we present data through Week 148.

Methods. HIV-infected adult patients with HIV-1 RNA < 50 c/mL received ART containing TDF for ≥6 months prior to randomization to DTG+RPV (Early Switch group, ES) or CAR on Day 1 (Baseline, BL) through Week 48 in SWORD-1/2. CAR patients suppressed at Week 48 switched to DTG+RPV at Week 52 (Late Switch group, LS). Hip and lumbar spine BMD were measured by DEXA scans read centrally. Secondary endpoints include a change in BMD and bone turnover markers through Week 148.

Results. Following switch to DTG+RPV significant increases were observed for total hip in the ES and LS groups through 100 weeks with a non-significant increase at Week 148 in ES (Figure 1a). Lumbar spine BMD significantly increased from BL at 48 weeks post switch, remained increased, though not significantly from BL through Week 148 (Figure 1b). The BMD of the LS group was similar to that of the ES group through 100 weeks exposure. The majority of patients remained in their pre-switch T-score category or improved a category for both hip and spine through Wk148 (Table 1). Through Wk148, BMI increased minimally and bone turnover markers significantly decreased ($P < 0.001$ to 0.042 across markers) from BL/LS BL except Type I Collagen C-Telopeptide at Wk148 in the LS group ($P = 0.279$).

Conclusion. Switch to the DTG+RPV 2DR was associated with sustained improvements in BMD through Week 148, along with a reduction in bone markers. The favorable effects on skeletal health were observed despite the ageing of study patients and other factors decreasing BMD. A switch to DTG+RPV in suppressed patients provides a robust option for preserving bone health while continuing suppressive HIV treatment.

Figure 1. (A) Percent Change From Baseline (BL)/Late Switch Baseline (LS BL) in Total Hip BMD (g/cm²). **(B)** Percent Change From BL/LS BL in Lumbar Spine BMD (g/cm²).



Mean % change and 95% CI data are shown in blue. Median data are shown in gray. *P* values are from 1-sample 2-sided *t*-test for % change from BL/LS BL. BL, baseline; BMD, bone mineral density; ES, early switch; LS, late switch; LS BL, Late Switch baseline – the latest pre-switch assessment.

Table 1a. Change From Baseline (BL) /Late Switch Baseline (LS BL) in T-score Category for Total Hip Through Week 148

	ES DTG + RPV (N=53)			LS DTG + RPV (N=44)	
Shifts from BL/LS BL	**Week 48**	**Week 100**	**Week 148**	**Week 100**	**Week 148**
n	46	41	**40**	41	**40**
Improvement					
From Osteopenia to Normal	3 (7%)	2 (5%)	**2 (5%)**	5 (12%)	**3 (8%)**
No change					
From Normal to Normal	32 (70%)	27 (66%)	**26 (65%)**	29 (71%)	**28 (70%)**
From Osteopenia to Osteopenia	11 (24%)	11 (27%)	**11 (28%)**	6 (15%)	**8 (20%)**
Deterioration					
From Normal to Osteopenia	0	1 (2%)	**1 (3%)**	1 (2%)	**1 (3%)**

BL, baseline; LS BL, Late Switch baseline - the latest pre-switch assessment; ES, early switch; LS, late switch; n, number of subjects with T-score total hip data at BL/LS BL and week of interest.
Normal: T-score > −1. Osteopenia: −2.5 < T-score ≤ −1.

Table 1b. Change From Baseline (BL) /Late Switch Baseline (LS BL) in T-score Category for Lumbar Spine Through Week 148

	ES DTG + RPV (N=53)			LS DTG + RPV (N=44)	
Shifts from BL/LS BL	**Week 48**	**Week 100**	**Week 148**	**Week 100**	**Week 148**
n	46	43	**42**	41	**40**
Improvement					
From Osteopenia to Normal	3 (7%)	4 (9%)	**1 (2%)**	1 (2%)	**2 (5%)**
From Osteoporosis to Osteopenia	1 (2%)	1 (2%)	**1 (2%)**	1 (2%)	**0**
From Severe Osteoporosis to Osteoporosis	2 (4%)	1 (2%)	**2 (5%)**	0	**0**
No change					
From Normal to Normal	26 (57%)	23 (53%)	**23 (55%)**	26 (63%)	**26 (65%)**
From Osteopenia to Osteopenia	14 (30%)	12 (28%)	**14 (33%)**	12 (29%)	**9 (23%)**
From Severe Osteoporosis to Severe Osteoporosis	0	1 (2%)	**0**	1 (2%)	**1 (3%)**
Deterioration					
From Osteopenia to Osteoporosis	0	1 (2%)	**1 (2%)**	0	**2 (5%)**

BL, baseline; LS BL, Late Switch baseline - the latest pre-switch assessment; ES, early switch; LS, late switch; n, number of subjects with T-score lumbar spine data at BL/LS BL and week of interest.
Normal: T-score > −1. Osteopenia: −2.5 < T-score ≤ −1. Osteoporosis: −3.5 < T-score ≤ −2.5. Severe osteoporosis: T-score ≤ −3.5.

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