Clinical trial results:
A Phase 3 Randomized, Active-Controlled, Double-Blind Clinical Study to Evaluate the Antiretroviral Activity, Safety, and Tolerability of Doravirine/Islatravir Once-Daily in HIV-1 Infected Treatment-Naïve Participants

Summary

EudraCT number	2019-000590-23
Trial protocol	ES FR DE IT
Global end of trial date	29 January 2025

Results information

Result version number	v1 (current)
This version publication date	25 January 2026
First version publication date	25 January 2026

Trial information

Trial identification

Sponsor protocol code	MK-8591A-020

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04233879
WHO universal trial number (UTN)	-
Other trial identifiers	jRCT: jRCT2031210024

Notes:

Sponsors

Sponsor organisation name	Merck Sharp & Dohme LLC
Sponsor organisation address	126 East Lincoln Avenue, P.O. Box 2000, Rahway, United States, 07065
Public contact	Clinical Trials Disclosure, Merck Sharp & Dohme LLC, ClinicalTrialsDisclosure@msd.com
Scientific contact	Clinical Trials Disclosure, Merck Sharp & Dohme LLC, ClinicalTrialsDisclosure@msd.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?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	29 January 2025
Is this the analysis of the primary completion data?	Yes
Primary completion date	17 November 2022
Global end of trial reached?	Yes
Global end of trial date	29 January 2025
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

This is a phase 3, randomized, controlled, double-blind, multisite clinical study of a once-daily fixed dose combination (FDC) of 100 mg doravirine/0.75 mg islatravir (DOR/ISL [also known as MK-8591A]) in treatment-naïve participants living with human immunodeficiency virus type-1 (HIV-1) infection. The primary objectives are to evaluate the antiretroviral activity, safety, and tolerability of DOR/ISL compared to bictegravir/emtricitabine/tenofovir alafenamide (BIC/FTC/TAF). The primary hypothesis is that DOR/ISL is noninferior or superior to BIC/FTC/TAF treatment based on the percentage of participants with HIV-1 ribonucleic acid (RNA) <50 copies/mL at Week 48.

Protection of trial subjects:

This study was conducted in conformance with Good Clinical Practice standards and applicable country and/or local statutes and regulations regarding ethical committee review, informed consent, and the protection of human subjects participating in biomedical research.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	28 February 2020
Long term follow-up planned	Yes
Long term follow-up rationale	Safety
Long term follow-up duration	27 Months
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Argentina: 35
Country: Number of subjects enrolled	Canada: 23
Country: Number of subjects enrolled	Chile: 67
Country: Number of subjects enrolled	Colombia: 37
Country: Number of subjects enrolled	France: 41
Country: Number of subjects enrolled	Germany: 26
Country: Number of subjects enrolled	Israel: 23
Country: Number of subjects enrolled	Italy: 31
Country: Number of subjects enrolled	Japan: 16
Country: Number of subjects enrolled	South Africa: 108
Country: Number of subjects enrolled	Spain: 76
Country: Number of subjects enrolled	Taiwan: 4
Country: Number of subjects enrolled	United States: 112

Worldwide total number of subjects	599
EEA total number of subjects	174

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)	0
Adults (18-64 years)	594
From 65 to 84 years	5
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Treatment-naïve participants living with Human Immunodeficiency Virus-1 (HIV-1) that had not received ≤10 days of prior antiretroviral therapy were enrolled.

Pre-assignment

Screening details:

A total of 599 participants were randomized in the study and 597 received at least 1 dose of study intervention. The safety analyses were conducted using all participants as treated population, which included all randomized participants who received at least 1 dose of study intervention.

Period 1

Period 1 title	Base Study (Day 1 to Week 144)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Group 1: DOR/ISL

Arm description:

Treatment-naïve participants living with human immunodeficiency virus-1 (HIV-1) that had not received ≤10 days of prior antiretroviral therapy received blinded fixed dose combination (FDC) Doravirine/Islatravir (DOR/ISL) (100 mg doravirine [DOR]/0.75 mg islatravir [ISL]) and placebo to Bictegravir/Tenofovir Alafenamide/Emtricitabine (BIC/FTC/TAF) once daily (QD) from Day 1 to Week 96, and open-label DOR/ISL up to Week 144. At Week 144, participants who consent to enter the optional open-label study extension continued to receive open-label QD FDC of DOR/ISL (100 mg/0.75 mg) for an additional 24 weeks, up to Week 168.

Arm type	Experimental
Investigational medicinal product name	doravirine (DOR)/islatravir (ISL)
Investigational medicinal product code	
Other name	MK-8591A
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

100 mg DOR/0.75 mg ISL fixed dose combination (FDC) single tablet taken once daily by mouth.

Investigational medicinal product name	Placebo to fixed dose combination (FDC) DOR/ISL
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Placebo to FDC DOR/ISL in a single tablet taken orally, once daily

Investigational medicinal product name	Placebo to BIC/FTC/TAF
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Placebo to BIC/FTC/TAF in a single tablet taken orally, once daily.

Arm title	Group 2: BIC/FTC/TAF

Arm description:

Treatment-naïve participants living with HIV-1 that had not received ≤10 days of prior antiretroviral therapy received blinded BIC/FTC/TAF (50 mg bictegravir [BIC], 200 mg emtricitabine [FTC], 25 mg tenofovir alafenamide [TAF]) and placebo to FDC DOR/ISL QD from Day 1 to Week 96, and open-label BIC/FTC/TAF up to Week 144. At Week 144, participants who consent to enter the optional open-label study extension continued to receive QD BIC/FTC/TAF (50 mg/200 mg/25 mg) for an additional 24 weeks, up to Week 168.

Arm type	Active comparator
Investigational medicinal product name	Bictegravir (BIC)/emtricitabine (FTC)/tenofovir alafenamide (TAF)
Investigational medicinal product code	
Other name	Bictegravir/emtricitabine/tenofovir alafenamide (BIC/FTC/TAF)
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

50 mg BIC, 200 mg FTC, and 25 mg TAF combined in a single tablet, taken orally once daily.

Number of subjects in period 1	Group 1: DOR/ISL	Group 2: BIC/FTC/TAF
Started	298	301
Treated	298	299
Completed	59	34
Not completed	239	267
Adverse event, serious fatal	3	-
Physician decision	11	7
Consent withdrawn by subject	35	34
Unknown	6	30
Sponsor Decision	168	179
Lost to follow-up	16	17

Period 2

Period 2 title	Extension Study (Week 144 to 168)
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Group 1: DOR/ISL

Arm description:

Treatment-naïve participants living with human immunodeficiency virus-1 (HIV-1) that had not received ≤10 days of prior antiretroviral therapy received blinded fixed dose combination (FDC) Doravirine/Islatravir (DOR/ISL) (100 mg doravirine [DOR]/0.75 mg islatravir [ISL]) and placebo to Bictegravir/Tenofovir Alafenamide/Emtricitabine (BIC/FTC/TAF) once daily (QD) from Day 1 to Week 96, and open-label DOR/ISL up to Week 144. At Week 144, participants who consent to enter the optional open-label study extension continued to receive open-label QD FDC of DOR/ISL (100 mg/0.75 mg) for

an additional 24 weeks, up to Week 168.

Arm type	Experimental
Investigational medicinal product name	doravirine (DOR)/islatravir (ISL)
Investigational medicinal product code	
Other name	MK-8591A
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

100 mg DOR/0.75 mg ISL fixed dose combination (FDC) single tablet taken once daily by mouth.

Arm title	Group 2: BIC/FTC/TAF

Arm description:

Treatment-naïve participants living with HIV-1 that had not received ≤10 days of prior antiretroviral therapy received blinded BIC/FTC/TAF (50 mg bictegravir [BIC], 200 mg emtricitabine [FTC], 25 mg tenofovir alafenamide [TAF]) and placebo to FDC DOR/ISL QD from Day 1 to Week 96, and open-label BIC/FTC/TAF up to Week 144. At Week 144, participants who consent to enter the optional open-label study extension continued to receive QD BIC/FTC/TAF (50 mg/200 mg/25 mg) for an additional 24 weeks, up to Week 168.

Arm type	Active comparator
Investigational medicinal product name	Bictegravir (BIC)/emtricitabine (FTC)/tenofovir alafenamide (TAF)
Investigational medicinal product code	
Other name	Bictegravir/emtricitabine/tenofovir alafenamide (BIC/FTC/TAF)
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

50 mg BIC, 200 mg FTC, and 25 mg TAF combined in a single tablet, taken orally once daily.

Number of subjects in period 2[1]	Group 1: DOR/ISL	Group 2: BIC/FTC/TAF
Started	21	27
Completed	0	1
Not completed	21	26
Consent withdrawn by subject	1	-
Sponsor Decision	20	25
Lost to follow-up	-	1

Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.
Justification: Subset of participants who completed the base study may have been eligible to enter the study extension. The extension was optional, and, in many cases, participants declined or chose to switch to another study.

Baseline characteristics

Reporting groups	
Reporting group title	Group 1: DOR/ISL
Reporting group description:	
Treatment-naïve participants living with human immunodeficiency virus-1 (HIV-1) that had not received ≤10 days of prior antiretroviral therapy received blinded fixed dose combination (FDC) Doravirine/Islatravir (DOR/ISL) (100 mg doravirine [DOR]/0.75 mg islatravir [ISL]) and placebo to Bictegravir/Tenofovir Alafenamide/Emtricitabine (BIC/FTC/TAF) once daily (QD) from Day 1 to Week 96, and open-label DOR/ISL up to Week 144. At Week 144, participants who consent to enter the optional open-label study extension continued to receive open-label QD FDC of DOR/ISL (100 mg/0.75 mg) for an additional 24 weeks, up to Week 168.	
Reporting group title	Group 2: BIC/FTC/TAF
Reporting group description:	
Treatment-naïve participants living with HIV-1 that had not received ≤10 days of prior antiretroviral therapy received blinded BIC/FTC/TAF (50 mg bictegravir [BIC], 200 mg emtricitabine [FTC], 25 mg tenofovir alafenamide [TAF]) and placebo to FDC DOR/ISL QD from Day 1 to Week 96, and open-label BIC/FTC/TAF up to Week 144. At Week 144, participants who consent to enter the optional open-label study extension continued to receive QD BIC/FTC/TAF (50 mg/200 mg/25 mg) for an additional 24 weeks, up to Week 168.	

Reporting group values	Group 1: DOR/ISL	Group 2: BIC/FTC/TAF	Total
Number of subjects	298	301	599
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	295	299	594
From 65-84 years	3	2	5
85 years and over	0	0	0
Age Continuous Units: Years			
arithmetic mean	34.7	35.7	
standard deviation	± 11.0	± 10.9	-
Sex: Female, Male Units: Participants			
Female	77	71	148
Male	221	230	451
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	2	2	4
Asian	16	20	36
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	86	90	176
White	171	169	340
More than one race	23	19	42

Unknown or Not Reported	0	1	1
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	123	112	235
Not Hispanic or Latino	171	184	355
Unknown or Not Reported	4	5	9
Baseline Human Immunodeficiency Virus (HIV)-1 Ribonucleic Acid (RNA) Level			
The Abbott RealTime polymerase chain reaction (PCR) assay with a reliable lower limit of quantification of 40 copies/mL was used to measure the HIV-1 RNA level in blood samples obtained at each visit. Participants were stratified into the following baseline HIV-1 RNA levels: ≤100,000 copies/mL, >100,000 copies/mL or missing.			
Units: Subjects			
≤100,000 copies/mL	244	239	483
>100,000 copies/mL	54	60	114
Missing	0	2	2
Baseline Cluster of Differentiation 4+ (CD4+) T-Cell Count			
Plasma CD4+ T-cell count was measured in cells/mm^3 for baseline by a central laboratory. Baseline measurements were defined as the Day 1 value of each participant. Participants were stratified into the following baseline CD4+ T-cell counts: <200 cells/mm^3, ≥200 cells/mm^3, or missing.			
Units: Subjects			
<200 cells/mm^3	61	60	121
≥200 cells/mm^3	237	239	476
Missing	0	2	2

End points

End points reporting groups

Reporting group title	Group 1: DOR/ISL

Reporting group description:

Treatment-naïve participants living with human immunodeficiency virus-1 (HIV-1) that had not received ≤10 days of prior antiretroviral therapy received blinded fixed dose combination (FDC) Doravirine/Islatravir (DOR/ISL) (100 mg doravirine [DOR]/0.75 mg islatravir [ISL]) and placebo to Bictegravir/Tenofovir Alafenamide/Emtricitabine (BIC/FTC/TAF) once daily (QD) from Day 1 to Week 96, and open-label DOR/ISL up to Week 144. At Week 144, participants who consent to enter the optional open-label study extension continued to receive open-label QD FDC of DOR/ISL (100 mg/0.75 mg) for an additional 24 weeks, up to Week 168.

Reporting group title	Group 2: BIC/FTC/TAF

Reporting group description:

Treatment-naïve participants living with HIV-1 that had not received ≤10 days of prior antiretroviral therapy received blinded BIC/FTC/TAF (50 mg bictegravir [BIC], 200 mg emtricitabine [FTC], 25 mg tenofovir alafenamide [TAF]) and placebo to FDC DOR/ISL QD from Day 1 to Week 96, and open-label BIC/FTC/TAF up to Week 144. At Week 144, participants who consent to enter the optional open-label study extension continued to receive QD BIC/FTC/TAF (50 mg/200 mg/25 mg) for an additional 24 weeks, up to Week 168.

Reporting group title	Group 1: DOR/ISL

Reporting group description:

Treatment-naïve participants living with human immunodeficiency virus-1 (HIV-1) that had not received ≤10 days of prior antiretroviral therapy received blinded fixed dose combination (FDC) Doravirine/Islatravir (DOR/ISL) (100 mg doravirine [DOR]/0.75 mg islatravir [ISL]) and placebo to Bictegravir/Tenofovir Alafenamide/Emtricitabine (BIC/FTC/TAF) once daily (QD) from Day 1 to Week 96, and open-label DOR/ISL up to Week 144. At Week 144, participants who consent to enter the optional open-label study extension continued to receive open-label QD FDC of DOR/ISL (100 mg/0.75 mg) for an additional 24 weeks, up to Week 168.

Reporting group title	Group 2: BIC/FTC/TAF

Reporting group description:

Treatment-naïve participants living with HIV-1 that had not received ≤10 days of prior antiretroviral therapy received blinded BIC/FTC/TAF (50 mg bictegravir [BIC], 200 mg emtricitabine [FTC], 25 mg tenofovir alafenamide [TAF]) and placebo to FDC DOR/ISL QD from Day 1 to Week 96, and open-label BIC/FTC/TAF up to Week 144. At Week 144, participants who consent to enter the optional open-label study extension continued to receive QD BIC/FTC/TAF (50 mg/200 mg/25 mg) for an additional 24 weeks, up to Week 168.

Primary: Percentage of Participants with Human Immunodeficiency Virus (HIV)-1 Ribonucleic Acid (RNA) <50 Copies/mL at Week 48

End point title	Percentage of Participants with Human Immunodeficiency Virus (HIV)-1 Ribonucleic Acid (RNA) <50 Copies/mL at Week 48

End point description:

The Abbott RealTime polymerase chain reaction (PCR) assay with a reliable lower limit of quantification of 40 copies/mL was used to measure the HIV-1 RNA level in blood samples obtained at each visit. The percentage of participants with HIV-1 RNA <50 copies/mL at Week 48 was presented using the Food and Drug Administration (FDA) Snapshot missing data approach. The analysis population consisted of all randomized participants who received at least one dose of study intervention. Participants were included in the treatment group to which they were randomized. The final analysis for this outcome is presented here.

End point type	Primary

End point timeframe:

Week 48

End point values	Group 1: DOR/ISL	Group 2: BIC/FTC/TAF		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	298	299		
Units: Percentage of participants				
number (not applicable)	88.9	88.3		

Statistical analyses

Statistical analysis title	Difference between treatment groups
Comparison groups	Group 2: BIC/FTC/TAF v Group 1: DOR/ISL
Number of subjects included in analysis	597
Analysis specification	Pre-specified
Analysis type	non-inferiority[1]
Parameter estimate	Treatment Difference
Point estimate	0.46
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.73
upper limit	5.6

Notes:

[1] - Non-inferiority was concluded if the upper bound of the 2-sided multiplicity-adjusted 95% confidence interval (95%CI) was less than 10 percentage points. Estimated differences, CIs, & p-value for treatment differences in percent response were calculated using Miettinen & Nurminen method stratified by stratum with CMH weights; multiplicity-adjusted 95% CI corresponds to 1-sided Type 1 error of 0.02495

Primary: Percentage of Participants Who Experienced an Adverse Event (AE) up to Week 48

End point title	Percentage of Participants Who Experienced an Adverse Event (AE) up to Week 48

End point description:

An AE was any untoward medical occurrence in a study participant administered a study drug, which does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of the study drug whether or not it is considered related to the study drug. The percentage of participants who experienced at least one AE up to Week 48 was reported. The analysis population consisted of all randomized participants who received at least one dose of study intervention. Participants were included in the treatment group corresponding to the study intervention received. The final analysis for this outcome is presented here.

End point type	Primary

End point timeframe:

Up to approximately 48 weeks

End point values	Group 1: DOR/ISL	Group 2: BIC/FTC/TAF		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	298	299		
Units: Percentage of participants				
number (not applicable)	90.6	86.3		

Statistical analyses

Statistical analysis title	Difference between treatment groups
Comparison groups	Group 1: DOR/ISL v Group 2: BIC/FTC/TAF
Number of subjects included in analysis	597
Analysis specification	Pre-specified
Analysis type	other[2]
Parameter estimate	Percentage Difference
Point estimate	4.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.8
upper limit	9.6

Notes:

[2] - Difference between treatment groups (Group 1: DOR/ISL and Group 2: BIC/FTC/TAF). Miettinen & Nurminen method was used to generate percentage difference and the associated 95%CI.

Primary: Percentage of Participants Who Discontinued Study Treatment Due to an AE up to Week 48

End point title	Percentage of Participants Who Discontinued Study Treatment Due to an AE up to Week 48

End point description:

An AE was any untoward medical occurrence in a study participant administered a study drug, which does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of the study drug whether or not it is considered related to the study drug. The percentage of participants who discontinued study treatment due to an AE up to Week 48 were reported. The analysis population consisted of all randomized participants who received at least one dose of study intervention. Participants were included in the treatment group corresponding to the study intervention received. The final analysis for this outcome is presented here.

End point type	Primary

End point timeframe:

Up to approximately 48 weeks

End point values	Group 1: DOR/ISL	Group 2: BIC/FTC/TAF		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	298	299		
Units: Percentage of participants				
number (not applicable)	7.4	3.3		

Statistical analyses

Statistical analysis title	Difference between treatment groups
Comparison groups	Group 1: DOR/ISL v Group 2: BIC/FTC/TAF
Number of subjects included in analysis	597
Analysis specification	Pre-specified
Analysis type	other[3]
Parameter estimate	Percentage Difference
Point estimate	4
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.4
upper limit	7.9

Notes:

[3] - Difference between treatment groups (Group 1: DOR/ISL and Group 2: BIC/FTC/TAF). Miettinen & Nurminen method was used to generate percentage difference and the associated 95%CI.

Secondary: Percentage of Participants with HIV-1 RNA <50 copies/mL at Week 96

End point title	Percentage of Participants with HIV-1 RNA <50 copies/mL at Week 96

End point description:

The Abbott RealTime PCR assay with a reliable lower limit of quantification of 40 copies/mL was used to measure the HIV-1 RNA level in blood samples obtained at each visit. The percentage of participants with HIV-1 RNA <50 copies/mL at Week 96 was presented using the FDA Snapshot missing data approach. The analysis population consisted of all randomized participants who received at least one dose of study intervention. Participants were included in the treatment group to which they were randomized. The final analysis for this outcome is presented here.

End point type	Secondary

End point timeframe:

Week 96

End point values	Group 1: DOR/ISL	Group 2: BIC/FTC/TAF		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	298	299		
Units: Percentage of participants				
number (not applicable)	51.7	57.9		

Statistical analyses

Statistical analysis title	Difference between treatment groups
Comparison groups	Group 1: DOR/ISL v Group 2: BIC/FTC/TAF
Number of subjects included in analysis	597
Analysis specification	Pre-specified
Analysis type	non-inferiority[4]
P-value	= 0.945 [5]
Method	Miettinen and Nurminen method
Parameter estimate	Estimated Difference
Point estimate	-6.42
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.21
upper limit	1.46

Notes:

[4] - Non-inferiority was concluded if the upper bound of the 2-sided multiplicity-adjusted 95% confidence interval (95%CI) was less than 10 percentage points. The multiplicity-adjusted 95% CI is shown corresponding to a 1-sided Type 1 error of 0.02495. Estimated Difference is Treatment difference for DOR/ISL group minus BIC/FTC/TAF group.

[5] - The estimated differences, CIs and p-value for the treatment differences in percent response were calculated using the Miettinen and Nurminen method stratified by stratum with Cochran-Mantel-Haenszel (CMH) weights.

Secondary: Percentage of Participants with HIV-1 RNA <50 copies/mL at Week 144

End point title	Percentage of Participants with HIV-1 RNA <50 copies/mL at Week 144

End point description:

The Abbott RealTime PCR assay with a reliable lower limit of quantification of 40 copies/mL was used to measure the HIV-1 RNA level in blood samples obtained at each visit. The percentage of participants with HIV-1 RNA <50 copies/mL at Week 144 was presented using the Data as Observed (DAO) missing data approach. The analysis population consisted of all randomized participants who received at least one dose of study intervention and had data available for this outcome measure at Week 144. Participants were included in the treatment group to which they were randomized. The final analysis for this outcome is presented here.

End point type	Secondary

End point timeframe:

Week 144

End point values	Group 1: DOR/ISL	Group 2: BIC/FTC/TAF		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	39	41		
Units: Percentage of participants				
number (not applicable)	64.1	82.9		

Statistical analyses

Statistical analysis title	Difference between treatment groups
Comparison groups	Group 1: DOR/ISL v Group 2: BIC/FTC/TAF

Number of subjects included in analysis	80
Analysis specification	Pre-specified
Analysis type	other[6]
Parameter estimate	Estimated Difference
Point estimate	-19.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-38
upper limit	0.2

Notes:

[6] - Type of statistical test 'other' denotes no hypothesis testing was conducted. The CIs for the treatment differences in percent response were calculated using the Miettinen and Nurminen method stratified by stratum with Cochran-Mantel-Haenszel (CMH) weights. Estimated Difference is Treatment difference for DOR/ISL group minus BIC/FTC/TAF group.

Secondary: Percentage of Participants with HIV-1 RNA <40 copies/mL at Week 48

End point title	Percentage of Participants with HIV-1 RNA <40 copies/mL at Week 48

End point description:

The percentage of participants with HIV-1 RNA <40 copies/mL was determined. The Abbott RealTime PCR assay with a reliable lower limit of quantification of 40 copies/mL was used to measure the HIV-1 RNA level in blood samples obtained at each visit. The percentage of participants with HIV-1 RNA <40 copies/mL at Week 48 was presented using the FDA Snapshot missing data approach. The analysis population consisted of all randomized participants who received at least one dose of study intervention. Participants were included in the treatment group to which they were randomized. The final analysis for this outcome is presented here.

End point type	Secondary

End point timeframe:

Week 48

End point values	Group 1: DOR/ISL	Group 2: BIC/FTC/TAF		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	298	299		
Units: Percentage of participants				
number (not applicable)	88.6	86.3		

Statistical analyses

Statistical analysis title	Difference between treatment groups
Comparison groups	Group 1: DOR/ISL v Group 2: BIC/FTC/TAF
Number of subjects included in analysis	597
Analysis specification	Pre-specified
Analysis type	non-inferiority[7]
Parameter estimate	Treatment Difference
Point estimate	2.12

Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.23
upper limit	7.48

Notes:

[7] - Non-inferiority was concluded if the upper bound of the 2-sided multiplicity-adjusted 95% CI was less than 10 percentage points. The estimated differences, CIs and p-value for the treatment differences in percent response were calculated using the Miettinen and Nurminen method stratified by stratum with Cochran-Mantel-Haenszel (CMH) weights.

Secondary: Percentage of Participants with HIV-1 RNA <200 copies/mL at Week 48

End point title	Percentage of Participants with HIV-1 RNA <200 copies/mL at Week 48

End point description:

The percentage of participants with HIV-1 RNA <200 copies/mL was determined. The Abbott RealTime PCR assay with a reliable lower limit of quantification of 40 copies/mL was used to measure the HIV-1 RNA level in blood samples obtained at each visit. The percentage of participants with HIV-1 RNA <200 copies/mL at Week 48 was presented using the FDA Snapshot missing data approach. The analysis population consisted of all randomized participants who received at least one dose of study intervention. Participants were included in the treatment group to which they were randomized. The final analysis for this outcome is presented here.

End point type	Secondary

End point timeframe:

Week 48

End point values	Group 1: DOR/ISL	Group 2: BIC/FTC/TAF		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	298	299		
Units: Percentage of participants				
number (not applicable)	89.6	88.6		

Statistical analyses

Statistical analysis title	Difference between treatment groups
Comparison groups	Group 1: DOR/ISL v Group 2: BIC/FTC/TAF
Number of subjects included in analysis	597
Analysis specification	Pre-specified
Analysis type	non-inferiority[8]
Parameter estimate	Treatment Difference
Point estimate	0.83
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.25
upper limit	5.9

Notes:

[8] - Non-inferiority was concluded if the upper bound of the 2-sided multiplicity-adjusted 95% CI was less than 10 percentage points. The estimated differences, CIs and p-value for the treatment differences in percent response were calculated using the Miettinen and Nurminen method stratified by stratum with

Cochran-Mantel-Haenszel (CMH) weights.

Secondary: Percentage of Participants with HIV-1 RNA <40 copies/mL at Week 96	
End point title	Percentage of Participants with HIV-1 RNA <40 copies/mL at Week 96

End point description:

The Abbott RealTime PCR assay with a reliable lower limit of quantification of 40 copies/mL was used to measure the HIV-1 RNA level in blood samples obtained at each visit. The percentage of participants with HIV-1 RNA <40 copies/mL at Week 96 was presented using the FDA Snapshot missing data approach. The analysis population consisted of all randomized participants who received at least one dose of study intervention. Participants were included in the treatment group to which they were randomized. The final analysis for this outcome is presented here.

End point type	Secondary

End point timeframe:

Week 96

End point values	Group 1: DOR/ISL	Group 2: BIC/FTC/TAF		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	298	299		
Units: Percentage of participants				
number (not applicable)	51.0	57.5		

Statistical analyses

Statistical analysis title	Difference between treatment groups
Comparison groups	Group 1: DOR/ISL v Group 2: BIC/FTC/TAF
Number of subjects included in analysis	597
Analysis specification	Pre-specified
Analysis type	other[9]
Parameter estimate	Estimated Difference
Point estimate	-6.74
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.53
upper limit	1.15

Notes:

[9] - Type of statistical test 'other' denotes no hypothesis testing was conducted. The estimated differences, and confidence intervals (CIs) for the treatment differences in percent response were calculated using the Miettinen and Nurminen method stratified by stratum with Cochran-Mantel-Haenszel (CMH) weights. Estimated difference is Treatment difference for DOR/ISL group minus BIC/FTC/TAF group.

Secondary: Percentage of Participants with HIV-1 RNA <200 copies/mL at Week 96	
End point title	Percentage of Participants with HIV-1 RNA <200 copies/mL at Week 96

End point description:

The Abbott RealTime PCR assay with a reliable lower limit of quantification of 40 copies/mL was used to measure the HIV-1 RNA level in blood samples obtained at each visit. The percentage of participants with HIV-1 RNA <200 copies/mL at Week 96 was presented using the FDA Snapshot missing data approach. The analysis population consisted of all randomized participants who received at least one dose of study intervention. Participants were included in the treatment group to which they were randomized. The final analysis for this outcome is presented here.

End point type	Secondary

End point timeframe:

Week 96

End point values	Group 1: DOR/ISL	Group 2: BIC/FTC/TAF		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	298	299		
Units: Percentage of participants				
number (not applicable)	52.3	58.5		

Statistical analyses

Statistical analysis title	Difference between treatment groups
Comparison groups	Group 1: DOR/ISL v Group 2: BIC/FTC/TAF
Number of subjects included in analysis	597
Analysis specification	Pre-specified
Analysis type	other[10]
Parameter estimate	Estimated Difference
Point estimate	-6.41
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.2
upper limit	1.46

Notes:

[10] - Type of statistical test 'other' denotes no hypothesis testing was conducted. The estimated differences, and confidence intervals (CIs) for the treatment differences in percent response were calculated using the Miettinen and Nurminen method stratified by stratum with Cochran-Mantel-Haenszel (CMH) weights. Estimated difference is Treatment difference for DOR/ISL group minus BIC/FTC/TAF group.

Secondary: Percentage of Participants with HIV-1 RNA <40 copies/mL at Week 144

End point title	Percentage of Participants with HIV-1 RNA <40 copies/mL at Week 144

End point description:

The Abbott RealTime PCR assay with a reliable lower limit of quantification of 40 copies/mL was used to measure the HIV-1 RNA level in blood samples obtained at each visit. The percentage of participants with HIV-1 RNA <40 copies/mL at Week 144 was presented using the DAO missing data approach. The analysis population consisted of all randomized participants who received at least one dose of study intervention and had data available for this outcome measure at Week 144. Participants were included in the treatment group to which they were randomized. The final analysis for this outcome is presented here.

End point type	Secondary

End point timeframe:

Week 144

End point values	Group 1: DOR/ISL	Group 2: BIC/FTC/TAF		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	39	41		
Units: Percentage of participants				
number (not applicable)	64.1	82.9		

Statistical analyses

Statistical analysis title	Difference between treatment groups
Comparison groups	Group 1: DOR/ISL v Group 2: BIC/FTC/TAF
Number of subjects included in analysis	80
Analysis specification	Pre-specified
Analysis type	other[11]
Parameter estimate	Estimated Difference
Point estimate	-19.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-38
upper limit	0.2

Notes:

[11] - Type of statistical test 'other' denotes no hypothesis testing was conducted. The CIs for the treatment differences in percent response were calculated using the Miettinen and Nurminen method stratified by stratum with Cochran-Mantel-Haenszel (CMH) weights. Estimated difference is Treatment difference for DOR/ISL group minus BIC/FTC/TAF group.

Secondary: Percentage of Participants with HIV-1 RNA <200 copies/mL at Week 144

End point title	Percentage of Participants with HIV-1 RNA <200 copies/mL at Week 144

End point description:

The Abbott RealTime PCR assay with a reliable lower limit of quantification of 40 copies/mL was used to measure the HIV-1 RNA level in blood samples obtained at each visit. The percentage of participants with HIV-1 RNA <200 copies/mL at Week 144 was presented using the DAO missing data approach. The analysis population consisted of all randomized participants who received at least one dose of study intervention and had data available for this outcome measure at Week 144. Participants were included in the treatment group to which they were randomized. The final analysis for this outcome is presented here.

End point type	Secondary

End point timeframe:

Week 144

End point values	Group 1: DOR/ISL	Group 2: BIC/FTC/TAF		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	39	41		
Units: Percentage of participants				
number (not applicable)	64.1	82.9		

Statistical analyses

Statistical analysis title	Difference between treatment groups
Comparison groups	Group 1: DOR/ISL v Group 2: BIC/FTC/TAF
Number of subjects included in analysis	80
Analysis specification	Pre-specified
Analysis type	other[12]
Parameter estimate	Estimated Difference
Point estimate	-19.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-38
upper limit	0.2

Notes:

[12] - Type of statistical test 'other' denotes no hypothesis testing was conducted. The CIs for the treatment differences in percent response were calculated using the Miettinen and Nurminen method stratified by stratum with Cochran-Mantel-Haenszel (CMH) weights. Estimated difference is Treatment difference for DOR/ISL group minus BIC/FTC/TAF group.

Secondary: Mean Change from Baseline in Cluster of Differentiation 4+ (CD4+) T-Cell Counts at Week 48

End point title	Mean Change from Baseline in Cluster of Differentiation 4+ (CD4+) T-Cell Counts at Week 48

End point description:

Plasma CD4+ T-cell count was measured in cells/mm^3 for baseline and at Week 48 by a central laboratory. Baseline measurements were defined as the Day 1 value of each participant. The mean change from baseline in CD4+ T-cell count at Week 48 using the Data as Observed (DAO) approach was presented. The analysis population consisted of all randomized participants who received at least one dose of study intervention and had data available, including baseline data available for CD4+ T-cell count at Week 48. Participants were included in the treatment group to which they were randomized. The final analysis for this outcome is presented here.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Week 48

End point values	Group 1: DOR/ISL	Group 2: BIC/FTC/TAF		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	263	263		
Units: cells/mm^3				
arithmetic mean (confidence interval 95%)	182.4 (162.0 to 202.7)	233.5 (211.8 to 255.3)		

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change from Baseline in Cluster of Differentiation 4+ (CD4+) T-Cell Counts at Week 96

End point title	Mean Change from Baseline in Cluster of Differentiation 4+ (CD4+) T-Cell Counts at Week 96

End point description:

Plasma CD4+ T-cell count was measured in cells/mm^3 for baseline and at Week 96 by a central laboratory. Baseline measurements were defined as the Day 1 value of each participant. The mean change from baseline in CD4+ T-cell count at Week 96 using the Data as Observed (DAO) approach was presented. The analysis population consisted of all randomized participants who received at least one dose of study intervention and had data available, including baseline data available for CD4+ T-cell count at Week 96. Participants were included in the treatment group to which they were randomized. The final analysis for this outcome is presented here.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Week 96

End point values	Group 1: DOR/ISL	Group 2: BIC/FTC/TAF		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	159	168		
Units: cells/mm^3				
arithmetic mean (confidence interval 95%)	217.05 (187.52 to 246.58)	319.92 (290.53 to 349.32)		

Statistical analyses

Statistical analysis title	Difference between treatment groups
Comparison groups	Group 1: DOR/ISL v Group 2: BIC/FTC/TAF
Number of subjects included in analysis	327
Analysis specification	Pre-specified
Analysis type	other[13]
Parameter estimate	Mean difference (final values)
Point estimate	-91.75
Confidence interval	
level	95 %
sides	2-sided
lower limit	-132.59
upper limit	-50.9

Notes:

[13] - Type of statistical test 'other' denotes no hypothesis testing was conducted. The CIs for mean difference in CD4+ T-cell count change from baseline were based on analysis of covariance (ANCOVA) models adjusted by baseline CD4+ T-cell count, stratum, and treatment group. Mean difference is Treatment difference for DOR/ISL group minus BIC/FTC/TAF group.

Secondary: Incidence of Viral Resistance-Associated Substitutions (RASs) at Week 48

End point title	Incidence of Viral Resistance-Associated Substitutions (RASs) at Week 48

End point description:

RASs was defined as participants with confirmed HIV-1 RNA ≥200 copies/mL and/or genotypic or phenotypic analysis of data showing evidence of resistance to the study drug administered. The number of participants who demonstrated RASs at Week 48 was presented. The analysis population consisted of participants with data available at Week 48. Per protocol, participants who met the definition of confirmed virologic rebound or incomplete virologic response, or who discontinued study intervention for another reason and had HIV-1 RNA ≥200 copies/mL at the time of discontinuation. Among such participants, those with HIV-1 RNA ≥400 copies/mL were included. Participants for whom available genotypic or phenotypic data showed evidence of resistance, irrespective of viral load, were also included. The final analysis for this outcome is presented here.

End point type	Secondary

End point timeframe:

Week 48

End point values	Group 1: DOR/ISL	Group 2: BIC/FTC/TAF		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	6		
Units: Participants	1	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Incidence of Viral RASs at Week 96

End point title	Incidence of Viral RASs at Week 96

End point description:

RASs was defined as participants with confirmed HIV-1 RNA ≥200 copies/mL and/or genotypic or phenotypic analysis of data showing evidence of resistance to the study drug administered. The number of participants who demonstrated RASs at Week 96 was presented. The analysis population consisted of participants with data available at Week 96. Per protocol, participants who met the definition of confirmed virologic rebound or incomplete virologic response, or who discontinued study intervention for another reason and had HIV-1 RNA ≥200 copies/mL at the time of discontinuation. Among such participants, those with HIV-1 RNA ≥400 copies/mL were included. Participants for whom available genotypic or phenotypic data showed evidence of resistance, irrespective of viral load, were also included. The final analysis for this outcome is presented here.

End point type	Secondary

End point timeframe:

Week 96

End point values	Group 1: DOR/ISL	Group 2: BIC/FTC/TAF		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5	9		
Units: Participants	2	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change from Baseline in Cluster of Differentiation 4+ (CD4+) T-Cell Counts at Week 144

End point title	Mean Change from Baseline in Cluster of Differentiation 4+ (CD4+) T-Cell Counts at Week 144

End point description:

Plasma CD4+ T-cell count was measured in cells/mm^3 for baseline and at Week 144 by a central laboratory. Baseline measurements were defined as the Day 1 value of each participant. The mean change from baseline in CD4+ T-cell count at Week 144 using the Data as Observed (DAO) approach was presented. The analysis population consisted of all randomized participants who received at least one dose of study intervention and had data available, including baseline data available for CD4+ T-cell count at Week 144. Participants were included in the treatment group to which they were randomized. The final analysis for this outcome is presented here.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Week 144

End point values	Group 1: DOR/ISL	Group 2: BIC/FTC/TAF		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	24	32		
Units: cells/mm^3				
arithmetic mean (confidence interval 95%)	239.6 (177.4 to 301.8)	350.9 (265.7 to 436.1)		

Statistical analyses

Statistical analysis title	Difference between treatment groups
Comparison groups	Group 1: DOR/ISL v Group 2: BIC/FTC/TAF
Number of subjects included in analysis	56
Analysis specification	Pre-specified
Analysis type	other[14]
Parameter estimate	Mean difference (final values)
Point estimate	-111.8

Confidence interval	
level	95 %
sides	2-sided
lower limit	-218.8
upper limit	-4.8

Notes:

[14] - Type of statistical test 'other' denotes no hypothesis testing was conducted. The CIs for mean difference in CD4+ T-cell count change from baseline were based on analysis of covariance (ANCOVA) models adjusted by baseline CD4+ T-cell count, stratum, and treatment group. Mean Difference is Treatment Difference (DOR/ISL minus BIC/FTC/TAF) .

Secondary: Mean Change From Baseline in Body Weight at Week 96

End point title	Mean Change From Baseline in Body Weight at Week 96

End point description:

Body weight was measured at baseline and at Week 96. Participants removed their shoes and wore a single layer of clothing at each measurement. Baseline measurements were defined as the Day 1 value of each participant. The mean change from baseline in body weight at Week 96 was presented. The analysis population consisted of all randomized participants who received at least one dose of intervention and had data available, including baseline data available, for this outcome measure at Week 96. Participants were included in the treatment group corresponding to the study intervention received. The final analysis for this outcome is presented here.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Week 96

End point values	Group 1: DOR/ISL	Group 2: BIC/FTC/TAF		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	189	201		
Units: kilogram				
arithmetic mean (confidence interval 95%)	3.31 (2.45 to 4.18)	4.13 (3.15 to 5.11)		

Statistical analyses

Statistical analysis title	Difference between treatment groups
Comparison groups	Group 1: DOR/ISL v Group 2: BIC/FTC/TAF
Number of subjects included in analysis	390
Analysis specification	Pre-specified
Analysis type	superiority[15]
P-value	= 0.268 [16]
Method	ANCOVA
Parameter estimate	Estimated Difference
Point estimate	-0.74
Confidence interval	
level	Other: 97 %
sides	2-sided
lower limit	-2.19
upper limit	0.71

Notes:

[15] - Superiority will be concluded if the upper bound of the 2-sided multiplicity-adjusted 95% CI was less than 0. The CIs for treatment difference were calculated from ANCOVA models with terms for baseline weight, sex, race, stratum & treatment. A 2-sided p-value was calculated using ANCOVA model. The CIs at week 96 is 97% corresponds to a 1-sided Type 1 error of 0.015.

[16] - A 2-sided p-value was calculated using the Analysis of covariance (ANCOVA) model.

Secondary: Incidence of Viral RASs at Week 144

End point title	Incidence of Viral RASs at Week 144

End point description:

RASs was defined as participants with confirmed HIV-1 RNA ≥200 copies/mL and/or genotypic or phenotypic analysis of data showing evidence of resistance to the study drug administered. The number of participants who demonstrated RASs at Week 144 was presented. The analysis population consisted of participants with data available at Week 144. Per protocol, participants who met the definition of confirmed virologic rebound or incomplete virologic response, or who discontinued study intervention for another reason and had HIV-1 RNA ≥200 copies/mL at the time of discontinuation. Among such participants, those with HIV-1 RNA ≥400 copies/mL were included. Participants for whom available genotypic or phenotypic data showed evidence of resistance, irrespective of viral load, were also included. The final analysis for this outcome is presented here.

End point type	Secondary

End point timeframe:

Week 144

End point values	Group 1: DOR/ISL	Group 2: BIC/FTC/TAF		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5	9		
Units: Participants	2	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change From Baseline in Body Weight at Week 48

End point title	Mean Change From Baseline in Body Weight at Week 48

End point description:

Body weight was measured at baseline and at Week 48. Participants removed their shoes and wore a single layer of clothing at each measurement. Baseline measurements were defined as the Day 1 value of each participant. The mean change from baseline in body weight at Week 48 was presented. The analysis population consisted of all randomized participants who received at least one dose of study intervention and had data available, including baseline data available, for this outcome measure at Week 48. Participants were included in the treatment group corresponding to the study intervention received. The final analysis for this outcome is presented here.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Week 48

End point values	Group 1: DOR/ISL	Group 2: BIC/FTC/TAF		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	270	268		
Units: kilogram				
arithmetic mean (confidence interval 95%)	3.45 (2.83 to 4.06)	3.32 (2.68 to 3.96)		

Statistical analyses

Statistical analysis title	Difference between treatment groups
Comparison groups	Group 1: DOR/ISL v Group 2: BIC/FTC/TAF
Number of subjects included in analysis	538
Analysis specification	Pre-specified
Analysis type	superiority[17]
P-value	= 0.73 [18]
Method	ANCOVA
Parameter estimate	Treatment Difference
Point estimate	0.15
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.71
upper limit	1.02

Notes:

[17] - Superiority will be concluded if the upper bound of the 2-sided multiplicity-adjusted 95% CI was less than 0. A 2-sided p-value was calculated using the Analysis of covariance (ANCOVA) model. ANCOVA model was used to generate treatment difference and the associated 95%CI.
[18] - A 2-sided p-value was calculated using the Analysis of covariance (ANCOVA) model.

Secondary: Percentage of Participants Who Experienced an Adverse Event (AE)

End point title	Percentage of Participants Who Experienced an Adverse Event (AE)

End point description:

An AE was any untoward medical occurrence in a study participant administered a study drug, which does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of the study drug whether or not it is considered related to the study drug. The percentage of participants who experienced at least one or more AEs is presented. Per protocol, pregnancy-related AEs collected for enrolled participants are reported separately and are presented in the AE module. The analysis population consisted of all randomized participants who received at least one dose of study intervention. Participants were included in the treatment group corresponding to the study intervention received. The final analysis for this outcome is presented here.

End point type	Secondary

End point timeframe:

Up to approximately 47 months

End point values	Group 1: DOR/ISL	Group 2: BIC/FTC/TAF		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	298	299		
Units: Percentage of participants				
number (not applicable)	96.6	94.0		

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change From Baseline in Body Weight at Week 144

End point title	Mean Change From Baseline in Body Weight at Week 144

End point description:

Body weight was measured at baseline and at Week 144. Participants removed their shoes and wore a single layer of clothing at each measurement. Baseline measurements were defined as the Day 1 value of each participant. The mean change from baseline in body weight at Week 144 was presented. The analysis population consisted of all randomized participants who received at least one dose of study intervention and had data available, including baseline data available, for this outcome measure at Week 144. Participants were included in the treatment group corresponding to the study intervention received. The final analysis for this outcome is presented here.

End point type	Secondary

End point timeframe:

Baseline (Day 1) and Week 144

End point values	Group 1: DOR/ISL	Group 2: BIC/FTC/TAF		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	40	42		
Units: kilogram				
arithmetic mean (confidence interval 95%)	4.55 (2.40 to 6.70)	3.55 (-1.46 to 8.56)		

Statistical analyses

Statistical analysis title	Difference between treatment groups
Comparison groups	Group 1: DOR/ISL v Group 2: BIC/FTC/TAF
Number of subjects included in analysis	82
Analysis specification	Pre-specified
Analysis type	other[19]
Parameter estimate	Estimated Difference
Point estimate	1.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.07
upper limit	6.24

Notes:

[19] - Type of statistical test 'other' denotes no hypothesis testing was conducted. The CIs for treatment difference were calculated from the Analysis of covariance (ANCOVA) models with terms for baseline weight, sex, race, stratum and treatment.

Secondary: Percentage of Participants Who Discontinued Study Treatment Due to an AE

End point title	Percentage of Participants Who Discontinued Study Treatment Due to an AE

End point description:

An AE was any untoward medical occurrence in a study participant administered a study drug, which does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of the study drug whether or not it is considered related to the study drug. The percentage of participants who discontinued study intervention due to an AE is presented. Per protocol, pregnancy-related AEs collected for enrolled participants are reported separately and are presented in the AE module. The analysis population consisted of all randomized participants who received at least one dose of study intervention. Participants were included in the treatment group corresponding to the study intervention received. The final analysis for this outcome is presented here.

End point type	Secondary

End point timeframe:

Up to approximately 38 months

End point values	Group 1: DOR/ISL	Group 2: BIC/FTC/TAF		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	298	299		
Units: Percentage of participants				
number (not applicable)	14.1	9.0		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to approximately 47 months

Adverse event reporting additional description:

All cause mortality: all randomized participants; AEs: all randomized participants who got ≥1 dose of study drug. Reported by base & extension. Per protocol, participants with drops in CD4+/total lymphocyte count reported as 'post treatment follow up'; all pregnancy-related AEs & infant SAEs collected & reported by arm that participants enrolled.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	27.1

Reporting groups

Reporting group title	Group 1: DOR/ISL Base Study Week 48-Week 96

Reporting group description:

Treatment-naïve participants living with human immunodeficiency virus-1 (HIV-1) that had not received ≤10 days of prior antiretroviral therapy received blinded fixed dose combination (FDC) Doravirine/Islatravir (DOR/ISL) (100 mg doravirine [DOR]/0.75 mg islatravir [ISL]) and placebo to Bictegravir/Tenofovir Alafenamide/Emtricitabine (BIC/FTC/TAF) once daily (QD) from Day 1 to Week 96, and open-label DOR/ISL up to Week 144. At Week 144, participants who consent to enter the optional open-label study extension continued to receive open-label QD FDC of DOR/ISL (100 mg/0.75 mg) for an additional 24 weeks, up to Week 168.

Reporting group title	Group 1: DOR/ISL Base Study Week 0 - Week 48

Reporting group description:

Treatment-naïve participants living with human immunodeficiency virus-1 (HIV-1) that had not received ≤10 days of prior antiretroviral therapy received blinded fixed dose combination (FDC) Doravirine/Islatravir (DOR/ISL) (100 mg doravirine [DOR]/0.75 mg islatravir [ISL]) and placebo to Bictegravir/Tenofovir Alafenamide/Emtricitabine (BIC/FTC/TAF) once daily (QD) from Day 1 to Week 96, and open-label DOR/ISL up to Week 144. At Week 144, participants who consent to enter the optional open-label study extension continued to receive open-label QD FDC of DOR/ISL (100 mg/0.75 mg) for an additional 24 weeks, up to Week 168.

Reporting group title	Group 2: BIC/FTC/TAF Open-Label Extension Week 144 - Week 168

Reporting group description:

Treatment-naïve participants living with HIV-1 that had not received ≤10 days of prior antiretroviral therapy received blinded BIC/FTC/TAF (50 mg bictegravir [BIC], 200 mg emtricitabine [FTC], 25 mg tenofovir alafenamide [TAF]) and placebo to FDC DOR/ISL QD from Day 1 to Week 96, and open-label BIC/FTC/TAF up to Week 144. At Week 144, participants who consent to enter the optional open-label study extension continued to receive QD BIC/FTC/TAF (50 mg/200 mg/25 mg) for an additional 24 weeks, up to Week 168.

Reporting group title	Group 1: DOR/ISL Post-Treatment Follow-Up

Reporting group description:

Treatment-naïve participants living with human immunodeficiency virus-1 (HIV-1) that had not received ≤10 days of prior antiretroviral therapy received blinded fixed dose combination (FDC) Doravirine/Islatravir (DOR/ISL) (100 mg doravirine [DOR]/0.75 mg islatravir [ISL]) and placebo to Bictegravir/Tenofovir Alafenamide/Emtricitabine (BIC/FTC/TAF) once daily (QD) from Day 1 to Week 96, and open-label DOR/ISL up to Week 144. At Week 144, participants who consent to enter the optional open-label study extension continued to receive open-label QD FDC of DOR/ISL (100 mg/0.75 mg) for an additional 24 weeks, up to Week 168.

Reporting group title	Group 2: BIC/FTC/TAF Base Study Week 0 - Week 48

Reporting group description:

Treatment-naïve participants living with HIV-1 that had not received ≤10 days of prior antiretroviral therapy received blinded BIC/FTC/TAF (50 mg bictegravir [BIC], 200 mg emtricitabine [FTC], 25 mg tenofovir alafenamide [TAF]) and placebo to FDC DOR/ISL QD from Day 1 to Week 96, and open-label BIC/FTC/TAF up to Week 144. At Week 144, participants who consent to enter the optional open-label study extension continued to receive QD BIC/FTC/TAF (50 mg/200 mg/25 mg) for an additional 24 weeks, up to Week 168.

Reporting group title	Group 2: BIC/FTC/TAF Base Study Week 48 - Week 96

Reporting group description:

Treatment-naïve participants living with HIV-1 that had not received ≤10 days of prior antiretroviral therapy received blinded BIC/FTC/TAF (50 mg bictegravir [BIC], 200 mg emtricitabine [FTC], 25 mg tenofovir alafenamide [TAF]) and placebo to FDC DOR/ISL QD from Day 1 to Week 96, and open-label BIC/FTC/TAF up to Week 144. At Week 144, participants who consent to enter the optional open-label study extension continued to receive QD BIC/FTC/TAF (50 mg/200 mg/25 mg) for an additional 24 weeks, up to Week 168.

Reporting group title	Group 2: BIC/FTC/TAF Base Study Week 96 - Week 144

Reporting group description:

Treatment-naïve participants living with HIV-1 that had not received ≤10 days of prior antiretroviral therapy received blinded BIC/FTC/TAF (50 mg bictegravir [BIC], 200 mg emtricitabine [FTC], 25 mg tenofovir alafenamide [TAF]) and placebo to FDC DOR/ISL QD from Day 1 to Week 96, and open-label BIC/FTC/TAF up to Week 144. At Week 144, participants who consent to enter the optional open-label study extension continued to receive QD BIC/FTC/TAF (50 mg/200 mg/25 mg) for an additional 24 weeks, up to Week 168.

Reporting group title	Group 1: DOR/ISL Base Study Week 96-Week 144

Reporting group description:

Treatment-naïve participants living with human immunodeficiency virus-1 (HIV-1) that had not received ≤10 days of prior antiretroviral therapy received blinded fixed dose combination (FDC) Doravirine/Islatravir (DOR/ISL) (100 mg doravirine [DOR]/0.75 mg islatravir [ISL]) and placebo to Bictegravir/Tenofovir Alafenamide/Emtricitabine (BIC/FTC/TAF) once daily (QD) from Day 1 to Week 96, and open-label DOR/ISL up to Week 144. At Week 144, participants who consent to enter the optional open-label study extension continued to receive open-label QD FDC of DOR/ISL (100 mg/0.75 mg) for an additional 24 weeks, up to Week 168.

Reporting group title	Group 2: BIC/FTC/TAF Post-Treatment Follow-Up

Reporting group description:

Treatment-naïve participants living with HIV-1 that had not received ≤10 days of prior antiretroviral therapy received blinded BIC/FTC/TAF (50 mg bictegravir [BIC], 200 mg emtricitabine [FTC], 25 mg tenofovir alafenamide [TAF]) and placebo to FDC DOR/ISL QD from Day 1 to Week 96, and open-label BIC/FTC/TAF up to Week 144. At Week 144, participants who consent to enter the optional open-label study extension continued to receive QD BIC/FTC/TAF (50 mg/200 mg/25 mg) for an additional 24 weeks, up to Week 168.

Reporting group title	Group 1: DOR/ISL Open-Label Extension Week 144-Week 168

Reporting group description:

Treatment-naïve participants living with human immunodeficiency virus-1 (HIV-1) that had not received ≤10 days of prior antiretroviral therapy received blinded fixed dose combination (FDC) Doravirine/Islatravir (DOR/ISL) (100 mg doravirine [DOR]/0.75 mg islatravir [ISL]) and placebo to Bictegravir/Tenofovir Alafenamide/Emtricitabine (BIC/FTC/TAF) once daily (QD) from Day 1 to Week 96, and open-label DOR/ISL up to Week 144. At Week 144, participants who consent to enter the optional open-label study extension continued to receive open-label QD FDC of DOR/ISL (100 mg/0.75 mg) for an additional 24 weeks, up to Week 168.

Serious adverse events	Group 1: DOR/ISL Base Study Week 48-Week 96	Group 1: DOR/ISL Base Study Week 0 - Week 48	Group 2: BIC/FTC/TAF Open-Label Extension Week 144 - Week 168
Total subjects affected by serious adverse events			
subjects affected / exposed	14 / 266 (5.26%)	19 / 298 (6.38%)	0 / 27 (0.00%)
number of deaths (all causes)	0	2	0
number of deaths resulting from adverse events	0	2	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Diffuse large B-cell lymphoma			

subjects affected / exposed	0 / 266 (0.00%)	1 / 298 (0.34%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hodgkin's disease			
subjects affected / exposed	0 / 266 (0.00%)	1 / 298 (0.34%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypertensive emergency			
subjects affected / exposed	0 / 266 (0.00%)	0 / 298 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep vein thrombosis			
subjects affected / exposed	0 / 266 (0.00%)	0 / 298 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral ischaemia			
subjects affected / exposed	1 / 266 (0.38%)	0 / 298 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	0 / 266 (0.00%)	1 / 298 (0.34%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abortion incomplete			
subjects affected / exposed	1 / 266 (0.38%)	0 / 298 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gestational hypertension			
subjects affected / exposed	0 / 266 (0.00%)	0 / 298 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	0 / 266 (0.00%)	3 / 298 (1.01%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Pulmonary embolism			
subjects affected / exposed	1 / 266 (0.38%)	0 / 298 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Anxiety disorder			
subjects affected / exposed	0 / 266 (0.00%)	0 / 298 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression			
subjects affected / exposed	0 / 266 (0.00%)	0 / 298 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Major depression			
subjects affected / exposed	0 / 266 (0.00%)	0 / 298 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal behaviour			
subjects affected / exposed	0 / 266 (0.00%)	0 / 298 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal ideation			
subjects affected / exposed	1 / 266 (0.38%)	0 / 298 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicide attempt			

subjects affected / exposed	1 / 266 (0.38%)	1 / 298 (0.34%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
CD4 lymphocytes decreased			
subjects affected / exposed	0 / 266 (0.00%)	0 / 298 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver function test increased			
subjects affected / exposed	0 / 266 (0.00%)	0 / 298 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Ankle fracture			
subjects affected / exposed	0 / 266 (0.00%)	0 / 298 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Craniofacial fracture			
subjects affected / exposed	1 / 266 (0.38%)	0 / 298 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hand fracture			
subjects affected / exposed	0 / 266 (0.00%)	0 / 298 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gun shot wound			
subjects affected / exposed	0 / 266 (0.00%)	1 / 298 (0.34%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Poisoning			
subjects affected / exposed	0 / 266 (0.00%)	0 / 298 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Suture rupture			
subjects affected / exposed	1 / 266 (0.38%)	0 / 298 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stab wound			
subjects affected / exposed	0 / 266 (0.00%)	0 / 298 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Exomphalos			
subjects affected / exposed	1 / 266 (0.38%)	0 / 298 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 266 (0.00%)	0 / 298 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina unstable			
subjects affected / exposed	0 / 266 (0.00%)	0 / 298 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heart failure with preserved ejection fraction			
subjects affected / exposed	0 / 266 (0.00%)	0 / 298 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial ischaemia			
subjects affected / exposed	0 / 266 (0.00%)	0 / 298 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis			

subjects affected / exposed	0 / 266 (0.00%)	0 / 298 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Migraine			
subjects affected / exposed	1 / 266 (0.38%)	0 / 298 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile convulsion			
subjects affected / exposed	0 / 266 (0.00%)	0 / 298 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 266 (0.38%)	0 / 298 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis			
subjects affected / exposed	0 / 266 (0.00%)	0 / 298 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis			
subjects affected / exposed	0 / 266 (0.00%)	1 / 298 (0.34%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	1 / 266 (0.38%)	0 / 298 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 266 (0.00%)	1 / 298 (0.34%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Hepatitis acute			
subjects affected / exposed	0 / 266 (0.00%)	1 / 298 (0.34%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 266 (0.00%)	0 / 298 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Intervertebral disc protrusion			
subjects affected / exposed	0 / 266 (0.00%)	0 / 298 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abdominal wall abscess			
subjects affected / exposed	0 / 266 (0.00%)	0 / 298 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess limb			
subjects affected / exposed	0 / 266 (0.00%)	0 / 298 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute hepatitis B			
subjects affected / exposed	1 / 266 (0.38%)	0 / 298 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 266 (0.00%)	0 / 298 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			

subjects affected / exposed	0 / 266 (0.00%)	0 / 298 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial infection			
subjects affected / exposed	0 / 266 (0.00%)	0 / 298 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	1 / 266 (0.38%)	2 / 298 (0.67%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 pneumonia			
subjects affected / exposed	1 / 266 (0.38%)	0 / 298 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus colitis			
subjects affected / exposed	0 / 266 (0.00%)	0 / 298 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated tuberculosis			
subjects affected / exposed	0 / 266 (0.00%)	1 / 298 (0.34%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	0 / 266 (0.00%)	0 / 298 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infectious pleural effusion			
subjects affected / exposed	0 / 266 (0.00%)	0 / 298 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			

subjects affected / exposed	0 / 266 (0.00%)	0 / 298 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 266 (0.00%)	1 / 298 (0.34%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	1 / 266 (0.38%)	0 / 298 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphogranuloma venereum			
subjects affected / exposed	0 / 266 (0.00%)	1 / 298 (0.34%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neurosyphilis			
subjects affected / exposed	0 / 266 (0.00%)	1 / 298 (0.34%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	0 / 266 (0.00%)	0 / 298 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 266 (0.00%)	1 / 298 (0.34%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Peritonsillar abscess			
subjects affected / exposed	0 / 266 (0.00%)	1 / 298 (0.34%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			

subjects affected / exposed	0 / 266 (0.00%)	0 / 298 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia pneumococcal			
subjects affected / exposed	0 / 266 (0.00%)	0 / 298 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary tuberculosis			
subjects affected / exposed	0 / 266 (0.00%)	0 / 298 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scrotal abscess			
subjects affected / exposed	0 / 266 (0.00%)	0 / 298 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scrotal cellulitis			
subjects affected / exposed	0 / 266 (0.00%)	0 / 298 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	0 / 266 (0.00%)	0 / 298 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 266 (0.00%)	0 / 298 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	1 / 266 (0.38%)	0 / 298 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Diabetes mellitus			

subjects affected / exposed	0 / 266 (0.00%)	1 / 298 (0.34%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Group 1: DOR/ISL Post-Treatment Follow-Up	Group 2: BIC/FTC/TAF Base Study Week 0 - Week 48	Group 2: BIC/FTC/TAF Base Study Week 48 - Week 96
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 112 (2.68%)	16 / 299 (5.35%)	13 / 267 (4.87%)
number of deaths (all causes)	1	0	0
number of deaths resulting from adverse events	1	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Diffuse large B-cell lymphoma			
subjects affected / exposed	0 / 112 (0.00%)	0 / 299 (0.00%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hodgkin's disease			
subjects affected / exposed	0 / 112 (0.00%)	0 / 299 (0.00%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypertensive emergency			
subjects affected / exposed	0 / 112 (0.00%)	1 / 299 (0.33%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep vein thrombosis			
subjects affected / exposed	0 / 112 (0.00%)	0 / 299 (0.00%)	1 / 267 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral ischaemia			
subjects affected / exposed	0 / 112 (0.00%)	0 / 299 (0.00%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			

subjects affected / exposed	0 / 112 (0.00%)	0 / 299 (0.00%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abortion incomplete			
subjects affected / exposed	0 / 112 (0.00%)	0 / 299 (0.00%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gestational hypertension			
subjects affected / exposed	0 / 112 (0.00%)	0 / 299 (0.00%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	0 / 112 (0.00%)	1 / 299 (0.33%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Pulmonary embolism			
subjects affected / exposed	0 / 112 (0.00%)	0 / 299 (0.00%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Anxiety disorder			
subjects affected / exposed	0 / 112 (0.00%)	0 / 299 (0.00%)	1 / 267 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression			
subjects affected / exposed	1 / 112 (0.89%)	0 / 299 (0.00%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Major depression			
subjects affected / exposed	0 / 112 (0.00%)	0 / 299 (0.00%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Suicidal behaviour			
subjects affected / exposed	0 / 112 (0.00%)	1 / 299 (0.33%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal ideation			
subjects affected / exposed	0 / 112 (0.00%)	0 / 299 (0.00%)	1 / 267 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicide attempt			
subjects affected / exposed	0 / 112 (0.00%)	0 / 299 (0.00%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
CD4 lymphocytes decreased			
subjects affected / exposed	0 / 112 (0.00%)	0 / 299 (0.00%)	1 / 267 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver function test increased			
subjects affected / exposed	0 / 112 (0.00%)	1 / 299 (0.33%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Ankle fracture			
subjects affected / exposed	0 / 112 (0.00%)	0 / 299 (0.00%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Craniofacial fracture			
subjects affected / exposed	0 / 112 (0.00%)	0 / 299 (0.00%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hand fracture			
subjects affected / exposed	0 / 112 (0.00%)	1 / 299 (0.33%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Gun shot wound			
subjects affected / exposed	0 / 112 (0.00%)	1 / 299 (0.33%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Poisoning			
subjects affected / exposed	0 / 112 (0.00%)	0 / 299 (0.00%)	1 / 267 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suture rupture			
subjects affected / exposed	0 / 112 (0.00%)	0 / 299 (0.00%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stab wound			
subjects affected / exposed	1 / 112 (0.89%)	0 / 299 (0.00%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Exomphalos			
subjects affected / exposed	0 / 112 (0.00%)	0 / 299 (0.00%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 112 (0.00%)	1 / 299 (0.33%)	1 / 267 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina unstable			
subjects affected / exposed	0 / 112 (0.00%)	0 / 299 (0.00%)	1 / 267 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heart failure with preserved ejection fraction			

subjects affected / exposed	0 / 112 (0.00%)	0 / 299 (0.00%)	1 / 267 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial ischaemia			
subjects affected / exposed	0 / 112 (0.00%)	1 / 299 (0.33%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis			
subjects affected / exposed	0 / 112 (0.00%)	1 / 299 (0.33%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Migraine			
subjects affected / exposed	0 / 112 (0.00%)	0 / 299 (0.00%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile convulsion			
subjects affected / exposed	0 / 112 (0.00%)	0 / 299 (0.00%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 112 (0.00%)	1 / 299 (0.33%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis			
subjects affected / exposed	0 / 112 (0.00%)	1 / 299 (0.33%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis			
subjects affected / exposed	0 / 112 (0.00%)	0 / 299 (0.00%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			

subjects affected / exposed	0 / 112 (0.00%)	0 / 299 (0.00%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 112 (0.00%)	0 / 299 (0.00%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis acute			
subjects affected / exposed	0 / 112 (0.00%)	0 / 299 (0.00%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 112 (0.00%)	1 / 299 (0.33%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Intervertebral disc protrusion			
subjects affected / exposed	0 / 112 (0.00%)	1 / 299 (0.33%)	1 / 267 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abdominal wall abscess			
subjects affected / exposed	0 / 112 (0.00%)	0 / 299 (0.00%)	1 / 267 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess limb			
subjects affected / exposed	0 / 112 (0.00%)	0 / 299 (0.00%)	1 / 267 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute hepatitis B			

subjects affected / exposed	0 / 112 (0.00%)	0 / 299 (0.00%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 112 (0.00%)	2 / 299 (0.67%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 112 (0.00%)	1 / 299 (0.33%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial infection			
subjects affected / exposed	0 / 112 (0.00%)	0 / 299 (0.00%)	1 / 267 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 112 (0.00%)	0 / 299 (0.00%)	1 / 267 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 pneumonia			
subjects affected / exposed	0 / 112 (0.00%)	0 / 299 (0.00%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus colitis			
subjects affected / exposed	0 / 112 (0.00%)	1 / 299 (0.33%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated tuberculosis			
subjects affected / exposed	0 / 112 (0.00%)	0 / 299 (0.00%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			

subjects affected / exposed	0 / 112 (0.00%)	0 / 299 (0.00%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infectious pleural effusion			
subjects affected / exposed	0 / 112 (0.00%)	1 / 299 (0.33%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 112 (0.00%)	1 / 299 (0.33%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 112 (0.00%)	0 / 299 (0.00%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 112 (0.00%)	0 / 299 (0.00%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphogranuloma venereum			
subjects affected / exposed	0 / 112 (0.00%)	0 / 299 (0.00%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neurosyphilis			
subjects affected / exposed	0 / 112 (0.00%)	0 / 299 (0.00%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	0 / 112 (0.00%)	0 / 299 (0.00%)	1 / 267 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis jirovecii pneumonia			

subjects affected / exposed	0 / 112 (0.00%)	0 / 299 (0.00%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonsillar abscess			
subjects affected / exposed	0 / 112 (0.00%)	0 / 299 (0.00%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			
subjects affected / exposed	0 / 112 (0.00%)	0 / 299 (0.00%)	1 / 267 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia pneumococcal			
subjects affected / exposed	1 / 112 (0.89%)	0 / 299 (0.00%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary tuberculosis			
subjects affected / exposed	0 / 112 (0.00%)	0 / 299 (0.00%)	1 / 267 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scrotal abscess			
subjects affected / exposed	0 / 112 (0.00%)	0 / 299 (0.00%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scrotal cellulitis			
subjects affected / exposed	0 / 112 (0.00%)	0 / 299 (0.00%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	0 / 112 (0.00%)	1 / 299 (0.33%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			

subjects affected / exposed	0 / 112 (0.00%)	0 / 299 (0.00%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 112 (0.00%)	0 / 299 (0.00%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Diabetes mellitus			
subjects affected / exposed	0 / 112 (0.00%)	0 / 299 (0.00%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Group 2: BIC/FTC/TAF Base Study Week 96 - Week 144	Group 1: DOR/ISL Base Study Week 96-Week 144	Group 2: BIC/FTC/TAF Post-Treatment Follow-Up
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 143 (0.70%)	3 / 146 (2.05%)	1 / 128 (0.78%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Diffuse large B-cell lymphoma			
subjects affected / exposed	0 / 143 (0.00%)	0 / 146 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hodgkin's disease			
subjects affected / exposed	0 / 143 (0.00%)	0 / 146 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypertensive emergency			
subjects affected / exposed	0 / 143 (0.00%)	0 / 146 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep vein thrombosis			

subjects affected / exposed	0 / 143 (0.00%)	0 / 146 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral ischaemia			
subjects affected / exposed	0 / 143 (0.00%)	0 / 146 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	0 / 143 (0.00%)	0 / 146 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abortion incomplete			
subjects affected / exposed	0 / 143 (0.00%)	0 / 146 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gestational hypertension			
subjects affected / exposed	0 / 143 (0.00%)	0 / 146 (0.00%)	1 / 128 (0.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	0 / 143 (0.00%)	0 / 146 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Pulmonary embolism			
subjects affected / exposed	0 / 143 (0.00%)	0 / 146 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Anxiety disorder			

subjects affected / exposed	0 / 143 (0.00%)	0 / 146 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression			
subjects affected / exposed	0 / 143 (0.00%)	0 / 146 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Major depression			
subjects affected / exposed	1 / 143 (0.70%)	0 / 146 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal behaviour			
subjects affected / exposed	0 / 143 (0.00%)	0 / 146 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal ideation			
subjects affected / exposed	0 / 143 (0.00%)	0 / 146 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicide attempt			
subjects affected / exposed	0 / 143 (0.00%)	0 / 146 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
CD4 lymphocytes decreased			
subjects affected / exposed	0 / 143 (0.00%)	0 / 146 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver function test increased			
subjects affected / exposed	0 / 143 (0.00%)	0 / 146 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			

Ankle fracture			
subjects affected / exposed	0 / 143 (0.00%)	1 / 146 (0.68%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Craniofacial fracture			
subjects affected / exposed	0 / 143 (0.00%)	0 / 146 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hand fracture			
subjects affected / exposed	0 / 143 (0.00%)	0 / 146 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gun shot wound			
subjects affected / exposed	0 / 143 (0.00%)	0 / 146 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Poisoning			
subjects affected / exposed	0 / 143 (0.00%)	0 / 146 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suture rupture			
subjects affected / exposed	0 / 143 (0.00%)	0 / 146 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stab wound			
subjects affected / exposed	0 / 143 (0.00%)	0 / 146 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Exomphalos			
subjects affected / exposed	0 / 143 (0.00%)	0 / 146 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 143 (0.00%)	0 / 146 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina unstable			
subjects affected / exposed	0 / 143 (0.00%)	0 / 146 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Heart failure with preserved ejection fraction			
subjects affected / exposed	0 / 143 (0.00%)	0 / 146 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial ischaemia			
subjects affected / exposed	0 / 143 (0.00%)	0 / 146 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis			
subjects affected / exposed	0 / 143 (0.00%)	0 / 146 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Migraine			
subjects affected / exposed	0 / 143 (0.00%)	0 / 146 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile convulsion			
subjects affected / exposed	0 / 143 (0.00%)	0 / 146 (0.00%)	1 / 128 (0.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			

subjects affected / exposed	0 / 143 (0.00%)	0 / 146 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis			
subjects affected / exposed	0 / 143 (0.00%)	0 / 146 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis			
subjects affected / exposed	0 / 143 (0.00%)	0 / 146 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 143 (0.00%)	0 / 146 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 143 (0.00%)	0 / 146 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis acute			
subjects affected / exposed	0 / 143 (0.00%)	0 / 146 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 143 (0.00%)	0 / 146 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Intervertebral disc protrusion			
subjects affected / exposed	0 / 143 (0.00%)	0 / 146 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Infections and infestations			
Abdominal wall abscess			
subjects affected / exposed	0 / 143 (0.00%)	0 / 146 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess limb			
subjects affected / exposed	0 / 143 (0.00%)	0 / 146 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute hepatitis B			
subjects affected / exposed	0 / 143 (0.00%)	0 / 146 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 143 (0.00%)	0 / 146 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 143 (0.00%)	0 / 146 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial infection			
subjects affected / exposed	0 / 143 (0.00%)	0 / 146 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 143 (0.00%)	0 / 146 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 pneumonia			
subjects affected / exposed	0 / 143 (0.00%)	0 / 146 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus colitis			

subjects affected / exposed	0 / 143 (0.00%)	0 / 146 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disseminated tuberculosis			
subjects affected / exposed	0 / 143 (0.00%)	0 / 146 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	0 / 143 (0.00%)	1 / 146 (0.68%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infectious pleural effusion			
subjects affected / exposed	0 / 143 (0.00%)	0 / 146 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 143 (0.00%)	0 / 146 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 143 (0.00%)	0 / 146 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 143 (0.00%)	0 / 146 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphogranuloma venereum			
subjects affected / exposed	0 / 143 (0.00%)	0 / 146 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neurosyphilis			

subjects affected / exposed	0 / 143 (0.00%)	0 / 146 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	0 / 143 (0.00%)	0 / 146 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 143 (0.00%)	0 / 146 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonsillar abscess			
subjects affected / exposed	0 / 143 (0.00%)	0 / 146 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			
subjects affected / exposed	0 / 143 (0.00%)	0 / 146 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia pneumococcal			
subjects affected / exposed	0 / 143 (0.00%)	0 / 146 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary tuberculosis			
subjects affected / exposed	0 / 143 (0.00%)	0 / 146 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scrotal abscess			
subjects affected / exposed	0 / 143 (0.00%)	1 / 146 (0.68%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scrotal cellulitis			

subjects affected / exposed	0 / 143 (0.00%)	1 / 146 (0.68%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	0 / 143 (0.00%)	0 / 146 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 143 (0.00%)	1 / 146 (0.68%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 143 (0.00%)	0 / 146 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Diabetes mellitus			
subjects affected / exposed	0 / 143 (0.00%)	0 / 146 (0.00%)	0 / 128 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Group 1: DOR/ISL Open-Label Extension Week 144-Week 168		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 21 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Diffuse large B-cell lymphoma			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hodgkin's disease			

subjects affected / exposed	0 / 21 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Hypertensive emergency			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Deep vein thrombosis			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Peripheral ischaemia			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abortion incomplete			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gestational hypertension			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Respiratory, thoracic and mediastinal disorders			
Pulmonary embolism			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Anxiety disorder			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Depression			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Major depression			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Suicidal behaviour			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Suicidal ideation			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Suicide attempt			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Investigations			
CD4 lymphocytes decreased			

subjects affected / exposed	0 / 21 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Liver function test increased				
subjects affected / exposed	0 / 21 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Injury, poisoning and procedural complications				
Ankle fracture				
subjects affected / exposed	0 / 21 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Craniofacial fracture				
subjects affected / exposed	0 / 21 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hand fracture				
subjects affected / exposed	0 / 21 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gun shot wound				
subjects affected / exposed	0 / 21 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Poisoning				
subjects affected / exposed	0 / 21 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Suture rupture				
subjects affected / exposed	0 / 21 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Stab wound				

subjects affected / exposed	0 / 21 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital, familial and genetic disorders			
Exomphalos			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Angina unstable			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Heart failure with preserved ejection fraction			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Myocardial ischaemia			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pericarditis			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Migraine			

subjects affected / exposed	0 / 21 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Febrile convulsion				
subjects affected / exposed	0 / 21 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal disorders				
Abdominal pain				
subjects affected / exposed	0 / 21 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Enteritis				
subjects affected / exposed	0 / 21 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oesophagitis				
subjects affected / exposed	0 / 21 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intestinal obstruction				
subjects affected / exposed	0 / 21 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatobiliary disorders				
Cholelithiasis				
subjects affected / exposed	0 / 21 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatitis acute				
subjects affected / exposed	0 / 21 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal and urinary disorders				

Acute kidney injury				
subjects affected / exposed	0 / 21 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal and connective tissue disorders				
Intervertebral disc protrusion				
subjects affected / exposed	0 / 21 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
Abdominal wall abscess				
subjects affected / exposed	0 / 21 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Abscess limb				
subjects affected / exposed	0 / 21 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Acute hepatitis B				
subjects affected / exposed	0 / 21 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Appendicitis				
subjects affected / exposed	0 / 21 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
COVID-19				
subjects affected / exposed	0 / 21 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bacterial infection				
subjects affected / exposed	0 / 21 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Cellulitis				
subjects affected / exposed	0 / 21 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
COVID-19 pneumonia				
subjects affected / exposed	0 / 21 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cytomegalovirus colitis				
subjects affected / exposed	0 / 21 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Disseminated tuberculosis				
subjects affected / exposed	0 / 21 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diverticulitis				
subjects affected / exposed	0 / 21 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infectious pleural effusion				
subjects affected / exposed	0 / 21 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis				
subjects affected / exposed	0 / 21 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Influenza				
subjects affected / exposed	0 / 21 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lower respiratory tract infection				

subjects affected / exposed	0 / 21 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lymphogranuloma venereum				
subjects affected / exposed	0 / 21 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neurosyphilis				
subjects affected / exposed	0 / 21 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peritonitis				
subjects affected / exposed	0 / 21 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumocystis jirovecii pneumonia				
subjects affected / exposed	0 / 21 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peritonsillar abscess				
subjects affected / exposed	0 / 21 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia bacterial				
subjects affected / exposed	0 / 21 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia pneumococcal				
subjects affected / exposed	0 / 21 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary tuberculosis				

subjects affected / exposed	0 / 21 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Scrotal abscess				
subjects affected / exposed	0 / 21 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Scrotal cellulitis				
subjects affected / exposed	0 / 21 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Septic shock				
subjects affected / exposed	0 / 21 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sepsis				
subjects affected / exposed	0 / 21 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urinary tract infection				
subjects affected / exposed	0 / 21 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metabolism and nutrition disorders				
Diabetes mellitus				
subjects affected / exposed	0 / 21 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

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

Non-serious adverse events	Group 1: DOR/ISL Base Study Week 48-Week 96	Group 1: DOR/ISL Base Study Week 0 - Week 48	Group 2: BIC/FTC/TAF Open-Label Extension Week 144 - Week 168
Total subjects affected by non-serious adverse events			
subjects affected / exposed	115 / 266 (43.23%)	146 / 298 (48.99%)	2 / 27 (7.41%)
Investigations			
CD4 lymphocytes decreased			
subjects affected / exposed	28 / 266 (10.53%)	2 / 298 (0.67%)	1 / 27 (3.70%)
occurrences (all)	35	2	1
Weight increased			
subjects affected / exposed	2 / 266 (0.75%)	19 / 298 (6.38%)	1 / 27 (3.70%)
occurrences (all)	2	19	1
Lymphocyte count decreased			
subjects affected / exposed	64 / 266 (24.06%)	27 / 298 (9.06%)	0 / 27 (0.00%)
occurrences (all)	75	28	0
Injury, poisoning and procedural complications			
Accidental overdose			
subjects affected / exposed	7 / 266 (2.63%)	17 / 298 (5.70%)	0 / 27 (0.00%)
occurrences (all)	12	21	0
Nervous system disorders			
Headache			
subjects affected / exposed	13 / 266 (4.89%)	31 / 298 (10.40%)	0 / 27 (0.00%)
occurrences (all)	14	36	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	6 / 266 (2.26%)	26 / 298 (8.72%)	0 / 27 (0.00%)
occurrences (all)	7	28	0
Psychiatric disorders			
Insomnia			
subjects affected / exposed	4 / 266 (1.50%)	13 / 298 (4.36%)	0 / 27 (0.00%)
occurrences (all)	4	14	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	11 / 266 (4.14%)	16 / 298 (5.37%)	0 / 27 (0.00%)
occurrences (all)	12	17	0
Infections and infestations			

COVID-19			
subjects affected / exposed	20 / 266 (7.52%)	42 / 298 (14.09%)	1 / 27 (3.70%)
occurrences (all)	21	45	1
Upper respiratory tract infection			
subjects affected / exposed	14 / 266 (5.26%)	15 / 298 (5.03%)	0 / 27 (0.00%)
occurrences (all)	14	16	0

Non-serious adverse events	Group 1: DOR/ISL Post-Treatment Follow-Up	Group 2: BIC/FTC/TAF Base Study Week 0 - Week 48	Group 2: BIC/FTC/TAF Base Study Week 48 - Week 96
Total subjects affected by non-serious adverse events			
subjects affected / exposed	8 / 112 (7.14%)	141 / 299 (47.16%)	124 / 267 (46.44%)
Investigations			
CD4 lymphocytes decreased			
subjects affected / exposed	0 / 112 (0.00%)	1 / 299 (0.33%)	25 / 267 (9.36%)
occurrences (all)	0	1	28
Weight increased			
subjects affected / exposed	1 / 112 (0.89%)	18 / 299 (6.02%)	8 / 267 (3.00%)
occurrences (all)	1	18	8
Lymphocyte count decreased			
subjects affected / exposed	0 / 112 (0.00%)	12 / 299 (4.01%)	55 / 267 (20.60%)
occurrences (all)	0	12	62
Injury, poisoning and procedural complications			
Accidental overdose			
subjects affected / exposed	0 / 112 (0.00%)	16 / 299 (5.35%)	17 / 267 (6.37%)
occurrences (all)	0	24	24
Nervous system disorders			
Headache			
subjects affected / exposed	1 / 112 (0.89%)	34 / 299 (11.37%)	13 / 267 (4.87%)
occurrences (all)	1	38	15
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 112 (0.00%)	20 / 299 (6.69%)	5 / 267 (1.87%)
occurrences (all)	0	21	5
Psychiatric disorders			
Insomnia			
subjects affected / exposed	2 / 112 (1.79%)	19 / 299 (6.35%)	3 / 267 (1.12%)
occurrences (all)	2	20	3

Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 112 (0.00%)	14 / 299 (4.68%)	5 / 267 (1.87%)
occurrences (all)	0	16	6
Infections and infestations			
COVID-19			
subjects affected / exposed	0 / 112 (0.00%)	47 / 299 (15.72%)	29 / 267 (10.86%)
occurrences (all)	0	49	29
Upper respiratory tract infection			
subjects affected / exposed	7 / 112 (6.25%)	15 / 299 (5.02%)	11 / 267 (4.12%)
occurrences (all)	8	18	11

Non-serious adverse events	Group 2: BIC/FTC/TAF Base Study Week 96 - Week 144	Group 1: DOR/ISL Base Study Week 96-Week 144	Group 2: BIC/FTC/TAF Post-Treatment Follow-Up
Total subjects affected by non-serious adverse events			
subjects affected / exposed	37 / 143 (25.87%)	42 / 146 (28.77%)	2 / 128 (1.56%)
Investigations			
CD4 lymphocytes decreased			
subjects affected / exposed	14 / 143 (9.79%)	12 / 146 (8.22%)	0 / 128 (0.00%)
occurrences (all)	17	13	0
Weight increased			
subjects affected / exposed	1 / 143 (0.70%)	0 / 146 (0.00%)	0 / 128 (0.00%)
occurrences (all)	1	0	0
Lymphocyte count decreased			
subjects affected / exposed	24 / 143 (16.78%)	25 / 146 (17.12%)	0 / 128 (0.00%)
occurrences (all)	27	29	0
Injury, poisoning and procedural complications			
Accidental overdose			
subjects affected / exposed	1 / 143 (0.70%)	3 / 146 (2.05%)	0 / 128 (0.00%)
occurrences (all)	1	3	0
Nervous system disorders			
Headache			
subjects affected / exposed	2 / 143 (1.40%)	2 / 146 (1.37%)	0 / 128 (0.00%)
occurrences (all)	2	2	0
Gastrointestinal disorders			
Diarrhoea			

subjects affected / exposed	2 / 143 (1.40%)	2 / 146 (1.37%)	1 / 128 (0.78%)
occurrences (all)	2	2	1
Psychiatric disorders			
Insomnia			
subjects affected / exposed	1 / 143 (0.70%)	1 / 146 (0.68%)	0 / 128 (0.00%)
occurrences (all)	1	1	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 143 (0.00%)	2 / 146 (1.37%)	0 / 128 (0.00%)
occurrences (all)	0	3	0
Infections and infestations			
COVID-19			
subjects affected / exposed	3 / 143 (2.10%)	2 / 146 (1.37%)	1 / 128 (0.78%)
occurrences (all)	3	2	1
Upper respiratory tract infection			
subjects affected / exposed	4 / 143 (2.80%)	4 / 146 (2.74%)	0 / 128 (0.00%)
occurrences (all)	4	4	0

Non-serious adverse events	Group 1: DOR/ISL Open-Label Extension Week 144-Week 168		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 21 (14.29%)		
Investigations			
CD4 lymphocytes decreased			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Weight increased			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Lymphocyte count decreased			
subjects affected / exposed	3 / 21 (14.29%)		
occurrences (all)	3		
Injury, poisoning and procedural complications			
Accidental overdose			
subjects affected / exposed	0 / 21 (0.00%)		
occurrences (all)	0		
Nervous system disorders			

Headache subjects affected / exposed occurrences (all)	0 / 21 (0.00%) 0		
Gastrointestinal disorders Diarrhoea subjects affected / exposed occurrences (all)	0 / 21 (0.00%) 0		
Psychiatric disorders Insomnia subjects affected / exposed occurrences (all)	0 / 21 (0.00%) 0		
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all)	0 / 21 (0.00%) 0		
Infections and infestations COVID-19 subjects affected / exposed occurrences (all) Upper respiratory tract infection subjects affected / exposed occurrences (all)	0 / 21 (0.00%) 0 0 / 21 (0.00%) 0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
08 June 2020	Amendment 01: The protocol was amended to: (1) update the hypothesis testing strategy in the statistical analysis plan, (2) update the prohibited concomitant therapies, and (3) allow participants to rescreen one time following approval from the Sponsor.
30 June 2021	Amendment 02: The protocol was amended to: (1) extend study intervention (open-label) from 96 weeks to 144 weeks for all participants; (2) provide an option for Group 2 to receive open-label DOR/ISL from Week 144 to Week 156; (3) offer the option to continue study intervention for participants who become pregnant; and (4) add a discontinuation criterion if a participant chooses to breastfeed.
22 February 2022	Amendment 04: The protocol was amended to: (1) increase the frequency of monitoring of CD4+ T-cell and total lymphocyte counts and to specify the management of participants who meet protocol-defined decreases in CD4+ T-cell and/or total lymphocyte counts, given the findings of decreases in CD4+ T-cell and total lymphocyte counts in clinical studies evaluating ISL and (2) to update the timing of when the Sponsor will be unblinded to individual participants' treatment assignments.
04 December 2022	Amendment 05: This protocol was amended to allow participants who continue to benefit (as determined by the Investigator) from their assigned study intervention, to continue their assigned study intervention through a study extension after Week 144. This extension will continue for up to 24 additional weeks (up to maximum Week 168) or until the participant has the option to enroll in a DOR/ISL 100 mg/0.25 mg study; whichever is sooner. Participants choosing not to enroll in a DOR/ISL 100 mg/0.25 mg study, will transition to commercially available ART as soon as possible.
20 May 2024	Amendment 06: The protocol was amended to revise the post-treatment management of participants with specific decreases in CD4+ T-cell or total lymphocyte counts. The recovery criteria were revised to account for normal physiologic variability in CD4+ T-cell or total lymphocyte counts and the frequency of monitoring was updated to minimize the burden on study participants.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported