Bone Mineral Density in Human Immunodeficiency Virus Type 1 (HIV-1)-Infected Adult Subjects Switching From a Tenofovir Regimen to a Dolutegravir Plus Rilpivirine Regimen

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Recruitment Status : Completed
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Sponsor:
ViiV Healthcare

Collaborators:
Janssen Pharmaceuticals
GlaxoSmithKline

Information provided by (Responsible Party):
ViiV Healthcare

Study Type	Interventional
Study Design	Allocation: Non-Randomized; Intervention Model: Parallel Assignment; Masking: None (Open Label); Primary Purpose: Treatment
Condition	HIV Infections
Intervention	Drug: Subjects do not receive study medication in this study 202094
Enrollment	102

Participant Flow

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Recruitment Details	Participants from early switch dolutegravir (DTG) plus rilpivirine (RPV) treatment groups and from late switch group who continue their current antiretroviral regimen (CAR) through Week 52 across both NCT02429791 and NCT02422797 were included in this sub-study 202094.
Pre-assignment Details	Total 146 participants were screened, of which, 44 were screen failures and 102 were registered to study 202094. The study included an early switch phase and a late switch phase.

Arm/Group Title	DTG + RPV	Current Antiretroviral Regimen
▼ Arm/Group Description	Participants received randomized DTG together with RPV once daily in an open-label fashion up to Week 52 during early switch phase in the parent study and continued to receive DTG + RPV up to Week 148 during the late switch phase in the parent study (study medication was administered in the parent study and not in study 202094).	Participants continued to receive their current antiretroviral regimen (CAR) (two nucleoside reverse transcriptase inhibitors [NRTIs] + a third agent). A third agent included either an: integrase strand transfer inhibitor (INSTI), a non-nucleoside reverse transcriptase inhibitor (NNRTI) or a protease inhibitor (PI). CAR was administered according to the approved labeling in an open-label fashion up to Week 52 during

		early switch phase in the parent study. At Week 52, participants with human immunodeficiency virus-1 (HIV-1) ribonucleic acid (RNA) <50 copies per milliliter (c/mL), switched to DTG + RPV once daily and were followed until Week 148 in the parent study (study medication was administered in the parent study and not in study 202094).
Period Title: **Early Switch Phase (Up to Week 52)**		
Started	53	49
Completed	49	44
Not Completed	4	5
Reason Not Completed		
Withdrawal from parent study	4	5
Period Title: **Late Switch Phase (Week 52 to Week 148)**		
Started	49	44
Completed	42	40
Not Completed	7	4
Reason Not Completed		
Withdrawal from parent study	2	3
Prohibited medication use	5	1

Baseline Characteristics

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Arm/Group Title	DTG + RPV	Current Antiretroviral Regimen	Total
Arm/Group Description	Participants received randomized DTG together with RPV once daily in an open-label fashion up to Week 52 during early switch phase in the	Participants continued to receive their current antiretroviral regimen (CAR) (two nucleoside reverse transcriptase inhibitors [NRTIs] + a third agent). A third	Total of all reporting groups

		parent study and continued to receive DTG + RPV up to Week 148 during the late switch phase in the parent study (study medication was administered in the parent study and not in study 202094).	agent included either an: integrase strand transfer inhibitor (INSTI), a non-nucleoside reverse transcriptase inhibitor (NNRTI) or a protease inhibitor (PI). CAR was administered according to the approved labeling in an open-label fashion up to Week 52 during early switch phase in the parent study. At Week 52, participants with human immunodeficiency virus-1 (HIV-1) ribonucleic acid (RNA) <50 copies per milliliter (c/mL), switched to DTG + RPV once daily and were followed until Week 148 in the parent study (study medication was administered in the parent study and not in study 202094).	
Overall Number of Baseline Participants		53	49	102
▼ Baseline Analysis Population Description		[Not Specified]		
Age, Continuous Mean (Standard				

Deviation) Unit of measure: Years				
	Number Analyzed	53 participants	49 participants	102 participants
		42.6 (10.80)	44.8 (10.66)	43.7 (10.73)
Sex: Female, Male Measure Type: Count of Participants Unit of measure: Participants				
	Number Analyzed	53 participants	49 participants	102 participants
	Female	27 50.9%	26 53.1%	53 52.0%
	Male	26 49.1%	23 46.9%	49 48.0%
Race/Ethnicity, Customized Measure Type: Count of Participants Unit of measure: Participants	Number Analyzed	53 participants	49 participants	102 participants
American Indian/ Alaska native Heritage		4 7.5%	1 2.0%	5 4.9%
Asian-Central/South Asian Heritage		0 0.0%	1 2.0%	1 1.0%
Asian-Japanese/East Asian (EA)/ South EA		2 3.8%	0 0.0%	2 2.0%

heritage							
Black / African American		3	5.7%	7	14.3%	10	9.8%
White		44	83.0%	40	81.6%	84	82.4%

Outcome Measures

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1. Primary Outcome

Title	Percent Change From Baseline in Total Hip Bone Mineral Density (BMD) at Week 48
▼ Description	Percent change in BMD (expressed as areal density in grams per centimeter square [g/cm^2]) as specified by dual energy X-ray absorptiometry (DEXA) scans of the left 'total hip' which included the femoral neck, trochanter and inter-trochanter areas was assessed by areal density at Baseline and Week 48. The estimated value in the statistical analysis is this difference and the upper and lower limit values shown are the 95% confidence intervals. Baseline was considered as Day 1 and percent change from Baseline was calculated as Value at Week 48 minus Baseline value divided by Baseline value multiplied by 100. An analysis of covariance (ANCOVA) model was used to compare the difference. The analysis was performed on Intent-to-Treat exposed DEXA (ITT-ED) Population which comprised of all participants in the ITT-E Population who received at least one dose of study treatment, and who were registered for the 202094 study.
Time Frame	Baseline (Day 1) and Week 48

▼ Outcome Measure Data

▼ Analysis Population Description
ITT-ED Population. Only those participants with data available at specified time point were analyzed.

Arm/Group Title	DTG + RPV	Current Antiretroviral Regimen
▼ Arm/Group Description:	Participants received randomized DTG together with RPV once daily in an open-label fashion up to Week 52 during early switch phase in the parent study and continued to receive DTG + RPV up to Week 148 during the late switch phase in the parent study (study medication was administered in the parent study and not in study 202094).	Participants continued to receive their current antiretroviral regimen (CAR) (two nucleoside reverse transcriptase inhibitors [NRTIs] + a third agent). A third agent included either an: integrase strand transfer inhibitor (INSTI), a non-nucleoside reverse transcriptase inhibitor (NNRTI) or a protease inhibitor (PI). CAR was administered according to the approved labeling in an open-label fashion up to Week 52 during early switch phase

2. Secondary Outcome

Title	Percent Change From Baseline in Lumbar Spine BMD at Week 48
▼ Description	Percent change in BMD (expressed as areal density in g/cm^2) as specified by DEXA scans of the 'lumbar spine' which included the first lumbar vertebra (L1) to the fourth lumbar vertebra (L4) was assessed by areal density at Baseline and Week 48. The difference is adjusted percent change from Baseline to Week 48 between treatment groups. The estimated value in the statistical analysis is this difference and the upper and lower limit values shown are the 95% confidence intervals. Baseline was considered as Day 1 value and percent change from Baseline was calculated as Value at Week 48 minus Baseline value divided by Baseline value multiplied by 100. An ANCOVA model was used to compare the difference in percentage change from Baseline at week 48 in lumbar spine BMD between the DTG+RPV and CAR arms.
Time Frame	Baseline (Day 1) and Week 48

▼ Outcome Measure Data

▼ Analysis Population Description
ITT-ED Population. Only those participants with data available at specified time point were analyzed.

Arm/Group Title	DTG + RPV	Current Antiretroviral Regimen
▼ Arm/Group Description:	Participants received randomized DTG together with RPV once daily in an open-label fashion up to Week 52 during early switch phase in the parent study and continued to receive DTG + RPV up to Week 148 during the late switch phase in the parent study (study medication was administered in the parent study and not in study 202094).	Participants continued to receive their current antiretroviral regimen (CAR) (two nucleoside reverse transcriptase inhibitors [NRTIs] + a third agent). A third agent included either an: integrase strand transfer inhibitor (INSTI), a non-nucleoside reverse transcriptase inhibitor (NNRTI) or a protease inhibitor (PI). CAR was administered according to the approved labeling in an open-label fashion up to Week 52 during early switch phase in the parent study. At Week 52, participants with human immunodeficiency virus-1 (HIV-1)

3. Secondary Outcome

Title	Percent Change From Baseline in Total Hip and Lumbar Spine BMD-DTG+RPV Early Switch Group Through Early and Late Switch Phase
▼ Description	Percent change in BMD (expressed as areal density in g/cm^2) as specified by DEXA scans of left 'total hip' which included femoral neck, trochanter and inter-trochanter areas and 'lumbar spine' which included L1 to L4 was assessed by areal density. Percent change from Baseline is post-dose value minus Baseline value divided by Baseline value multiplied by 100. BMD parameters at Weeks 48, 100 and 148 reflect data adjusted following the ongoing longitudinal and cross-calibration of multiple DEXA scanner instruments in this study. Data presented through Week 48 only represent results of Week 48 Primary Endpoint analysis which applied DEXA scanner calibrations though Week 48, with no subsequent calibration applied. In the final analysis conducted at Week 148, DEXA scanner calibration data acquired from Day 1 to Week 148 was applied to all raw DEXA BMD data at Weeks 48, 100 and 148. Hence, actual values of Week 48 DEXA data may vary slightly between Weeks 48 and 148 analyses.
Time Frame	Baseline (Day 1), Week 48, Week 100 and Week 148

▼ Outcome Measure Data

▼ Analysis Population Description
ITT-ED Population. Only those participants with data available at specified time point were analyzed (represented by n=X) in category titles.

Arm/Group Title		DTG + RPV
▼ Arm/Group Description:		Participants received randomized DTG together with RPV once daily in an open-label fashion up to Week 52 during early switch phase in the parent study and continued to receive DTG + RPV up to Week 148 during the late switch phase in the parent study (study medication was administered in the parent study and not in study 202094).
Overall Number of Participants Analyzed		53
Mean (95% Confidence Interval) Unit of Measure: Percent change		
Total hip: Week 48:	Number Analyzed	46 participants

4. Secondary Outcome

Title	Percent Change From Late Switch (LS) Baseline (Week 48) Through Week 148 in Total Hip and Lumbar Spine BMD-CAR Late Switch Group Through Late Switch Phase
▼ Description	Percent change in BMD (expressed as areal density in g/cm^2) as specified by DEXA scans of the left 'total hip' which included the femoral neck, trochanter and inter-trochanter areas was assessed by areal density at indicated time points. Percent change in BMD as specified by DEXA scans of the 'lumbar spine' which included the first lumbar vertebra (L1) to the fourth lumbar vertebra (L4) was assessed by areal density at indicated time points. The last pre-switch value (Week 48) was considered as LS Baseline and percent change from LS Baseline was calculated as post-dose visit value minus LS Baseline value divided by LS Baseline value multiplied by 100. The analysis was based on Late-Switch Intent-to-Treat Exposed DEXA (LS-ITT-ED) Population which comprised of all participants in the LS-ITT-E Population, and who were registered for the DEXA study.
Time Frame	LS Baseline (Week 48), Week 100 and Week 148

▼ Outcome Measure Data

▼ Analysis Population Description
LS ITT-ED Population. Only those participants with data available at specified time point were analyzed (represented by n=X) in category titles.

Arm/Group Title	Current Antiretroviral Regimen
▼ Arm/Group Description:	Participants continued to receive their current antiretroviral regimen (CAR) (two nucleoside reverse transcriptase inhibitors [NRTIs] + a third agent). A third agent included either an: integrase strand transfer inhibitor (INSTI), a non-nucleoside reverse transcriptase inhibitor (NNRTI) or a protease inhibitor (PI). CAR was administered according to the approved labeling in an open-label fashion up to Week 52 during early switch phase in the parent study. At Week 52, participants with human immunodeficiency virus-1 (HIV-1) ribonucleic acid (RNA) <50 copies per milliliter (c/mL), switched to DTG + RPV once

5. Secondary Outcome

Title	Change From Baseline in Total Hip and Lumbar Spine BMD at Week 48 Assessed by T-score and Z-score
▼ Description	Total hip and lumbar spine BMD was assessed by T-scores and Z-scores. Day 1 was considered as Baseline. Change from Baseline was calculated as the value at Week 48 minus Baseline. DEXA scans of the left 'total hip' (femoral neck, hip, inter-trochanter areas, trochanter) and 'lumbar spine' (lumbar vertebral column) were performed. T-score is the number of standard deviations above or below the mean BMD of a 30-year-old participant of the same sex. Caucasian reference values were used for all participants to calculate T-scores. T-score values > -1.0 are considered normal, T-score values <= -1.0 to > -2.5 indicate osteopenia, T-score values <= -2.5 to <-3.5 indicate osteoporosis and T-score values <= -3.5 indicate severe osteoporosis. The Z-score is the number of standard deviations above or below the mean BMD for a reference population of same age and sex and in this study. Caucasian reference values were used in calculation of Z-scores.
Time Frame	Baseline (Day 1) and Week 48

▼ Outcome Measure Data

▼ Analysis Population Description
ITT-ED Population. Only those participants with data available at specified time point were analyzed.

Arm/Group Title	DTG + RPV	Current Antiretroviral Regimen
▼ Arm/Group Description:	Participants received randomized DTG together with RPV once daily in an open-label fashion up to Week 52 during early switch phase in the parent study and continued to receive DTG + RPV up to Week 148 during the late switch phase in the parent study (study medication was administered in the parent study and not in study 202094).	Participants continued to receive their current antiretroviral regimen (CAR) (two nucleoside reverse transcriptase inhibitors [NRTIs] + a third agent). A third agent included either an: integrase strand transfer inhibitor (INSTI), a non-nucleoside reverse transcriptase inhibitor (NNRTI) or a protease inhibitor (PI). CAR was administered according to the approved labeling in an open-label fashion up to

6. Secondary Outcome

Title	Change From Baseline in Total Hip and Lumbar Spine BMD as Assessed by T-scores and Z-scores - DTG+RPV Early Switch Group Through Early and Late Switch Phase
▼ Description	T-score is the number of standard deviations above or below the mean BMD of a 30-year-old participant of same sex. Caucasian reference values were used to calculate T- and Z- scores. T-score values: > -1.0 is normal; <= -1.0 to > -2.5 indicate osteopenia; <= -2.5 to <-3.5 indicate osteoporosis; <= -3.5 indicate severe osteoporosis. Z-score is the number of standard deviations above or below the mean BMD for a reference population of same age and sex in this study. Change from Baseline is post-dose visit value minus Baseline value. Data for Week 48 only represent final results of Week 48 Primary Endpoint analysis which applied DEXA scanner calibrations through Week 48, with no subsequent calibration applied. In the final analysis conducted at Week 148, DEXA scanner calibration data acquired from Day 1 to Week 148 was applied to all raw DEXA BMD data at Weeks 48, 100 and 148. Hence, actual values of Week 48 DEXA data may vary slightly between Weeks 48 and 148 analyses.
Time Frame	Baseline (Day 1), Week 48, Week 100 and Week 148

▼ Outcome Measure Data

▼ Analysis Population Description
ITT-ED Population. Only those participants with data available at specified time point were analyzed (represented by n=X) in category titles.

Arm/Group Title	DTG + RPV
▼ Arm/Group Description:	Participants received randomized DTG together with RPV once daily in an open-label fashion up to Week 52 during early switch phase in the parent study and continued to receive DTG + RPV up to Week 148 during the late switch phase in the parent study (study medication was administered in the parent study and not in study 202094).
Overall Number of Participants Analyzed	53
Mean (Standard Deviation) Unit of Measure: Scores on a scale	

7. Secondary Outcome

Title	Change From LS Baseline (Week 48) Through Week 148 in Total Hip and Lumbar Spine BMD as Assessed by T-scores and Z-scores-CAR Late Switch Group Through Late Switch Phase
▼ Description	The last pre-switch value (Week 48) was considered as LS Baseline and change from LS Baseline was calculated as the post-dose visit value minus LS Baseline value. DEXA scans of the left 'total hip' (femoral neck, hip, inter-trochanter areas, trochanter) and 'lumbar spine' (lumbar vertebral column) were performed. T-score is the number of standard deviations above or below the mean BMD of a 30-year-old participant of the same sex. Caucasian reference values were used for all participants to calculate T-scores. T-score values > -1.0 are considered normal, T-score values <= -1.0 to > -2.5 indicate osteopenia, T-score values <= -2.5 to <-3.5 indicate osteoporosis and T-score values <= -3.5 indicate severe osteoporosis. The Z-score is the number of standard deviations above or below the mean BMD for a reference population of same age and sex and in this study. Caucasian reference values were used in calculation of Z-scores.
Time Frame	LS Baseline (Week 48), Week 100, Week 148

▼ Outcome Measure Data

▼ Analysis Population Description
LS ITT-ED Population. Only those participants with data available at specified time point were analyzed (represented by n=X in category titles).

Arm/Group Title	Current Antiretroviral Regimen
▼ Arm/Group Description:	Participants continued to receive their current antiretroviral regimen (CAR) (two nucleoside reverse transcriptase inhibitors [NRTIs] + a third agent). A third agent included either an: integrase strand transfer inhibitor (INSTI), a non-nucleoside reverse transcriptase inhibitor (NNRTI) or a protease inhibitor (PI). CAR was administered according to the approved labeling in an open-label fashion up to Week 52 during early switch phase in the parent study. At Week 52, participants with human immunodeficiency virus-1 (HIV-1) ribonucleic acid (RNA) <50 copies

8. Secondary Outcome

Title	Percent Change From Baseline in Total Hip and Lumbar Spine BMD at Week 48 by Baseline Third Agent
▼ Description	Total hip and lumbar spine BMD (expressed as areal density in g/cm^2) assessed by third agent class (INSTI, NNRTI, PI) at indicated time points. Percent change from Baseline was calculated as value at Week 48 minus Baseline value divided by Baseline value multiplied by 100. Value at Day 1 was considered as Baseline. An ANCOVA model adjusted for Baseline BMD values was used to compare the difference in percent change from Baseline to Week 48 in total hip BMD or in lumbar spine BMD between the DTG+RPV and CAR arms by third agent class: INSTI, NNRTI or PI.
Time Frame	Baseline (Day 1) and Week 48

▼ Outcome Measure Data

▼ Analysis Population Description
ITT-ED Population. Only those participants with data available at specified time point were analyzed (represented by n=X in category titles).

Arm/Group Title	DTG + RPV	Current Antiretroviral Regimen
▼ Arm/Group Description:	Participants received randomized DTG together with RPV once daily in an open-label fashion up to Week 52 during early switch phase in the parent study and continued to receive DTG + RPV up to Week 148 during the late switch phase in the parent study (study medication was administered in the parent study and not in study 202094).	Participants continued to receive their current antiretroviral regimen (CAR) (two nucleoside reverse transcriptase inhibitors [NRTIs] + a third agent). A third agent included either an: integrase strand transfer inhibitor (INSTI), a non-nucleoside reverse transcriptase inhibitor (NNRTI) or a protease inhibitor (PI). CAR was administered according to the approved

9. Secondary Outcome

Title	Change From Baseline in Total Hip and Lumbar Spine BMD T-scores and Z-scores at Week 48 by Baseline Third Agent
▼ Description	Total hip and lumbar spine BMD was assessed by Baseline third agent class (INSTI, NNRTI, PI) using T-scores and Z-scores at Baseline and Week 48. DEXA scans of hip and spine were performed. Value at Day 1 was considered as Baseline. Change from Baseline was calculated as the value at Week 48 minus Baseline value. T-score is the number of standard deviations above or below the mean BMD of a 30-year-old participant of the same sex. Caucasian reference values were used for all participants to calculate T-scores. T-score values > -1.0 are considered normal, T-score values <= -1.0 to > -2.5 indicate osteopenia, T-score values <= -2.5 to <-3.5 indicate osteoporosis and T-score values <= -3.5 indicate severe osteoporosis. The Z-score is the number of standard deviations above or below the mean BMD for a reference population of same age and sex and in this study. Caucasian reference values were used in calculation of Z-scores.
Time Frame	Baseline (Day 1) and Week 48

▼ Outcome Measure Data

▼ Analysis Population Description
ITT-ED Population. Only those participants with data available at specified time point were analyzed (represented by n=X in category titles).

Arm/Group Title	DTG + RPV	Current Antiretroviral Regimen
▼ Arm/Group Description:	Participants received randomized DTG together with RPV once daily in an open-label fashion up to Week 52 during early switch phase in the parent study and continued to receive DTG + RPV up to Week 148 during the late switch phase in the	Participants continued to receive their current antiretroviral regimen (CAR) (two nucleoside reverse transcriptase inhibitors [NRTIs] + a third agent). A third agent included either an: integrase strand transfer inhibitor (INSTI), a non-nucleoside reverse

10. Secondary Outcome

Title	Percent Change From Baseline (Day 1) in Total Hip and Lumbar BMD by Baseline Third Agent-DTG+RPV Early Switch Group Through Early and Late Switch Phase
▼ Description	Total hip and lumbar spine BMD (expressed as areal density in g/cm^2) assessed by third agent class (INSTI, NNRTI, PI) at indicated time points. Percent change from Baseline was calculated as post-dose value minus Baseline value divided by Baseline value multiplied by 100. BMD parameters expressed as areal density (g/cm^2) at Weeks 48, 100 and 148 reflect data adjusted following the ongoing longitudinal and cross-calibration of the multiple DEXA scanner instruments in this study. Data and analyses presented through Week 48 only represent the final results of Week 48 Primary Endpoint analysis which applied DEXA scanner calibrations though Week 48, with no subsequent calibration applied. In the final analysis conducted at Week 148, DEXA scanner calibration data acquired from Day 1 to Week 148 was applied to all raw DEXA BMD data at Weeks 48, 100 and 148. Hence, the actual values of Week 48 DEXA data may vary slightly between the Week 48 and Week 148 analyses.
Time Frame	Baseline (Day 1), Week 48, Week 100 and Week 148

▼ Outcome Measure Data

▼ Analysis Population Description
ITT-ED Population. Only those participants with data available at specified time point were analyzed (represented by n=X in category titles).

Arm/Group Title	DTG + RPV
▼ Arm/Group Description:	Participants received randomized DTG together with RPV once daily in an open-label fashion up to Week 52 during early switch phase in the parent study and continued to receive DTG + RPV up to Week 148 during the late switch phase in the parent study (study medication was administered in the parent study and not in study 202094).
Overall Number of Participants Analyzed	53
Mean (Standard Deviation) Unit of Measure: Percent change	

11. Secondary Outcome

Title	Change From Baseline (Day 1) in Total Hip and Lumbar Spine BMD T-scores and Z-scores by Baseline Third Agent-DTG+RPV Early Switch Group Through Early and Late Switch Phase
▼ Description	T-score is the number of standard deviations above or below the mean BMD of a 30-year-old participant of same sex. Caucasian reference values were used to calculate T- and Z-scores. T-score values > -1.0 is normal; <= -1.0 to > -2.5 indicate osteopenia; <= -2.5 to <-3.5 indicate osteoporosis; <= -3.5 indicate severe osteoporosis. Z-score is the number of standard deviations above or below the mean BMD for a reference population of same age and sex in this study. Change from Baseline is the post-dose value minus Baseline value. Data for Week 48 only represents final results of Week 48 Primary Endpoint analysis which applied DEXA scanner calibrations through 48, with no subsequent calibration applied. In the final analysis conducted at Week 148, DEXA scanner calibration data acquired from Day 1 to Week 148 was applied to all raw DEXA BMD data at Weeks 48, 100 and 148. Hence, actual values of Week 48 DEXA data may vary slightly between Weeks 48 and 148 analyses.
Time Frame	Baseline (Day 1), Week 48, Week 100 and Week 148

▼ Outcome Measure Data

▼ Analysis Population Description
ITT-ED Population. Only those participants with data available at specified time point were analyzed (represented by n=X in category titles).

Arm/Group Title	DTG + RPV
▼ Arm/Group Description:	Participants received randomized DTG together with RPV once daily in an open-label fashion up to Week 52 during early switch phase in the parent study and continued to receive DTG + RPV up to Week 148 during the late switch phase in the parent study (study medication was administered in the parent study and not in study 202094).
Overall Number of Participants Analyzed	53
Mean (Standard Deviation) Unit of Measure: Scores on a scale	

12. Secondary Outcome

Title	Percent Change From LS Baseline (Week 48) Through Week 148 in Total Hip and Lumbar Spine BMD by Baseline Third Agent-CAR Late Switch Group Through Late Switch Phase
▼ Description	Total hip and lumbar spine BMD (expressed as areal density in g/cm^2) assessed by third agent class (INSTI, NNRTI, PI) at indicated time points. The last pre-switch value (Week 48) was considered as LS Baseline and percent change from LS Baseline was calculated as post-dose value minus LS Baseline value divided by LS Baseline value multiplied by 100.
Time Frame	LS Baseline (Week 48), Week 100 and Week 148

▼ Outcome Measure Data

▼ Analysis Population Description
LS ITT-ED Population. Only those participants with data available at specified time point were analyzed (represented by n=X in category titles).

Arm/Group Title		Current Antiretroviral Regimen
▼ Arm/Group Description:		Participants continued to receive their current antiretroviral regimen (CAR) (two nucleoside reverse transcriptase inhibitors [NRTIs] + a third agent). A third agent included either an: integrase strand transfer inhibitor (INSTI), a non-nucleoside reverse transcriptase inhibitor (NNRTI) or a protease inhibitor (PI). CAR was administered according to the approved labeling in an open-label fashion up to Week 52 during early switch phase in the parent study. At Week 52, participants with human immunodeficiency virus-1 (HIV-1) ribonucleic acid (RNA) <50 copies per milliliter (c/mL), switched to DTG + RPV once daily and were followed until Week 148 in the parent study (study medication was administered in the parent study and not in study 202094).
Overall Number of Participants Analyzed		44
Mean (Standard Deviation) Unit of Measure: Percent change		
Total hip: INSTI:	Number Analyzed	3 participants

13. Secondary Outcome

Title	Change From LS Baseline (Week 48) Through Week 148 in Total Hip and Lumbar Spine BMD T-scores and Z-scores by Baseline Third Agent-CAR Late Switch Group Through Late Switch Phase
▼ Description	Total hip and lumbar spine BMD was assessed by Baseline third agent (INSTI, NNRTI, PI) using T-scores and Z-scores at indicated time points. DEXA scans of hip and spine were performed. The last pre-switch value (Week 48) was considered as LS Baseline and change from LS Baseline was calculated as the post-dose value minus LS Baseline value. T-score is the number of standard deviations above or below the mean BMD of a 30-year-old participant of the same sex. Caucasian reference values were used for all participants to calculate T-scores. T-score values > -1.0 are considered normal, T-score values <= -1.0 to > -2.5 indicate osteopenia, T-score values <= -2.5 to <-3.5 indicate osteoporosis and T-score values <= -3.5 indicate severe osteoporosis. The Z-score is the number of standard deviations above or below the mean BMD for a reference population of same age and sex and in this study. Caucasian reference values were used in calculation of Z-scores.
Time Frame	LS Baseline (Week 48), Week 100 and Week 148

▼ Outcome Measure Data

▼ Analysis Population Description
LS ITT-ED Population.Only those participants with data available at specified time point were analyzed (represented by n=X in category titles).

Arm/Group Title	Current Antiretroviral Regimen
▼ Arm/Group Description:	Participants continued to receive their current antiretroviral regimen (CAR) (two nucleoside reverse transcriptase inhibitors [NRTIs] + a third agent). A third agent included either an: integrase strand transfer inhibitor (INSTI), a non-nucleoside reverse transcriptase inhibitor (NNRTI) or a protease inhibitor (PI). CAR was administered according to the approved labeling in an open-label fashion up to Week 52 during early switch phase in the parent study. At Week 52, participants with human immunodeficiency

Adverse Events

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Time Frame	On-treatment SAEs and non-serious AEs were collected from the start of the study treatment up to 148 weeks.
Adverse Event Reporting Description	AEs were reported for the Safety DEXA Population defined as participants in the parent Safety Populations who participated in the DEXA study. Only AEs considered related to the DEXA study procedure were collected in this study. All other AEs will be public disclosed for the parent studies (201636 [NCT02429791] and 201637 [NCT02422797]). Through the 148 weeks of conduct, no AEs considered related to the DEXA study procedure were reported. No deaths were reported for 202094 study participants.

Arm/Group Title	DTG + RPV (Early Switch)	CAR (Early Switch)	DTG + RPV (Early + Late Switch)	CAR (Late Switch)
▼ Arm/Group Description	Participants received DTG together with RPV once daily in an open-label fashion up to Week 52 during early switch phase in the parent study. Study medication was administered in the parent study (201636 [NCT02429791] and 201637 [NCT02422797]) and not in study 202094.	Participants continued to receive their CAR (two NRTIs + a third agent). A third agent included either: an INSTI, a NNRTI or a PI. CAR was administered according to the approved labeling in an open-label fashion up to Week 52 during early switch phase in the parent study. Study medication was administered in the parent study	Participants received DTG together with RPV once daily in an open-label fashion up to Week 52 during early switch phase in the parent study and continued to receive DTG + RPV up to Week 148 during the Late Switch Phase in the parent study. Study medication was administered in the parent study (201636 [NCT02429791] and 201637	At Week 52, participants who received CAR during the early switch phase, with HIV-1 RNA <50 c/mL, switched to DTG + RPV once daily and were followed until Week 148 in the parent study. Study medication was administered in the parent study (201636 [NCT02429791] and 201637 [NCT02422797]) and not in study 202094.

		(201636 [NCT02429791] and 201637 [NCT02422797]) and not in study 202094.	[NCT02422797]) and not in study 202094.	

All-Cause Mortality

	DTG + RPV (Early Switch)	CAR (Early Switch)	DTG + RPV (Early + Late Switch)	CAR (Late Switch)
	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)
Total	0/53 (0.00%)	0/49 (0.00%)	0/53 (0.00%)	0/44 (0.00%)

Serious Adverse Events

	DTG + RPV (Early Switch)	CAR (Early Switch)	DTG + RPV (Early + Late Switch)	CAR (Late Switch)
	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)
Total	0/53 (0.00%)	0/49 (0.00%)	0/53 (0.00%)	0/44 (0.00%)

Other (Not Including Serious) Adverse Events

Frequency Threshold for Reporting Other Adverse Events	5%

	DTG + RPV (Early Switch)	CAR (Early Switch)	DTG + RPV (Early + Late Switch)	CAR (Late Switch)
	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)
Total	0/53 (0.00%)	0/49 (0.00%)	0/53 (0.00%)	0/44 (0.00%)

Limitations and Caveats

Go to

[Not Specified]

More Information

Go to

Certain Agreements

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

GSK agreements may vary with individual investigators, but will not prohibit any investigator from publishing. GSK supports the publication of results from all centers of a multi-center trial but requests that reports based on single-site data not precede the primary publication of the entire clinical trial.

Results Point of Contact

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Publications:

McComsey GA, Lupo S, Parks D, Poggio MC, De Wet J, Kahl LP, Angelis K, Wynne B, Vandermeulen K, Gartland M, Cupo M, Aboud M; 202094 Sub-Study Investigators. Switch from tenofovir disoproxil fumarate combination to dolutegravir with rilpivirine improves parameters of bone health. AIDS. 2018 Feb 20;32(4):477-485. doi: 10.1097/QAD.0000000000001725.

Responsible Party:	ViiV Healthcare
ClinicalTrials.gov Identifier:	NCT02478632 History of Changes
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