Clinical trial results:
An open-label, single arm study to evaluate the week 48 efficacy and safety of a two-drug regimen of dolutegravir/lamivudine (DTG/3TC) as a fixed dose combination (FDC), in antiretroviral therapy (ART)-naive HIV-1-infected adolescents, 12 to <18 years of age who weigh at least 25 kg

Summary

EudraCT number	2025-000361-93
Trial protocol	Outside EU/EEA
Global end of trial date	22 May 2025

Results information

Result version number	v1 (current)
This version publication date	06 December 2025
First version publication date	06 December 2025

Trial information

Trial identification

Sponsor protocol code	205861

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03682848
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline
Sponsor organisation address	Rue de l'Institut 89, Rixensart, Belgium, B-1330
Public contact	GSK Response Center, GlaxoSmithKline, 44 8664357343, GSKClinicalSupportHD@gsk.com
Scientific contact	GSK Response Center, GlaxoSmithKline, 44 8664357343, GSKClinicalSupportHD@gsk.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	25 June 2025
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	22 May 2025
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The study consists of Screening Phase (up to 28 days prior to the first dose of drug) followed by Treatment Phase (up to 48 weeks). Participants who successfully complete 48 weeks of therapy and who continue to receive benefit from DTG/3TC FDC may enter a 96 weeks study Extension Phase. Study participants who have successfully completed both the Treatment Phase through 48 weeks and the Extension Phase through 144 weeks and continue to receive benefit from this two-drug regimen will continue to receive DTG/3TC FDC in a Continuation Phase (after Week 144) until: DTG and 3TC are both locally approved for use as part of a dual regimen and the single entities of DTG and 3TC are available to participants or the DTG/3TC FDC tablet, if required by local regulations, is locally approved and available (e.g. commercially or through public health services), or the participant no longer derives clinical benefit or the participant meets a protocol-defined reason for discontinuation.

Protection of trial subjects:

All study activities at the study center were performed by trained clinical staff authorized by the study Investigator. The attendance of the study participants at in-person study visit did not pose risks that extend beyond the risks associated with clinic visits for routine immunization. Considering the measures taken to minimize possible risks to the participants in this study, the potential risks associated with the study interventions and study assessments were balanced by the potential benefits that may be provided to the participants. Study participants were observed for a minimum of 30 minutes after the administration of study interventions with appropriate medical attention available in case of anaphylaxis.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	06 May 2019
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Kenya: 10
Country: Number of subjects enrolled	South Africa: 3
Country: Number of subjects enrolled	Thailand: 19
Worldwide total number of subjects	32
EEA total number of subjects	0

Notes:

Subjects enrolled per age group

In utero	0

Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	32
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

All participants that were screened were eligible to start the study and receive the study intervention, and were included in the Intent-to-Treat Exposed set.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	DTG/3TC FDC

Arm description:

Participants received dolutegravir/lamivudine (DTG/3TC) (50/300 mg) Fixed Dose Combination (FDC) tablets orally once daily.

Arm type	Experimental
Investigational medicinal product name	DTG + 3TC FDC
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

DTG + 3TC FDC tablets administered once daily.

Number of subjects in period 1	DTG/3TC FDC
Started	32
Completed	20
Not completed	12
Consent withdrawn by subject	3
Protocol Deviation	1
Adverse event, non-fatal	2
Site closed	5
Lack of efficacy	1

Baseline characteristics

Reporting groups	
Reporting group title	DTG/3TC FDC
Reporting group description:	
Participants received dolutegravir/lamivudine (DTG/3TC) (50/300 mg) Fixed Dose Combination (FDC) tablets orally once daily.	

Reporting group values	DTG/3TC FDC	Total	
Number of subjects	32	32	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	32	32	
Adults (18-64 years)	0	0	
From 65-84 years	0	0	
85 years and over	0	0	
Age Continuous Units: Years			
arithmetic mean	16.0		
standard deviation	± 1.27	-	
Sex: Female, Male Units: Participants			
Female	11	11	
Male	21	21	
Race/Ethnicity, Customized Units: Subjects			
African American/African Heritage	13	13	
Asian - South East Asian Heritage	19	19	

End points

End points reporting groups

Reporting group title	DTG/3TC FDC

Reporting group description:

Participants received dolutegravir/lamivudine (DTG/3TC) (50/300 mg) Fixed Dose Combination (FDC) tablets orally once daily.

Primary: Percentage of participants with plasma Human Immunodeficiency Virus type 1 (HIV-1) ribonucleic acid (RNA) less than 50 copies per milliliter (c/mL) at Week 48

End point title	Percentage of participants with plasma Human Immunodeficiency Virus type 1 (HIV-1) ribonucleic acid (RNA) less than 50 copies per milliliter (c/mL) at Week 48[1]

End point description:

Percentage of participants with plasma HIV-1 RNA <50 c/mL was assessed at Week 48 according to the Food and Drug Administration (FDA) snapshot algorithm. Intent To Treat-Exposed (ITT-E) population includes all enrolled participants who received at least one dose of DTG/3TC.

End point type	Primary

End point timeframe:

Week 48

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	DTG/3TC FDC			
Subject group type	Reporting group			
Number of subjects analysed	32			
Units: Percentage of Participants				
number (confidence interval 95%)	81 (64 to 93)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with plasma HIV-1 RNA <200 c/mL at Week 24

End point title	Percentage of participants with plasma HIV-1 RNA <200 c/mL at Week 24

End point description:

Percentage of participants with plasma HIV-1 RNA <200 c/mL was assessed at Week 24 according to the FDA snapshot algorithm. Analysis was performed on the Intent To Treat-Exposed.

End point type	Secondary

End point timeframe:

Week 24

End point values	DTG/3TC FDC			
Subject group type	Reporting group			
Number of subjects analysed	32			
Units: Percentage of Participants				
number (confidence interval 95%)	91 (75 to 98)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with plasma HIV-1 RNA <50 c/mL at Week 144

End point title	Percentage of participants with plasma HIV-1 RNA <50 c/mL at Week 144

End point description:

Percentage of participants with plasma HIV-1 RNA <50 c/mL was assessed at Week 144 according to the FDA Snapshot algorithm. Analysis was performed on the Intent To Treat-Exposed.

End point type	Secondary

End point timeframe:

Week 144

End point values	DTG/3TC FDC			
Subject group type	Reporting group			
Number of subjects analysed	32			
Units: Percentage of Participants				
number (confidence interval 95%)	66 (47 to 81)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with plasma HIV-1 RNA <50 c/mL at Week 24

End point title	Percentage of participants with plasma HIV-1 RNA <50 c/mL at Week 24

End point description:

Percentage of participants with plasma HIV-1 RNA <50 c/mL was assessed at Week 24 according to the FDA snapshot algorithm. Analysis was performed on the Intent To Treat-Exposed.

End point type	Secondary

End point timeframe:

Week 24

End point values	DTG/3TC FDC			
Subject group type	Reporting group			
Number of subjects analysed	32			
Units: Percentage of Participants				
number (confidence interval 95%)	84 (67 to 95)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with plasma HIV-1 RNA <200 c/mL at Week 96

End point title	Percentage of participants with plasma HIV-1 RNA <200 c/mL at Week 96

End point description:

Percentage of participants with plasma HIV-1 RNA <200 c/mL was assessed at Week 96 according to the FDA snapshot algorithm. Analysis was performed on the Intent To Treat-Exposed.

End point type	Secondary

End point timeframe:

Week 96

End point values	DTG/3TC FDC			
Subject group type	Reporting group			
Number of subjects analysed	32			
Units: Percentage of Participants				
number (confidence interval 95%)	69 (50 to 84)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with plasma HIV-1 RNA <200 c/mL at Week 144

End point title	Percentage of participants with plasma HIV-1 RNA <200 c/mL at Week 144

End point description:

Percentage of participants with plasma HIV-1 RNA <200 c/mL was assessed at Week 144 according to the FDA snapshot algorithm. Analysis was performed on the Intent To Treat-Exposed.

End point type	Secondary

End point timeframe:

Week 144

End point values	DTG/3TC FDC			
Subject group type	Reporting group			
Number of subjects analysed	32			
Units: Percentage of Participants				
number (confidence interval 95%)	66 (47 to 81)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with plasma HIV-1 RNA <200 c/mL at Week 48

End point title	Percentage of participants with plasma HIV-1 RNA <200 c/mL at Week 48

End point description:

Percentage of participants with plasma HIV-1 RNA <200 c/mL was assessed at Week 48 according to the FDA snapshot algorithm. Analysis was performed on the Intent To Treat-Exposed.

End point type	Secondary

End point timeframe:

Week 48

End point values	DTG/3TC FDC			
Subject group type	Reporting group			
Number of subjects analysed	32			
Units: Percentage of Participants				
number (confidence interval 95%)	84 (67 to 95)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with adverse events (AEs) and serious adverse events (SAEs) through 144 weeks

End point title	Number of participants with adverse events (AEs) and serious adverse events (SAEs) through 144 weeks

End point description:

An adverse event is any untoward medical occurrence in a clinical study participant, temporally associated with the use of a study treatment, whether or not considered related to the study treatment. A serious adverse event is any untoward medical occurrence that, at any dose results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent disability/incapacity, is a congenital anomaly/birth defect or any other situation according to medical or scientific judgment. Safety population includes participants who have received at least

one dose of DTG/3TC.

End point type	Secondary

End point timeframe:

Up to 144 weeks

End point values	DTG/3TC FDC			
Subject group type	Reporting group			
Number of subjects analysed	32			
Units: Participants				
AEs	29			
SAEs	5			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with plasma HIV-1 RNA <50 c/mL at Week 96

End point title	Percentage of participants with plasma HIV-1 RNA <50 c/mL at Week 96

End point description:

Percentage of participants with plasma HIV-1 RNA <50 c/mL was assessed at Week 96 according to the FDA snapshot algorithm. Analysis was performed on the Intent To Treat-Exposed.

End point type	Secondary

End point timeframe:

Week 96

End point values	DTG/3TC FDC			
Subject group type	Reporting group			
Number of subjects analysed	32			
Units: Percentage of Participants				
number (confidence interval 95%)	69 (50 to 84)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with abnormal findings for hematology parameters through 144 weeks

End point title	Number of participants with abnormal findings for hematology parameters through 144 weeks

End point description:

Blood samples were collected from participants for analysis of hematology parameters including hemoglobin, leukocytes and neutrophils. The DAIDS criteria for grading the severity of adult and pediatric adverse events was used to assess severity. Grades were defined based on numeric criteria as follows: Grade 1 - mild; Grade 2 - moderate; Grade 3 - severe or medically significant; Grade 4 - life-threatening consequences. Analysis was performed on the Safety population.

End point type	Secondary

End point timeframe:

Up to 144 weeks

End point values	DTG/3TC FDC			
Subject group type	Reporting group			
Number of subjects analysed	32			
Units: Participants				
Hemoglobin - Grade 1	0			
Hemoglobin - Grade 2	4			
Hemoglobin - Grade 3	0			
Hemoglobin - Grade 4	0			
Leukocytes - Grade 1	2			
Leukocytes - Grade 2	0			
Leukocytes - Grade 3	0			
Leukocytes - Grade 4	0			
Neutrophils - Grade 1	0			
Neutrophils - Grade 2	1			
Neutrophils - Grade 3	0			
Neutrophils - Grade 4	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with AEs through 144 weeks by severity

End point title	Number of participants with AEs through 144 weeks by severity

End point description:

The Division of Acquired Immunodeficiency Syndrome (DAIDS) criteria for grading the severity of adult and pediatric adverse events was used to assess severity. Grades were defined based on numeric criteria as follows: Grade 1 - mild; Grade 2 - moderate; Grade 3 - severe or medically significant; Grade 4 - life-threatening consequences; Grade 5 - death. A higher grade indicates a greater severity. Analysis was performed on the Safety population.

End point type	Secondary

End point timeframe:

Up to 144 weeks

End point values	DTG/3TC FDC			
Subject group type	Reporting group			
Number of subjects analysed	32			
Units: Participants				
Grade 1	5			
Grade 2	19			
Grade 3	5			
Grade 4	0			
Grade 5	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with abnormal findings for clinical chemistry parameters through 144 weeks

End point title	Number of participants with abnormal findings for clinical chemistry parameters through 144 weeks

End point description:

Blood samples were collected from participants for analysis of clinical chemistry parameters including potassium, aspartate aminotransferase, creatinine, alanine aminotransferase (ALT), carbon dioxide, alkaline phosphatase, bilirubin, direct bilirubin, sodium, GFR from creatinine adjusted for BSA, calcium, and creatine kinase. Grades were defined based on numeric criteria as follows: Grade 1 - mild; Grade 2 - moderate; Grade 3 - severe or medically significant; Grade 4 - life-threatening consequences. Analysis was performed on the Safety population.

End point type	Secondary

End point timeframe:

Up to 144 weeks

End point values	DTG/3TC FDC			
Subject group type	Reporting group			
Number of subjects analysed	32			
Units: Participants				
Alanine Aminotransferase|Grade 1	3			
Alkaline Phosphatase|Grade 1	1			
Aspartate Aminotransferase|Grade 1	2			
Bilirubin|Grade 1	1			
Calcium|Grade 1	0			
Carbon Dioxide|Grade 1	17			
Creatine Kinase|Grade 1	2			
Creatinine|Grade 1	2			
Direct Bilirubin|Grade 1	0			
GFR from Creatinine Adjusted for BSA|Grade 1	0			
Potassium|Grade 1	2			
Sodium|Grade 1	6			
Alanine Aminotransferase|Grade 2	1			
Alkaline Phosphatase|Grade 2	2			

Aspartate Aminotransferase|Grade 2	0			
Bilirubin|Grade 2	1			
Calcium|Grade 2	1			
Carbon Dioxide|Grade 2	5			
Creatine Kinase|Grade 2	2			
Creatinine|Grade 2	0			
Direct Bilirubin|Grade 2	0			
GFR from Creatinine Adjusted for BSA|Grade 2	14			
Potassium|Grade 2	0			
Sodium|Grade 2	1			
Alanine Aminotransferase|Grade 3	0			
Alkaline Phosphatase|Grade 3	0			
Aspartate Aminotransferase|Grade 3	0			
Bilirubin|Grade 3	0			
Calcium|Grade 3	0			
Carbon Dioxide|Grade 3	0			
Creatine Kinase|Grade 3	2			
Creatinine|Grade 3	0			
Direct Bilirubin|Grade 3	1			
GFR from Creatinine Adjusted for BSA|Grade 3	5			
Potassium|Grade 3	0			
Sodium|Grade 3	0			
Alanine Aminotransferase|Grade 4	0			
Alkaline Phosphatase|Grade 4	0			
Aspartate Aminotransferase|Grade 4	0			
Bilirubin|Grade 4	0			
Calcium|Grade 4	1			
Carbon Dioxide|Grade 4	2			
Creatine Kinase|Grade 4	0			
Creatinine|Grade 4	0			
Direct Bilirubin|Grade 4	0			
GFR from Creatinine Adjusted for BSA|Grade 4	0			
Potassium|Grade 4	0			
Sodium|Grade 4	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with abnormal findings for fasting lipids through 144 weeks

End point title	Number of participants with abnormal findings for fasting lipids through 144 weeks

End point description:

Lipid assessments including cholesterol, low density lipoprotein (LDL) cholesterol, LDL Cholesterol Calculation, LDL Cholesterol Direct, and triglycerides were performed. Grades were defined based on numeric criteria as follows: Grade 1 - mild; Grade 2 - moderate; Grade 3 - severe or medically significant; Grade 4 - life-threatening consequences. Analysis was performed on the Safety population.

End point type	Secondary

End point timeframe:

Up to 144 weeks

End point values	DTG/3TC FDC			
Subject group type	Reporting group			
Number of subjects analysed	32			
Units: Participants				
Cholesterol|Grade 1	7			
LDL Cholesterol|Grade 1	2			
LDL Cholesterol Calculation|Grade 1	2			
LDL Cholesterol Direct|Grade 1	6			
Triglycerides|Grade 1	5			
Cholesterol|Grade 2	1			
LDL Cholesterol|Grade 2	0			
LDL Cholesterol Calculation|Grade 2	0			
LDL Cholesterol Direct|Grade 2	3			
Triglycerides|Grade 2	0			
Cholesterol|Grade 3	0			
LDL Cholesterol|Grade 3	0			
LDL Cholesterol Calculation|Grade 3	0			
LDL Cholesterol Direct|Grade 3	0			
Triglycerides|Grade 3	0			
Cholesterol|Grade 4	0			
LDL Cholesterol|Grade 4	0			
LDL Cholesterol Calculation|Grade 4	0			
LDL Cholesterol Direct|Grade 4	0			
Triglycerides|Grade 4	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with abnormal findings for urinalysis parameters through 144 weeks

End point title	Number of participants with abnormal findings for urinalysis parameters through 144 weeks

End point description:

Urine samples were collected from participants for the analysis of urinalysis parameters including urinary glucose, urinary protein, and urine erythrocytes. Grades were defined based on numeric criteria as follows: Grade 1 - mild; Grade 2 - moderate; Grade 3 - severe or medically significant; Grade 4 - life-threatening consequences. Analysis was performed on the Safety population.

End point type	Secondary

End point timeframe:

Up to 144 weeks

End point values	DTG/3TC FDC			
Subject group type	Reporting group			
Number of subjects analysed	32			
Units: Participants				
Urinary Glucose|Grade 1	1			
Urinary Protein|Grade 1	5			
Urine Erythrocytes|Grade 1	2			
Urinary Glucose|Grade 2	0			
Urinary Protein|Grade 2	2			
Urine Erythrocytes|Grade 2	0			
Urinary Glucose|Grade 3	0			
Urinary Protein|Grade 3	0			
Urine Erythrocytes|Grade 3	0			
Urinary Glucose|Grade 4	0			
Urinary Protein|Grade 4	0			
Urine Erythrocytes|Grade 4	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with adverse events and serious adverse events through 96 weeks

End point title	Number of participants with adverse events and serious adverse events through 96 weeks
End point description:	
Analysis was performed on the Safety population.	
End point type	Secondary
End point timeframe:	
Up to 96 weeks	

End point values	DTG/3TC FDC			
Subject group type	Reporting group			
Number of subjects analysed	32			
Units: Participants				
AEs	29			
SAEs	3			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants who discontinue treatment due to adverse events through 144 weeks

End point title	Number of participants who discontinue treatment due to adverse events through 144 weeks

End point description:

Analysis was performed on the Safety population.

End point type	Secondary

End point timeframe:

Up to 144 weeks

End point values	DTG/3TC FDC			
Subject group type	Reporting group			
Number of subjects analysed	32			
Units: Participants	2			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with severity of adverse events through 96 weeks

End point title	Number of participants with severity of adverse events through 96 weeks

End point description:

AEs were evaluated by the investigator and graded according to the DAIDS toxicity scales as follows: Grade 1 - mild; Grade 2 - moderate; Grade 3 - severe or medically significant; Grade 4 - life-threatening consequences; Grade 5 - death. The higher the grade, the more severe the symptoms. Analysis was performed on the Safety population.

End point type	Secondary

End point timeframe:

Up to 96 weeks

End point values	DTG/3TC FDC			
Subject group type	Reporting group			
Number of subjects analysed	32			
Units: Participants				
Grade 1	8			
Grade 2	19			
Grade 3	2			
Grade 4	0			
Grade 5	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with abnormal findings for hematology parameters through 96 weeks

End point title	Number of participants with abnormal findings for hematology parameters through 96 weeks

End point description:

Blood samples were collected from participants for analysis of hematology parameters including hemoglobin, leukocytes and neutrophils. Grades were defined based on numeric criteria as follows: Grade 1 - mild; Grade 2 - moderate; Grade 3 - severe or medically significant; Grade 4 - life-threatening consequences. Analysis was performed on the Safety population.

End point type	Secondary

End point timeframe:

Up to 96 weeks

End point values	DTG/3TC FDC			
Subject group type	Reporting group			
Number of subjects analysed	32			
Units: Participants				
Hemoglobin|Grade 1	0			
Leukocytes|Grade 1	2			
Neutrophils|Grade 1	0			
Hemoglobin|Grade 2	4			
Leukocytes|Grade 2	0			
Neutrophils|Grade 2	1			
Hemoglobin|Grade 3	0			
Leukocytes|Grade 3	0			
Neutrophils|Grade 3	0			
Hemoglobin|Grade 4	0			
Leukocytes|Grade 4	0			
Neutrophils|Grade 4	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with abnormal findings for clinical chemistry parameters through 96 weeks

End point title	Number of participants with abnormal findings for clinical

	chemistry parameters through 96 weeks

End point description:

Blood samples were collected from participants for analysis of clinical chemistry parameters including potassium, aspartate aminotransferase, creatinine, alanine aminotransferase, carbon dioxide, alkaline phosphatase, bilirubin, sodium, GFR from creatinine adjusted for BSA, calcium, and creatine kinase. Grades were defined based on numeric criteria as follows: Grade 1 - mild; Grade 2 - moderate; Grade 3 - severe or medically significant; Grade 4 - life-threatening consequences. Analysis was performed on the Safety population.

End point type	Secondary

End point timeframe:

Up to 96 weeks

End point values	DTG/3TC FDC			
Subject group type	Reporting group			
Number of subjects analysed	32			
Units: Participants				
Alanine Aminotransferase|Grade 1	2			
Alkaline Phosphatase|Grade 1	1			
Aspartate Aminotransferase|Grade 1	2			
Bilirubin|Grade 1	2			
Calcium|Grade 1	0			
Carbon Dioxide|Grade 1	14			
Creatine Kinase|Grade 1	2			
Creatinine|Grade 1	2			
GFR from Creatinine Adjusted for BSA|Grade 1	0			
Potassium|Grade 1	2			
Sodium|Grade 1	5			
Alanine Aminotransferase|Grade 2	1			
Alkaline Phosphatase|Grade 2	2			
Aspartate Aminotransferase|Grade 2	0			
Bilirubin|Grade 2	0			
Calcium|Grade 2	1			
Carbon Dioxide|Grade 2	5			
Creatine Kinase|Grade 2	1			
Creatinine|Grade 2	0			
GFR from Creatinine Adjusted for BSA|Grade 2	13			
Potassium|Grade 2	0			
Sodium|Grade 2	1			
Alanine Aminotransferase|Grade 3	0			
Alkaline Phosphatase|Grade 3	0			
Aspartate Aminotransferase|Grade 3	0			
Bilirubin|Grade 3	0			
Calcium|Grade 3	0			
Carbon Dioxide|Grade 3	0			
Creatine Kinase|Grade 3	2			
Creatinine|Grade 3	0			
GFR from Creatinine Adjusted for BSA|Grade 3	5			
Potassium|Grade 3	0			

Sodium|Grade 3	0			
Alanine Aminotransferase|Grade 4	0			
Alkaline Phosphatase|Grade 4	0			
Aspartate Aminotransferase|Grade 4	0			
Bilirubin|Grade 4	0			
Calcium|Grade 4	1			
Carbon Dioxide|Grade 4	2			
Creatine Kinase|Grade 4	0			
Creatinine|Grade 4	0			
GFR from Creatinine Adjusted for BSA|Grade 4	0			
Potassium|Grade 4	0			
Sodium|Grade 4	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with abnormal findings for fasting lipids through 96 weeks

End point title	Number of participants with abnormal findings for fasting lipids through 96 weeks

End point description:

Lipid assessments including cholesterol, LDL cholesterol, LDL cholesterol calculation, LDL cholesterol direct, and triglycerides were performed. Grades were defined based on numeric criteria as follows: Grade 1 - mild; Grade 2 - moderate; Grade 3 - severe or medically significant; Grade 4 - life-threatening consequences. Analysis was performed on the Safety population.

End point type	Secondary

End point timeframe:

Up to 96 weeks

End point values	DTG/3TC FDC			
Subject group type	Reporting group			
Number of subjects analysed	32			
Units: Participants				
Cholesterol|Grade 1	7			
LDL Cholesterol|Grade 1	2			
LDL Cholesterol Calculation|Grade 1	1			
LDL Cholesterol Direct|Grade 1	6			
Triglycerides|Grade 1	4			
Cholesterol|Grade 2	1			
LDL Cholesterol|Grade 2	0			
LDL Cholesterol Calculation|Grade 2	0			
LDL Cholesterol Direct|Grade 2	2			
Triglycerides|Grade 2	0			
Cholesterol|Grade 3	0			
LDL Cholesterol|Grade 3	0			
LDL Cholesterol Calculation|Grade 3	0			

LDL Cholesterol Direct|Grade 3	0			
Triglycerides|Grade 3	0			
Cholesterol|Grade 4	0			
LDL Cholesterol|Grade 4	0			
LDL Cholesterol Calculation|Grade 4	0			
LDL Cholesterol Direct|Grade 4	0			
Triglycerides|Grade 4	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with abnormal findings for urinalysis parameters through 96 weeks

End point title	Number of participants with abnormal findings for urinalysis parameters through 96 weeks

End point description:

Urine samples will be collected from participants for the analysis of urinalysis parameters including urinary glucose, urinary protein, and urine erythrocytes. Grades were defined based on numeric criteria as follows: Grade 1 - mild; Grade 2 - moderate; Grade 3 - severe or medically significant; Grade 4 - life-threatening consequences. Analysis was performed on the Safety population.

End point type	Secondary

End point timeframe:

Up to 96 weeks

End point values	DTG/3TC FDC			
Subject group type	Reporting group			
Number of subjects analysed	32			
Units: Participants				
Urinary Glucose|Grade 1	1			
Urinary Protein|Grade 1	3			
Urine Erythrocytes|Grade 1	2			
Urinary Glucose|Grade 2	0			
Urinary Protein|Grade 2	2			
Urine Erythrocytes|Grade 2	0			
Urinary Glucose|Grade 3	0			
Urinary Protein|Grade 3	0			
Urine Erythrocytes|Grade 3	0			
Urinary Glucose|Grade 4	0			
Urinary Protein|Grade 4	0			
Urine Erythrocytes|Grade 4	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants undergoing viral load monitoring from Week 48 through 144 weeks

End point title	Number of participants undergoing viral load monitoring from Week 48 through 144 weeks

End point description:

Viral load was defined as plasma HIV-RNA <50 copies per mL. Viral load monitoring of participants was performed from Week 48 through 144 weeks. Analysis was performed on the Safety population.

End point type	Secondary

End point timeframe:

Weeks 48, 60, 72, 84, 96, 108, 120, 132, and 144

End point values	DTG/3TC FDC			
Subject group type	Reporting group			
Number of subjects analysed	32			
Units: Participants				
Week 48	28			
Week 60	27			
Week 72	23			
Week 84	23			
Week 96	23			
Week 108	21			
Week 120	21			
Week 132	21			
Week 144	21			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in ratio of CD4+ and CD8+ at Weeks 24 and 48

End point title	Change from Baseline in ratio of CD4+ and CD8+ at Weeks 24 and 48

End point description:

Baseline value was defined as the latest pre-dose assessment with a non-missing value (Day 1). Change from Baseline was defined as post-dose visit value minus Baseline value.
Analysis was performed on the Intent-To-Treat Exposed. Only those participants with data available at specified time points were analyzed.
N = the number of participants analyzed at the specified timepoints.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Weeks 24 and 48

End point values	DTG/3TC FDC			
Subject group type	Reporting group			
Number of subjects analysed	32			
Units: Ratio				
median (inter-quartile range (Q1-Q3))				
Baseline (Day 1) (N = 32)	0.395 (0.33 to 0.64)			
Week 24 (N = 26)	0.215 (0.14 to 0.30)			
Week 48 (N = 28)	0.345 (0.24 to 0.49)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in CD8+ cell count at Weeks 24 and 48

End point title	Change from Baseline in CD8+ cell count at Weeks 24 and 48

End point description:

Baseline value was defined as the latest pre-dose assessment with a non-missing value (Day 1). Change from Baseline was defined as post-dose visit value minus Baseline value.
Analysis was performed on the Intent-To-Treat Exposed. Only those participants with data available at specified time points were analyzed.
N = the number of participants analyzed at the specified timepoints.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Weeks 24 and 48

End point values	DTG/3TC FDC			
Subject group type	Reporting group			
Number of subjects analysed	32			
Units: 10^6 cells per liter				
median (inter-quartile range (Q1-Q3))				
Baseline (Day 1) (N = 32)	828.000 (679.50 to 1031.50)			
Week 24 (N = 29)	-15.000 (-117.00 to 301.00)			
Week 48 (N = 28)	-78.500 (-243.00 to 176.00)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in cluster of differentiation 4+ (CD4+) cell count at Weeks 24 and 48

End point title	Change from Baseline in cluster of differentiation 4+ (CD4+) cell count at Weeks 24 and 48

End point description:

Baseline value was defined as the latest pre-dose assessment with a non-missing value (Day 1). Change from Baseline was defined as post-dose visit value minus Baseline value.
Analysis was performed on the Intent-To-Treat Exposed. Only those participants with data available at specified time points were analyzed.
N = the number of participants analyzed at the specified timepoints.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Weeks 24 and 48

End point values	DTG/3TC FDC			
Subject group type	Reporting group			
Number of subjects analysed	32			
Units: 10^6 cells per liter				
median (inter-quartile range (Q1-Q3))				
Baseline (Day 1) (N = 32)	371.500 (270.00 to 507.50)			
Week 24 (N = 29)	167.000 (103.00 to 319.00)			
Week 48 (N = 28)	223.500 (85.50 to 380.50)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with severity of adverse events from Week 24 through Week 48

End point title	Number of participants with severity of adverse events from Week 24 through Week 48

End point description:

AEs were evaluated by the investigator and graded according to the DAIDS toxicity scales as follows: Grade 1 - mild; Grade 2 - moderate; Grade 3 - severe or medically significant; Grade 4 - life-threatening consequences; Grade 5 - death. The higher the grade, the more severe the symptoms. Analysis was performed on the Safety population.

End point type	Secondary

End point timeframe:

Week 24 and up to Week 48

End point values	DTG/3TC FDC			
Subject group type	Reporting group			
Number of subjects analysed	32			
Units: Participants				
Grade 1 (Week 24)	9			
Grade 2 (Week 24)	13			
Grade 3 (Week 24)	1			
Grade 4 (Week 24)	0			
Grade 5 (Week 24)	0			
Grade 1 (Week 48)	11			
Grade 2 (Week 48)	16			
Grade 3 (Week 48)	1			
Grade 4 (Week 48)	0			
Grade 5 (Week 48)	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with any adverse events and serious adverse events from Week 24 through Week 48

End point title	Number of participants with any adverse events and serious adverse events from Week 24 through Week 48

End point description:

Analysis was performed on the Safety population.

End point type	Secondary

End point timeframe:

Week 24 and up to Week 48

End point values	DTG/3TC FDC			
Subject group type	Reporting group			
Number of subjects analysed	32			
Units: Participants				
AEs (Week 24)	23			
AEs (Week 48)	28			
SAEs (Week 24)	1			
SAEs (Week 48)	2			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with disease progression from Week 24 through Week 48

End point title	Number of participants with disease progression from Week 24 through Week 48

End point description:

Participants with disease progression included incidences of HIV-associated conditions, Acquired Immuno Deficiency Syndrome (AIDS) and death. HIV-associated conditions were assessed according to the 2014 HIV infection by Centers for Disease Control and Prevention (CDC) classification system for HIV Infection in adults to evaluate the immune effects of DTG /3TC FDC. Analysis was performed on the Safety population.

End point type	Secondary

End point timeframe:

Week 24 and up to Week 48

End point values	DTG/3TC FDC			
Subject group type	Reporting group			
Number of subjects analysed	32			
Units: Participants				
Week 24	0			
Week 48	1			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with abnormal findings for hematology parameters from Week 24 through Week 48

End point title	Number of participants with abnormal findings for hematology parameters from Week 24 through Week 48

End point description:

Blood samples were collected from participants for analysis of hematology parameters including hemoglobin, leukocytes and neutrophils. Grades were defined based on numeric criteria as follows: Grade 1 - mild; Grade 2 - moderate; Grade 3 - severe or medically significant; Grade 4 - life-threatening consequences. Analysis was performed on the Safety population.

End point type	Secondary

End point timeframe:

Week 24 and up to Week 48

End point values	DTG/3TC FDC			
Subject group type	Reporting group			
Number of subjects analysed	32			
Units: Participants				
Hemoglobin - Grade 1 (Week 24)	0			
Hemoglobin - Grade 2 (Week 24)	2			
Hemoglobin - Grade 3 (Week 24)	0			
Hemoglobin - Grade 4 (Week 24)	0			
Leukocytes - Grade 1 (Week 24)	1			
Leukocytes - Grade 2 (Week 24)	0			

Leukocytes - Grade 3 (Week 24)	0			
Leukocytes - Grade 4 (Week 24)	0			
Neutrophils - Grade 1 (Week 24)	0			
Neutrophils - Grade 2 (Week 24)	1			
Neutrophils - Grade 3 (Week 24)	0			
Neutrophils - Grade 4 (Week 24)	0			
Hemoglobin - Grade 1 (Week 48)	0			
Hemoglobin - Grade 2 (Week 48)	2			
Hemoglobin - Grade 3 (Week 48)	0			
Hemoglobin - Grade 4 (Week 48)	0			
Leukocytes - Grade 1 (Week 48)	2			
Leukocytes - Grade 2 (Week 48)	0			
Leukocytes - Grade 3 (Week 48)	0			
Leukocytes - Grade 4 (Week 48)	0			
Neutrophils - Grade 1 (Week 48)	0			
Neutrophils - Grade 2 (Week 48)	1			
Neutrophils - Grade 3 (Week 48)	0			
Neutrophils - Grade 4 (Week 48)	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with abnormal findings for clinical chemistry parameters from Week (W) 24 through Week 48

End point title	Number of participants with abnormal findings for clinical chemistry parameters from Week (W) 24 through Week 48

End point description:

Blood samples were collected from participants for analysis of clinical chemistry parameters including potassium, aspartate aminotransferase, creatinine, alanine aminotransferase, carbon dioxide, alkaline phosphatase, bilirubin, sodium, GFR from creatinine adjusted (adj) for BSA, calcium, and creatine kinase. Grades were defined based on numeric criteria as follows: Grade 1 - mild; Grade 2 - moderate; Grade 3 - severe or medically significant; Grade 4 - life-threatening consequences. Analysis was performed on the Safety population.

End point type	Secondary

End point timeframe:

Week 24 and up to Week 48

End point values	DTG/3TC FDC			
Subject group type	Reporting group			
Number of subjects analysed	32			
Units: Participants				
Alanine Aminotransferase - Grade 1 (Week 24)	1			
Alanine Aminotransferase - Grade 2 (Week 24)	0			
Alanine Aminotransferase - Grade 3 (Week 24)	0			

Alanine Aminotransferase - Grade 4 (Week 24)	0			
Alkaline Phosphatase - Grade 1 (Week 24)	1			
Alkaline Phosphatase - Grade 2 (Week 24)	2			
Alkaline Phosphatase - Grade 3 (Week 24)	0			
Alkaline Phosphatase - Grade 4 (Week 24)	0			
Aspartate Aminotransferase - Grade 1 (Week 24)	1			
Aspartate Aminotransferase - Grade 2 (Week 24)	0			
Aspartate Aminotransferase - Grade 3 (Week 24)	0			
Aspartate Aminotransferase - Grade 4 (Week 24)	0			
Bilirubin - Grade 1 (Week 24)	1			
Bilirubin - Grade 2 (Week 24)	0			
Bilirubin - Grade 3 (Week 24)	0			
Bilirubin - Grade 4 (Week 24)	0			
Calcium - Grade 1 (Week 24)	0			
Calcium - Grade 2 (Week 24)	1			
Calcium - Grade 3 (Week 24)	0			
Calcium - Grade 4 (Week 24)	1			
Carbon Dioxide - Grade 1 (Week 24)	11			
Carbon Dioxide - Grade 2 (Week 24)	4			
Carbon Dioxide - Grade 3 (Week 24)	0			
Carbon Dioxide - Grade 4 (Week 24)	2			
Creatine Kinase - Grade 1 (Week 24)	1			
Creatine Kinase - Grade 2 (Week 24)	0			
Creatine Kinase - Grade 3 (Week 24)	0			
Creatine Kinase - Grade 4 (Week 24)	0			
Creatinine - Grade 1 (Week 24)	1			
Creatinine - Grade 2 (Week 24)	0			
Creatinine - Grade 3 (Week 24)	0			
Creatinine - Grade 4 (Week 24)	0			
GFR from Creatinine Adj for BSA - Grade 1 (W 24)	0			
GFR from Creatinine Adj for BSA - Grade 2 (W 24)	12			
GFR from Creatinine Adj for BSA - Grade 3 (W 24)	3			
GFR from Creatinine Adj for BSA - Grade 4 (W 24)	0			
Potassium - Grade 1 (Week 24)	1			
Potassium - Grade 2 (Week 24)	0			
Potassium - Grade 3 (Week 24)	0			
Potassium - Grade 4 (Week 24)	0			
Sodium - Grade 1 (Week 24)	5			
Sodium - Grade 2 (Week 24)	1			
Sodium - Grade 3 (Week 24)	0			
Sodium - Grade 4 (Week 24)	0			
Alanine Aminotransferase - Grade 1 (Week 48)	1			

Alanine Aminotransferase - Grade 2 (Week 48)	0			
Alanine Aminotransferase - Grade 3 (Week 48)	0			
Alanine Aminotransferase - Grade 4 (Week 48)	0			
Alkaline Phosphatase - Grade 1 (Week 48)	1			
Alkaline Phosphatase - Grade 2 (Week 48)	2			
Alkaline Phosphatase - Grade 3 (Week 48)	0			
Alkaline Phosphatase - Grade 4 (Week 48)	0			
Aspartate Aminotransferase - Grade 1 (Week 48)	1			
Aspartate Aminotransferase - Grade 2 (Week 48)	0			
Aspartate Aminotransferase - Grade 3 (Week 48)	0			
Aspartate Aminotransferase - Grade 4 (Week 48)	0			
Bilirubin - Grade 1 (Week 48)	1			
Bilirubin - Grade 2 (Week 48)	0			
Bilirubin - Grade 3 (Week 48)	0			
Bilirubin - Grade 4 (Week 48)	0			
Calcium - Grade 1 (Week 48)	0			
Calcium - Grade 2 (Week 48)	1			
Calcium - Grade 3 (Week 48)	0			
Calcium - Grade 4 (Week 48)	1			
Carbon Dioxide - Grade 1 (Week 48)	12			
Carbon Dioxide - Grade 2 (Week 48)	5			
Carbon Dioxide - Grade 3 (Week 48)	0			
Carbon Dioxide - Grade 4 (Week 48)	2			
Creatine Kinase - Grade 1 (Week 48)	1			
Creatine Kinase - Grade 2 (Week 48)	0			
Creatine Kinase - Grade 3 (Week 48)	0			
Creatine Kinase - Grade 4 (Week 48)	0			
Creatinine - Grade 1 (Week 48)	2			
Creatinine - Grade 2 (Week 48)	0			
Creatinine - Grade 3 (Week 48)	0			
Creatinine - Grade 4 (Week 48)	0			
GFR from Creatinine Adj for BSA - Grade 1 (W 48)	0			
GFR from Creatinine Adj for BSA - Grade 2 (W 48)	13			
GFR from Creatinine Adj for BSA - Grade 3 (W 48)	6			
GFR from Creatinine Adj for BSA - Grade 4 (W 48)	0			
Potassium - Grade 1 (Week 48)	1			
Potassium - Grade 2 (Week 48)	0			
Potassium - Grade 3 (Week 48)	0			
Potassium - Grade 4 (Week 48)	0			
Sodium - Grade 1 (Week 48)	5			
Sodium - Grade 2 (Week 48)	1			
Sodium - Grade 3 (Week 48)	0			

Sodium - Grade 4 (Week 48)	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with abnormal findings for fasting lipids from Week 24 through Week 48

End point title	Number of participants with abnormal findings for fasting lipids from Week 24 through Week 48

End point description:

Lipid assessments including cholesterol, LDL cholesterol, LDL cholesterol calculation, LDL cholesterol direct, and triglycerides were performed. Grades were defined based on numeric criteria as follows: Grade 1 - mild; Grade 2 - moderate; Grade 3 - severe or medically significant; Grade 4 - life-threatening consequences. Analysis was performed on the Safety population.

End point type	Secondary

End point timeframe:

Week 24 and up to Week 48

End point values	DTG/3TC FDC			
Subject group type	Reporting group			
Number of subjects analysed	32			
Units: Participants				
Cholesterol - Grade 1 (Week 24)	2			
Cholesterol - Grade 2 (Week 24)	0			
Cholesterol - Grade 3 (Week 24)	0			
Cholesterol - Grade 4 (Week 24)	0			
LDL cholesterol - Grade 1 (Week 24)	1			
LDL cholesterol - Grade 2 (Week 24)	0			
LDL cholesterol - Grade 3 (Week 24)	0			
LDL cholesterol - Grade 4 (Week 24)	0			
Triglycerides - Grade 1 (Week 24)	1			
Triglycerides - Grade 2 (Week 24)	0			
Triglycerides - Grade 3 (Week 24)	0			
Triglycerides - Grade 4 (Week 24)	0			
Cholesterol - Grade 1 (Week 48)	5			
Cholesterol - Grade 2 (Week 48)	1			
Cholesterol - Grade 3 (Week 48)	0			
Cholesterol - Grade 4 (Week 48)	0			
LDL cholesterol - Grade 1 (Week 48)	1			
LDL cholesterol - Grade 2 (Week 48)	0			
LDL cholesterol - Grade 3 (Week 48)	0			
LDL cholesterol - Grade 4 (Week 48)	0			
Triglycerides - Grade 1 (Week 48)	1			
Triglycerides - Grade 2 (Week 48)	0			

Triglycerides - Grade 3 (Week 48)	0			
Triglycerides - Grade 4 (Week 48)	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with abnormal findings for urinalysis parameters from Week 24 through Week 48

End point title	Number of participants with abnormal findings for urinalysis parameters from Week 24 through Week 48

End point description:

Urine samples will be collected from participants for the analysis of urinalysis parameters including urinary glucose, urinary protein, and urine erythrocytes. Grades were defined based on numeric criteria as follows: Grade 1 - mild; Grade 2 - moderate; Grade 3 - severe or medically significant; Grade 4 - life-threatening consequences. Analysis was performed on the Safety population.

End point type	Secondary

End point timeframe:

Week 24 and up to Week 48

End point values	DTG/3TC FDC			
Subject group type	Reporting group			
Number of subjects analysed	32			
Units: Participants				
Urinary Glucose - Grade 1 (Week 24)	0			
Urinary Glucose - Grade 2 (Week 24)	0			
Urinary Glucose - Grade 3 (Week 24)	0			
Urinary Glucose - Grade 4 (Week 24)	0			
Urinary Protein - Grade 1 (Week 24)	0			
Urinary Protein - Grade 2 (Week 24)	0			
Urinary Protein - Grade 3 (Week 24)	0			
Urinary Protein - Grade 4 (Week 24)	0			
Urinary Glucose - Grade 1 (Week 48)	1			
Urinary Glucose - Grade 2 (Week 48)	0			
Urinary Glucose - Grade 3 (Week 48)	0			
Urinary Glucose - Grade 4 (Week 48)	0			
Urinary Protein - Grade 1 (Week 48)	1			
Urinary Protein - Grade 2 (Week 48)	1			
Urinary Protein - Grade 3 (Week 48)	0			
Urinary Protein - Grade 4 (Week 48)	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Maximum observed plasma concentration (Cmax) following dosing with DTG and 3TC

End point title	Maximum observed plasma concentration (Cmax) following dosing with DTG and 3TC

End point description:

Blood samples were collected on a subset of participants for intensive pharmacokinetic analysis. Intensive Pharmacokinetic Population includes all participants who received at least 1 dose of DTG/3TC FDC and have evaluable drug concentrations reported, where samples are collected according to the intensive sampling schedule.

End point type	Secondary

End point timeframe:

Pre-dose, 0.5, 1.0, 1.5, 2, 3, 4, 6, 10, and 24 hours post-dose at Week 1

End point values	DTG/3TC FDC			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: Nanogram per milliliter (ng/mL)				
geometric mean (geometric coefficient of variation)				
Maximum observed plasma concentration - DTG	5354.870 (± 25.02)			
Maximum observed plasma concentration - 3TC	2778.555 (± 27.80)			

Statistical analyses

No statistical analyses for this end point

Secondary: Area under the plasma concentration-time curve from time zero (pre-dose) to last time of quantifiable concentration (AUC[0-t]) following dosing with DTG and 3TC

End point title	Area under the plasma concentration-time curve from time zero (pre-dose) to last time of quantifiable concentration (AUC[0-t]) following dosing with DTG and 3TC

End point description:

Blood samples were collected on a subset of participants for intensive pharmacokinetic analysis. Analysis was performed on the Intensive Pharmacokinetic Population.

End point type	Secondary

End point timeframe:

Pre-dose, 0.5, 1.0, 1.5, 2, 3, 4, 6, 10, and 24 hours post-dose at Week 1

End point values	DTG/3TC FDC			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: hours*nanogram per milliliter (h*ng/mL)				
geometric mean (geometric coefficient of variation)				
AUC[0-t] - DTG	74001.76 (± 23.2)			
AUC[0-t] - 3TC	12277.62 (± 17.7)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants who discontinued treatment due to adverse events from Week 24 through Week 48

End point title	Number of participants who discontinued treatment due to adverse events from Week 24 through Week 48

End point description:

Analysis was performed on the Safety population.

End point type	Secondary

End point timeframe:

Week 24 and up to Week 48

End point values	DTG/3TC FDC			
Subject group type	Reporting group			
Number of subjects analysed	32			
Units: Participants				
Week 24	1			
Week 48	1			

Statistical analyses

No statistical analyses for this end point

Secondary: Time of maximum observed plasma concentration (Tmax) following dosing with DTG and 3TC

End point title	Time of maximum observed plasma concentration (Tmax) following dosing with DTG and 3TC

End point description:

Blood samples were collected on a subset of participants for intensive pharmacokinetic analysis. Analysis was performed on the Intensive Pharmacokinetic Population.

End point type	Secondary

End point timeframe:

Pre-dose, 0.5, 1.0, 1.5, 2, 3, 4, 6, 10, and 24 hours post-dose at Week 1

End point values	DTG/3TC FDC			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: Hours				
median (full range (min-max))				
DTG	2.000 (1.00 to 3.00)			
3TC	1.000 (1.00 to 3.00)			

Statistical analyses

No statistical analyses for this end point

Secondary: Area under the curve (AUC) over the dosing interval (AUC[0-tau]) following dosing with DTG and 3TC

End point title	Area under the curve (AUC) over the dosing interval (AUC[0-tau]) following dosing with DTG and 3TC

End point description:

Blood samples were collected on a subset of participants for intensive pharmacokinetic analysis. Analysis was performed on the Intensive Pharmacokinetic Population.

End point type	Secondary

End point timeframe:

Pre-dose, 0.5, 1.0, 1.5, 2, 3, 4, 6, 10, and 24 hours post-dose at Week 1

End point values	DTG/3TC FDC			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: hours*nanogram per milliliter (h*ng/mL)				
geometric mean (geometric coefficient of variation)				
AUC[0-tau] - DTG	74001.76 (± 23.2)			
AUC[0-tau] - 3TC	12277.62 (± 17.7)			

Statistical analyses

No statistical analyses for this end point

Secondary: Apparent terminal half-life (t1/2) following dosing with DTG and 3TC

End point title	Apparent terminal half-life (t1/2) following dosing with DTG and 3TC

End point description:

Blood samples were collected on a subset of participants for intensive pharmacokinetic analysis. Analysis was performed on the Intensive Pharmacokinetic Population.

End point type	Secondary

End point timeframe:

Pre-dose, 0.5, 1.0, 1.5, 2, 3, 4, 6, 10, and 24 hours post-dose at Week 1

End point values	DTG/3TC FDC			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: Hours				
geometric mean (geometric coefficient of variation)				
Apparent terminal half-life - DTG	12.910 (± 15.35)			
Apparent terminal half-life - 3TC	4.823 (± 13.26)			

Statistical analyses

No statistical analyses for this end point

Secondary: Observed plasma concentration at 24 hours following dosing with DTG and 3TC

End point title	Observed plasma concentration at 24 hours following dosing with DTG and 3TC

End point description:

Blood samples were collected on a subset of participants for intensive pharmacokinetic analysis. Analysis was performed on the Intensive Pharmacokinetic Population.

End point type	Secondary

End point timeframe:

24 hours post-dose at Week 1

End point values	DTG/3TC FDC			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: ng/mL				
geometric mean (geometric coefficient of variation)				

DTG 3TC	1635.606 (± 25.36) 53.453 (± 33.42)			

Statistical analyses

No statistical analyses for this end point

Secondary: Observed pre-dose plasma concentration following dosing with DTG and 3TC

End point title	Observed pre-dose plasma concentration following dosing with DTG and 3TC

End point description:

Blood samples were collected on a subset of participants for intensive pharmacokinetic analysis. Analysis was performed on the Intensive Pharmacokinetic Population.

End point type	Secondary

End point timeframe:

Pre-dose at Week 1

End point values	DTG/3TC FDC			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
DTG 3TC	1636.791 (± 39.26) 51.073 (± 60.88)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with observed genotypic resistance to DTG and 3TC

End point title	Number of participants with observed genotypic resistance to DTG and 3TC

End point description:

Protocol-defined confirmed virologic withdrawal (CVW) through Week 144 was low with 1 participant meeting CVW criteria. Resistance testing failed, and therefore no genotypic data were available for this participant at the time of virologic failure.
The analysis used the CVW population, comprising ITT-E participants meeting CVW criteria: confirmed virologic non-response (HIV-1 RNA <1 log10 c/mL at/after Week 12 or =200 c/mL at/after Week 24) or confirmed rebound (HIV-1 RNA =200 c/mL after prior suppression <200 c/mL).

End point type	Secondary

End point timeframe:

Up to 144 weeks

End point values	DTG/3TC FDC			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: Participants	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with observed phenotypic resistance to DTG and 3TC

End point title	Number of participants with observed phenotypic resistance to DTG and 3TC

End point description:

Protocol-defined CVW through Week 144 was low with 1 participant meeting CVW criteria. Resistance testing failed, and therefore no phenotypic data were available for this participant at the time of virologic failure.
The analysis used the CVW population.

End point type	Secondary

End point timeframe:

Up to 144 weeks

End point values	DTG/3TC FDC			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: Participants	0			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
All-Cause mortality, Non-SAEs and SAEs were collected from Day 1 up to Week 144	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	28.0

Reporting groups	
Reporting group title	DTG/3TC FDC
Reporting group description:	
Participants received dolutegravir/lamivudine (DTG/3TC) (50/300 (mg) Fixed Dose Combination (FDC) tablets orally once daily through Week 48.	

Serious adverse events	DTG/3TC FDC		
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 32 (15.63%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Vulvovaginal warts			
subjects affected / exposed	1 / 32 (3.13%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Postoperative wound complication			
subjects affected / exposed	1 / 32 (3.13%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Eye disorders			
Ulcerative keratitis			
subjects affected / exposed	1 / 32 (3.13%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Major depression			

subjects affected / exposed	1 / 32 (3.13%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Anal abscess			
subjects affected / exposed	1 / 32 (3.13%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Orchitis			
subjects affected / exposed	1 / 32 (3.13%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	DTG/3TC FDC		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	29 / 32 (90.63%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Anogenital warts			
subjects affected / exposed	2 / 32 (6.25%)		
occurrences (all)	2		
General disorders and administration site conditions			
Influenza like illness			
subjects affected / exposed	3 / 32 (9.38%)		
occurrences (all)	6		
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	2 / 32 (6.25%)		
occurrences (all)	2		
Respiratory, thoracic and mediastinal disorders			
Allergic cough			
subjects affected / exposed	2 / 32 (6.25%)		
occurrences (all)	2		
Rhinitis allergic			

subjects affected / exposed occurrences (all) Cough subjects affected / exposed occurrences (all)	2 / 32 (6.25%) 2 4 / 32 (12.50%) 4		
Psychiatric disorders Suicidal ideation subjects affected / exposed occurrences (all) Depression subjects affected / exposed occurrences (all)	 2 / 32 (6.25%) 2 2 / 32 (6.25%) 2		
Investigations Glomerular filtration rate decreased subjects affected / exposed occurrences (all)	 2 / 32 (6.25%) 3		
Injury, poisoning and procedural complications Immunisation reaction subjects affected / exposed occurrences (all)	 2 / 32 (6.25%) 3		
Nervous system disorders Headache subjects affected / exposed occurrences (all)	 4 / 32 (12.50%) 5		
Gastrointestinal disorders Aphthous ulcer subjects affected / exposed occurrences (all) Food poisoning subjects affected / exposed occurrences (all) Diarrhoea subjects affected / exposed occurrences (all)	 2 / 32 (6.25%) 3 2 / 32 (6.25%) 3 2 / 32 (6.25%) 2		
Skin and subcutaneous tissue disorders			

Dermatitis allergic			
subjects affected / exposed	2 / 32 (6.25%)		
occurrences (all)	2		
Acne			
subjects affected / exposed	2 / 32 (6.25%)		
occurrences (all)	2		
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	2 / 32 (6.25%)		
occurrences (all)	3		
Myalgia			
subjects affected / exposed	2 / 32 (6.25%)		
occurrences (all)	3		
Infections and infestations			
Pharyngitis			
subjects affected / exposed	5 / 32 (15.63%)		
occurrences (all)	5		
Genital herpes			
subjects affected / exposed	2 / 32 (6.25%)		
occurrences (all)	2		
Upper respiratory tract infection			
subjects affected / exposed	6 / 32 (18.75%)		
occurrences (all)	7		
Folliculitis			
subjects affected / exposed	3 / 32 (9.38%)		
occurrences (all)	3		
Vulvovaginal candidiasis			
subjects affected / exposed	2 / 32 (6.25%)		
occurrences (all)	2		
Nasopharyngitis			
subjects affected / exposed	8 / 32 (25.00%)		
occurrences (all)	10		
Urinary tract infection			
subjects affected / exposed	2 / 32 (6.25%)		
occurrences (all)	2		
Tonsillitis			

subjects affected / exposed	3 / 32 (9.38%)		
occurrences (all)	3		
Herpes zoster			
subjects affected / exposed	2 / 32 (6.25%)		
occurrences (all)	2		
COVID-19			
subjects affected / exposed	10 / 32 (31.25%)		
occurrences (all)	16		
Secondary syphilis			
subjects affected / exposed	3 / 32 (9.38%)		
occurrences (all)	4		
Urethritis			
subjects affected / exposed	2 / 32 (6.25%)		
occurrences (all)	2		
Impetigo			
subjects affected / exposed	2 / 32 (6.25%)		
occurrences (all)	2		
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	2 / 32 (6.25%)		
occurrences (all)	2		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
13 June 2018	The amendment was developed in order to reinforce the importance of pregnancy avoidance and contraception requirements.
12 November 2019	The amendment was developed to incorporate a Continuation Phase to enable post study drug provision for eligible participants who may benefit from continued treatment.
20 November 2020	The amendment was developed to include stepwise instruction, based on severity grade, for confirmatory testing and assessment, and parameters for temporary holding or permanent discontinuation of study treatment, in order to to clarify and simplify participant management.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported