Clinical trial results:
A Phase IIb Study Evaluating a Long-Acting Intramuscular Regimen of GSK1265744 plus TMC278 For The Maintenance of Virologic Suppression Following an Induction of Virologic Suppression on an Oral regimen of GSK1265744 plus Abacavir/Lamivudine in HIV-1 Infected, Antiretroviral Therapy-Naive Adult Subjects

Summary

EudraCT number	2013-000783-29
Trial protocol	DE ES
Global end of trial date	20 April 2023

Results information

Result version number	v3 (current)
This version publication date	17 July 2024
First version publication date	23 April 2016
Version creation reason	• Correction of full data set Full data set corrected based on final review.

Trial information

Trial identification

Sponsor protocol code	200056

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	ViiV Healthcare
Sponsor organisation address	980 Great West Road, Brentford, Middlesex, United Kingdom,
Public contact	GSK Response Center, ViiV Healthcare, 1 8664357343, GSKClinicalSupportHD@gsk.com
Scientific contact	GSK Response Center, ViiV Healthcare, 1 8664357343, GSKClinicalSupportHD@gsk.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	01 June 2023
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	20 April 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To select an intramuscular dosing regimen of GSK744 LA plus TMC278 LA based on a comparison of the Week 32 antiviral activity, tolerability, and safety of two IM dosing regimens, relative to GSK744 30 mg plus Abacavir/Lamivudine (ABC/3TC) orally once daily.

Protection of trial subjects:

An IDMC committee will evaluate the efficacy, tolerability, and safety of cabotegravir (CAB) and Rilpivirine (RPV) at the following times: before all eligible subjects have transitioned from the Induction Period to the Maintenance Period; after approximately 45 subjects have reached Week 8 of the Maintenance Period. Futility guidance (e.g., a Bayesian posterior probability approach when 50% of subjects have completed Week 24 of the Maintenance Period) is included to monitor the performance of all treatment arms in order to prevent subjects from continuing on a dosing regimen if existing data indicates that subjects are at unacceptable risk of inadequate maintenance of virologic suppression. A CAB treatment arm should be recommended to stop if there is an indication of any safety signal/effect that would not support continuation of one or more of the CAB treatment groups. This should take into consideration any of the following which are felt to be clinically significant: I. Serious adverse events (e.g. liver event). II. Combinations of non-serious events. III. Treatment-limiting adverse events. IV. Unacceptable number of protocol defined virologic failures with CAB or RPV resistance defined as at least 3 or more virologic failures comprising of ≥ 20% of the treated subjects in an IM treatment arm. V. Mean predose concentrations for the long acting (LA) treatment arm less than 1x protein-adjusted 90% inhibitory concentration (PAIC) 90 (0.166 µg/mL) for CAB and less than 12ng/mL for RPV.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	28 April 2014
Long term follow-up planned	Yes
Long term follow-up rationale	Safety, Efficacy, Ethical reason, Regulatory reason, Scientific research
Long term follow-up duration	1 Years
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 83
Country: Number of subjects enrolled	Canada: 33
Country: Number of subjects enrolled	Spain: 105
Country: Number of subjects enrolled	France: 36
Country: Number of subjects enrolled	Germany: 52
Worldwide total number of subjects	309
EEA total number of subjects	193

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)	309
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study was conducted across 50 sites in five countries (United States, Canada, France, Germany and Spain). The results presented are based on final analysis, up to approximately Week 468.

Pre-assignment

Screening details:

Study consisted of 28 days Screening Period, 20 weeks Induction Period, 96 weeks Maintenance Period (MP), Extension Period (EP) and 52 weeks Long-Term Follow Up Period (LTFP). A total of 309 participants were enrolled in the study and entered the Induction Period, of which 288 completed and 286 were qualified and randomized into the MP.

Period 1

Period 1 title	Induction Period (20 Weeks)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Arm title	CAB 30 mg+ABC/3TC QD (Induction Period)

Arm description:

In induction period, all participants received an oral regimen of cabotegravir (CAB) 30 milligrams (mg) once daily (QD) plus abacavir/lamivudine (ABC/3TC) 600/300 mg QD for 20 weeks. They also received an oral dose of Rilpivirine (RPV) 25 mg tablet once daily in the last 4 weeks of the Induction Period.

Arm type	Experimental
Investigational medicinal product name	Cabotegravir Oral Tablet
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Cabotegravir (CAB) Oral Tablet was formulated as white to almost white oval shaped film coated 30 mg tablets for oral administration. In IP, participants received CAB 30 mg once daily for 20 weeks

Investigational medicinal product name	Abacavir/Lamivudine Oral Tablet
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Abacavir/Lamivudine (ABC/3TC)was supplied as fixed dose combination (FDC) oral tablet, which contained 600 mg of ABC (as abacavir sulfate) and 300 mg of 3TC. The tablets were orange, film-coated, modified capsule-shaped and debossed with "GS FC2" on one side with no markings on the reverse side. ABC/3TC was packaged in bottles of 30 tablets. In IP, participants received ABC/3TC 600/300 mg once daily for 20 weeks.

Investigational medicinal product name	Rilpivirine Oral Tablet
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Rilpivirine (RPV) Oral Tablet was supplied as a 25 mg tablet that was off-white, round, biconvex, film-coated and debossed on one side with “TMC” and the other side with “25”. Participants received RPV 25 mg tablet once daily in last 4 weeks of IP.

Number of subjects in period 1	CAB 30 mg+ABC/3TC QD (Induction Period)
Started	309
Completed	288
Not completed	21
Consent withdrawn by subject	5
Physician decision	1
Adverse event, non-fatal	3
Lost to follow-up	2
Met protocol-defined stopping criteria	3
Lack of efficacy	5
Protocol deviation	2

Period 2

Period 2 title	Maintenance Period (Up to Week 96)
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	CAB LA 600 mg+RPV LA 900 mg IM-Q8W (Maintenance and Extension)

Arm description:

On Day 1 of the Maintenance period, participants who successfully completed the Induction period, were randomized to receive following intramuscular (IM) doses: Day 1 only: CAB long acting (LA) 800 mg (loading dose delivered as two 400 mg IM injections) + RPV LA 900 mg IM; Week 4 only: CAB LA 600 mg IM (second loading dose, no RPV); and from Week 8: CAB LA 600 mg IM +RPV LA 900 mg IM every 8 Weeks (Q8W) for 96 weeks. Eligible participants had the option to continue study participation in the Extension Period.

Arm type	Experimental
Investigational medicinal product name	Rilpivirine Injectable Suspension
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Rilpivirine Injectable Suspension was a sterile white suspension containing 300 mg/mL of TMC278 as free base for administration by intramuscular (IM) injection. The product was packaged in a 2 mL USP Type I glass vial with a 13 mm grey stopper and aluminium seal. Each vial was for single use containing a nominal fill of 2.0 mL, and did not require dilution prior to administration but required refrigeration. Participants randomized to Q8W regimen arm received following intra muscular (IM) doses: RPV LA 900 mg IM every 8 Weeks (Q8W) for 96 weeks

Investigational medicinal product name	Cabotegravir Injectable Suspension
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

CAB Injectable Suspension was a sterile white to slightly colored suspension containing 200 mg/mL of CAB as free acid for administration by intramuscular (IM) injection. The product was packaged in a 3 mL United States Pharmacopeia (USP) Type I glass vial with a 13 mm gray stopper and aluminium seal. Each vial was for single use containing a withdrawable volume of 2.0 mL, and did not require dilution prior to administration. Participants randomized to Q8W regimen arm received following intra muscular (IM) doses: Day 1 only – CAB LA 800 mg (loading dose delivered as two 400 mg IM injections). Week 4 only - CAB LA 600 mg IM. Week 8 - CAB LA 600 mg IM every 8 Weeks (Q8W) for 96 weeks.

Arm title	CAB LA 400 mg+RPV LA 600 mg IM-Q4W (Maintenance and Extension)

Arm description:

On Day 1 of the Maintenance period, participants who successfully completed the Induction period, were randomized to receive following IM doses: Day 1 only: CAB LA 800 mg (loading dose delivered as two 400 mg IM injections) + RPV LA 600 mg IM; and from Week 4: CAB LA 400 mg IM + RPV LA 600 mg IM every 4 Weeks (Q4W) for 96 weeks. Eligible participants had the option to continue study participation in the Extension Period.

Arm type	Experimental
Investigational medicinal product name	Rilpivirine Injectable Suspension
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Rilpivirine Injectable Suspension was a sterile white suspension containing 300 mg/mL of TMC278 as free base for administration by intramuscular (IM) injection. The product was packaged in a 2 mL USP Type I glass vial with a 13 mm grey stopper and aluminium seal. Each vial was for single use containing a nominal fill of 2.0 mL, and did not require dilution prior to administration but required refrigeration. Participants randomized to Q4W regimen arm received following IM doses: RPV LA 600 mg IM every 4 weeks (Q4W) for 96 weeks.

Investigational medicinal product name	Cabotegravir Injectable Suspension
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

CAB Injectable Suspension was a sterile white to slightly colored suspension containing 200 mg/mL of CAB as free acid for administration by intramuscular (IM) injection. The product was packaged in a 3 mL USP Type I glass vial with a 13 mm gray stopper and aluminium seal. Each vial was for single use containing a withdrawable volume of 2.0 mL, and did not require dilution prior to administration. Participants randomized to Q4W regimen arm received following IM doses: Day 1 only - CAB LA 800 mg (loading dose delivered as two 400 mg IM injections). Week 4 - CAB LA 400 mg IM + every 4 weeks (Q4W) for 96 weeks

Arm title	CAB 30 mg+ABC/3TC QD (Induction Period and Maintenance Period)

Arm description:

On Day 1 of the Maintenance period, participants who successfully completed the Induction period, were randomized to receive CAB and ABC/3TC QD for 96 weeks. Eligible participants had the option to continue study participation in Extension Period by switching to an optimized IM CAB LA+ RPV LA regimen of their choice (Q8W or Q4W).

Arm type	Experimental

Investigational medicinal product name	Abacavir/Lamivudine Oral Tablet
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Abacavir/Lamivudine (ABC/3TC)was supplied as fixed dose combination (FDC) oral tablet, which contained 600 mg of ABC (as abacavir sulfate) and 300 mg of 3TC. The tablets were orange, film-coated, modified capsule-shaped and debossed with "GS FC2" on one side with no markings on the reverse side. ABC/3TC was packaged in bottles of 30 tablets. In IP, participants received ABC/3TC 600/300 mg once daily for 20 weeks.

Investigational medicinal product name	Cabotegravir Oral Tablet
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Cabotegravir (CAB) Oral Tablet was formulated as white to almost white oval shaped film coated 30 mg tablets for oral administration. In IP, participants received CAB 30 mg once daily for 20 weeks

Number of subjects in period 2[1]	CAB LA 600 mg+RPV LA 900 mg IM-Q8W (Maintenance and Extension)	CAB LA 400 mg+RPV LA 600 mg IM-Q4W (Maintenance and Extension)	CAB 30 mg+ABC/3TC QD (Induction Period and Maintenance Period)
Started	115	115	56
Completed	110	101	47
Not completed	5	14	9
Consent withdrawn by subject	1	3	5
Physician decision	1	-	-
Adverse event, non-fatal	1	8	1
Met protocol-defined stopping criteria	-	1	1
Lost to follow-up	-	-	1
Lack of efficacy	1	-	1
Protocol deviation	1	2	-

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: 2 participants did not enter Maintenance phase as they had Day 1 viral loads >50 copies/milliliter.

Period 3

Period 3 title	Extension Period (Week 97 to Study End)
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes

Arm title	Optimized CAB LA 600 mg+RPV LA 900 mg IM-Q8W (Extension)

Arm description:

Participants who completed 96 weeks of CAB 30 mg + ABC/3TC QD regimen in Maintenance Period transitioned to Extension Period and received an optimized loading dose of CAB LA 600 mg+RPV LA 900 mg IM at Week 100 and Week 104 followed by CAB LA 600 mg+RPV LA 900 mg IM-Q8W in the Extension Phase. Participants were followed up until end of Extension Period.

Arm type	Experimental
Investigational medicinal product name	Rilpivirine Injectable Suspension
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Rilpivirine Injectable Suspension was a sterile white suspension containing 300 mg/mL of TMC278 as free base for administration by intramuscular (IM) injection. The product was packaged in a 2 mL USP Type I glass vial with a 13 mm grey stopper and aluminium seal. Each vial was for single use containing a nominal fill of 2.0 mL, and did not require dilution prior to administration but required refrigeration. Participants randomized to Q8W regimen arm received following intra muscular (IM) doses: RPV LA 900 mg IM every 8 Weeks (Q8W) for 96 weeks

Investigational medicinal product name	Cabotegravir Injectable Suspension
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

CAB Injectable Suspension was a sterile white to slightly colored suspension containing 200 mg/mL of CAB as free acid for administration by intramuscular (IM) injection. The product was packaged in a 3 mL United States Pharmacopeia (USP) Type I glass vial with a 13 mm gray stopper and aluminium seal. Each vial was for single use containing a withdrawable volume of 2.0 mL, and did not require dilution prior to administration. Participants randomized to Q8W regimen arm received following intra muscular (IM) doses: Day 1 only – CAB LA 800 mg (loading dose delivered as two 400 mg IM injections). Week 4 only - CAB LA 600 mg IM. Week 8 - CAB LA 600 mg IM every 8 Weeks (Q8W) for 96 weeks.

Arm title	Optimized CAB LA 400 mg+RPV LA 600 mg IM-Q4W (Extension)

Arm description:

Participants who completed 96 weeks of CAB 30 mg + ABC/3TC QD regimen in Maintenance Period transitioned to Extension Period and received an optimized loading dose of CAB LA 400 mg+RPV LA 900 mg IM at Week 100 followed by CAB LA 400 mg+RPV LA 900 mg IM-Q8W in the Extension Phase. Participants were followed up until end of Extension Period.

Arm type	Experimental
Investigational medicinal product name	Rilpivirine Injectable Suspension
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Rilpivirine Injectable Suspension was a sterile white suspension containing 300 mg/mL of TMC278 as free base for administration by intramuscular (IM) injection. The product was packaged in a 2 mL USP Type I glass vial with a 13 mm grey stopper and aluminium seal. Each vial was for single use containing a nominal fill of 2.0 mL, and did not require dilution prior to administration but required refrigeration. Participants randomized to Q8W regimen arm received following intra muscular (IM) doses: RPV LA 900 mg IM every 8 Weeks (Q8W) for 96 weeks

Investigational medicinal product name	Cabotegravir Injectable Suspension
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

CAB Injectable Suspension was a sterile white to slightly colored suspension containing 200 mg/mL of CAB as free acid for administration by intramuscular (IM) injection. The product was packaged in a 3 mL United States Pharmacopeia (USP) Type I glass vial with a 13 mm gray stopper and aluminium seal. Each vial was for single use containing a withdrawable volume of 2.0 mL, and did not require dilution prior to administration. Participants randomized to Q8W regimen arm received following intra muscular (IM) doses: Day 1 only – CAB LA 800 mg (loading dose delivered as two 400 mg IM injections). Week 4 only - CAB LA 600 mg IM. Week 8 - CAB LA 600 mg IM every 8 Weeks (Q8W) for 96 weeks.

Number of subjects in period 3[2]	Optimized CAB LA 600 mg+RPV LA 900 mg IM-Q8W (Extension)	Optimized CAB LA 400 mg+RPV LA 600 mg IM-Q4W (Extension)
Started	34	10
Completed	26	8
Not completed	8	2
Consent withdrawn by subject	2	-
Adverse event, non-fatal	2	1
Site closed	-	1
Lost to follow-up	1	-
Lack of efficacy	1	-
Protocol deviation	2	-

Notes:

[2] - 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: Only the eligible participants had the option to continue study participation in Extension Period by switching to an optimized IM CAB LA+ RPV LA regimen of their choice (Q8W or Q4W), hence a part of participants were excluded from this period.

Period 4

Period 4 title	Long-Term Follow-up Period (52 weeks)
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Arm title	Long-Term Follow-Up Group

Arm description:

This group included participants that were withdrawn from CAB LA+RPV LA IM regimens based on protocol criteria and were required to access Highly Active Antiretroviral Therapy (HAART) of choice. Participants were followed up for approximately 52 weeks. Due to system limitation: 43 participants transitioned in this group and accessed a HAART of choice.

Arm type	Experimental
Investigational medicinal product name	HAART
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection, Injection, Tablet
Routes of administration	Intramuscular use, Intramuscular use, Oral use

Dosage and administration details:

Higly-active antiretroviral therapy chosen by participant based on investigator recommendations and

based on availability.

Number of subjects in period 4	Long-Term Follow-Up Group
Started	34
Completed	34

Baseline characteristics

Reporting groups

Reporting group title	CAB 30 mg+ABC/3TC QD (Induction Period)

Reporting group description:

In induction period, all participants received an oral regimen of cabotegravir (CAB) 30 milligrams (mg) once daily (QD) plus abacavir/lamivudine (ABC/3TC) 600/300 mg QD for 20 weeks. They also received an oral dose of Rilpivirine (RPV) 25 mg tablet once daily in the last 4 weeks of the Induction Period.

Reporting group values	CAB 30 mg+ABC/3TC QD (Induction Period)	Total	
Number of subjects	309	309	
Age categorical Units: Subjects			
Adults (18-64 years)	309	309	
Age Continuous Units: Years			
arithmetic mean	36.6		
standard deviation	± 10.39	-	
Sex: Female, Male Units: Participants			
Female	27	27	
Male	282	282	
Race/Ethnicity, Customized Units: Subjects			
African American/African Heritage	46	46	
American Indian or Alaskan Native	10	10	
Asian - Central/South Asian Heritage	1	1	
Asian - Japanese Heritage	1	1	
Asian - South East Asian Heritage	2	2	
Native Hawaiian or Other Pacific Islander	1	1	
White - Arabic/North African Heritage	6	6	
White - White/Caucasian/European Heritage	240	240	
Mixed Race	2	2	

Subject analysis sets

Subject analysis set title	CAB 30 mg+ABC/3TC QD
Subject analysis set type	Intention-to-treat

Subject analysis set description:

In induction period, all participants received an oral regimen of cabotegravir (CAB) 30 milligrams (mg) once daily (QD) plus abacavir/lamivudine (ABC/3TC) 600/300 mg QD for 20 weeks. They also received an oral dose of Rilpivirine (RPV) 25 mg tablet once daily in the last 4 weeks of the Induction Period.

Reporting group values	CAB 30 mg+ABC/3TC QD		
Number of subjects	309		
Age categorical Units: Subjects			
Adults (18-64 years)	309		
Age Continuous Units: Years			
arithmetic mean	36.6		
standard deviation	± 10.39		
Sex: Female, Male Units: Participants			
Female	27		
Male	282		
Race/Ethnicity, Customized Units: Subjects			
African American/African Heritage	46		
American Indian or Alaskan Native	10		
Asian - Central/South Asian Heritage	1		
Asian - Japanese Heritage	1		
Asian - South East Asian Heritage	2		
Native Hawaiian or Other Pacific Islander	1		
White - Arabic/North African Heritage	6		
White - White/Caucasian/European Heritage	240		
Mixed Race	2		

End points

End points reporting groups

Reporting group title	CAB 30 mg+ABC/3TC QD (Induction Period)

Reporting group description:

In induction period, all participants received an oral regimen of cabotegravir (CAB) 30 milligrams (mg) once daily (QD) plus abacavir/lamivudine (ABC/3TC) 600/300 mg QD for 20 weeks. They also received an oral dose of Rilpivirine (RPV) 25 mg tablet once daily in the last 4 weeks of the Induction Period.

Reporting group title	CAB LA 600 mg+RPV LA 900 mg IM-Q8W (Maintenance and Extension)

Reporting group description:

On Day 1 of the Maintenance period, participants who successfully completed the Induction period, were randomized to receive following intramuscular (IM) doses: Day 1 only: CAB long acting (LA) 800 mg (loading dose delivered as two 400 mg IM injections) + RPV LA 900 mg IM; Week 4 only: CAB LA 600 mg IM (second loading dose, no RPV); and from Week 8: CAB LA 600 mg IM +RPV LA 900 mg IM every 8 Weeks (Q8W) for 96 weeks. Eligible participants had the option to continue study participation in the Extension Period.

Reporting group title	CAB LA 400 mg+RPV LA 600 mg IM-Q4W (Maintenance and Extension)

Reporting group description:

On Day 1 of the Maintenance period, participants who successfully completed the Induction period, were randomized to receive following IM doses: Day 1 only: CAB LA 800 mg (loading dose delivered as two 400 mg IM injections) + RPV LA 600 mg IM; and from Week 4: CAB LA 400 mg IM + RPV LA 600 mg IM every 4 Weeks (Q4W) for 96 weeks. Eligible participants had the option to continue study participation in the Extension Period.

Reporting group title	CAB 30 mg+ABC/3TC QD (Induction Period and Maintenance Period)

Reporting group description:

On Day 1 of the Maintenance period, participants who successfully completed the Induction period, were randomized to receive CAB and ABC/3TC QD for 96 weeks. Eligible participants had the option to continue study participation in Extension Period by switching to an optimized IM CAB LA+ RPV LA regimen of their choice (Q8W or Q4W).

Reporting group title	Optimized CAB LA 600 mg+RPV LA 900 mg IM-Q8W (Extension)

Reporting group description:

Participants who completed 96 weeks of CAB 30 mg + ABC/3TC QD regimen in Maintenance Period transitioned to Extension Period and received an optimized loading dose of CAB LA 600 mg+RPV LA 900 mg IM at Week 100 and Week 104 followed by CAB LA 600 mg+RPV LA 900 mg IM-Q8W in the Extension Phase. Participants were followed up until end of Extension Period.

Reporting group title	Optimized CAB LA 400 mg+RPV LA 600 mg IM-Q4W (Extension)

Reporting group description:

Participants who completed 96 weeks of CAB 30 mg + ABC/3TC QD regimen in Maintenance Period transitioned to Extension Period and received an optimized loading dose of CAB LA 400 mg+RPV LA 900 mg IM at Week 100 followed by CAB LA 400 mg+RPV LA 900 mg IM-Q8W in the Extension Phase. Participants were followed up until end of Extension Period.

Reporting group title	Long-Term Follow-Up Group

Reporting group description:

This group included participants that were withdrawn from CAB LA+RPV LA IM regimens based on protocol criteria and were required to access Highly Active Antiretroviral Therapy (HAART) of choice. Participants were followed up for approximately 52 weeks. Due to system limitation: 43 participants transitioned in this group and accessed a HAART of choice.

Subject analysis set title	CAB 30 mg+ABC/3TC QD
Subject analysis set type	Intention-to-treat

Subject analysis set description:

In induction period, all participants received an oral regimen of cabotegravir (CAB) 30 milligrams (mg) once daily (QD) plus abacavir/lamivudine (ABC/3TC) 600/300 mg QD for 20 weeks. They also received an oral dose of Rilpivirine (RPV) 25 mg tablet once daily in the last 4 weeks of the Induction Period.

Primary: Percentage of participants with plasma Human Immunodeficiency Virus-1 (HIV-1) Ribonucleic Acid (RNA) level below 50 copies/milliliter (c/mL) at Week 32

End point title	Percentage of participants with plasma Human Immunodeficiency Virus-1 (HIV-1) Ribonucleic Acid (RNA) level below 50 copies/milliliter (c/mL) at Week 32

End point description:

Percentage of participants with HIV-1 RNA<50 c/mL was obtained using Food and Drug Administration (FDA) Snapshot algorithm. The algorithm treated all participants without HIV-1 RNA data at the visit of interest (due to missing data or discontinuation of investigational product prior to the visit window) as well as participants who switch their concomitant antiretroviral therapy (ART) prior to the visit of interest as non-responders. The Intent-to-Treat Maintenance Exposed (ITT-ME) Population consisted of all randomized participants who received at least one injection or one dose of investigational product during the Maintenance Period of the study (on or after Day 1 visit).

End point type	Primary

End point timeframe:

Week 32

End point values	CAB LA 600 mg+RPV LA 900 mg IM-Q8W (Maintenance and Extension)	CAB LA 400 mg+RPV LA 600 mg IM-Q4W (Maintenance and Extension)	CAB 30 mg+ABC/3TC QD (Induction Period and Maintenance Period)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	115	115	56	
Units: Percentage of participants	95	94	91	

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	CAB LA 600 mg+RPV LA 900 mg IM-Q8W (Maintenance and Extension) v CAB 30 mg+ABC/3TC QD (Induction Period and Maintenance Period)
Number of subjects included in analysis	171
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference in Percentage
Point estimate	3.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.8
upper limit	12.2

Statistical analysis title	Statistical analysis 2
Comparison groups	CAB LA 400 mg+RPV LA 600 mg IM-Q4W (Maintenance and Extension) v CAB 30 mg+ABC/3TC QD (Induction Period and Maintenance Period)

Number of subjects included in analysis	171
Analysis specification	Pre-specified
Analysis type	
Parameter estimate	Difference in Percentage
Point estimate	2.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.8
upper limit	11.5

Primary: Number of participants with protocol defined virologic failure (PDVF) until Week 32

End point title	Number of participants with protocol defined virologic failure (PDVF) until Week 32[1]

End point description:

Virologic failure was defined as any of the following: (1) Non-response as indicated by a less than 1.0 logarithm to base 10 (log10) c/mL decrease in plasma HIV-1 RNA after 4 weeks of starting the Induction Period, which is subsequently confirmed, unless the plasma HIV-1 RNA is < 400 c/mL; (2) Rebound as indicated by two consecutive plasma HIV-1 RNA levels >=200 c/mL after prior suppression to < 200 c/mL; (3) Rebound as indicated by two consecutive plasma HIV-1 RNA that are > 0.5 log10 c/mL increase in plasma HIV-1 RNA from the nadir value on study, where the lowest HIV-1 RNA value is >=200 c/mL.

End point type	Primary

End point timeframe:

Up to Week 32

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was descriptive, hence no statistical analysis was performed.

End point values	CAB LA 600 mg+RPV LA 900 mg IM-Q8W (Maintenance and Extension)	CAB LA 400 mg+RPV LA 600 mg IM-Q4W (Maintenance and Extension)	CAB 30 mg+ABC/3TC QD (Induction Period and Maintenance Period)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	115	115	56	
Units: Participants	1	0	1	

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with any serious adverse event (SAE) and any non-serious adverse event (non-SAE) (Induction Period)

End point title	Number of participants with any serious adverse event (SAE) and any non-serious adverse event (non-SAE) (Induction Period)[2]

End point description:

An AE is defined as any untoward medical occurrence in a participant or clinical investigation participant, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. A SAE is defined as any untoward medical occurrence that, at any dose, results in death, is life threatening, requires hospitalization or prolongation of existing hospitalization, results in disability/incapacity, or is a congenital anomaly/birth defect, important medical events which may require medical or surgical intervention, drug-induced liver injury with hyperbilirubinaemia.

End point type	Primary

End point timeframe:

Up to 20 weeks

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was descriptive, hence no statistical analysis was performed.

End point values	CAB 30 mg+ABC/3TC QD (Induction Period)			
Subject group type	Reporting group			
Number of subjects analysed	309			
Units: Participants				
Any non-SAE	246			
Any SAE	8			

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with any serious adverse event (SAE) and any non-serious adverse event (non-SAE) (Maintenance Period)

End point title	Number of participants with any serious adverse event (SAE) and any non-serious adverse event (non-SAE) (Maintenance Period)[3]

End point description:

An AE is defined as any untoward medical occurrence in a participant or clinical investigation participant, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. A SAE is defined as any untoward medical occurrence that, at any dose, results in death, is life threatening, requires hospitalization or prolongation of existing hospitalization, results in disability/incapacity, or is a congenital anomaly/birth defect, important medical events which may require medical or surgical intervention, drug-induced liver injury with hyperbilirubinaemia. Data presented includes all post-baseline induction period and maintenance period adverse events, as well as long-term follow-up period adverse events for those participants who did not enter the extension period.

End point type	Primary

End point timeframe:

Up to an average of 59 weeks

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was descriptive, hence no statistical analysis was performed.

End point values	CAB LA 600 mg+RPV LA 900 mg IM-Q8W (Maintenance and Extension)	CAB LA 400 mg+RPV LA 600 mg IM-Q4W (Maintenance and Extension)	CAB 30 mg+ABC/3TC QD (Induction Period and Maintenance Period)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	115	115	56	
Units: Participants				
Any non-SAE	115	113	52	
Any SAE	9	8	5	

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with post-Baseline adverse events by maximum toxicity Grade

End point title	Number of participants with post-Baseline adverse events by maximum toxicity Grade[4]

End point description:

An AE is defined as any untoward medical occurrence in a participant or clinical investigation participant, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. Toxicity was graded according to Division of Acquired Immunodeficiency Syndrome (DAIDS) grading criteria, where Grade 1-mild, Grade 2-moderate, Grade 3-severe, Grade 4-potentially life-threatening. Data presented includes all post-baseline treatment emergent Induction Period and MP toxicities, as well as LTFP toxicities for those participants who did not enter the extension period. Number of participants with post-Baseline adverse events by maximum toxicity Grade have been presented.

End point type	Primary

End point timeframe:

Up to an average of 59 weeks

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was descriptive, hence no statistical analysis was performed.

End point values	CAB LA 600 mg+RPV LA 900 mg IM-Q8W (Maintenance and Extension)	CAB LA 400 mg+RPV LA 600 mg IM-Q4W (Maintenance and Extension)	CAB 30 mg+ABC/3TC QD (Induction Period and Maintenance Period)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	115	115	56	
Units: Participants				
Any AE with maximum toxicity Grade 1	31	25	19	
Any AE with maximum toxicity Grade 2	67	72	29	
Any AE with maximum toxicity Grade 3	15	14	3	
Any AE with maximum toxicity Grade 4	2	2	1	

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with maximum post-Baseline emergent toxicities for clinical chemistry parameters

End point title	Number of participants with maximum post-Baseline emergent toxicities for clinical chemistry parameters[5]

End point description:

Clinical chemistry parameters aspartate amino transferase (AST), alanine amino transferase (ALT), alkaline phosphatase (ALP), carbon dioxide(CO2) content/bicarbonate (HCO3), cholesterol, creatine kinase (CK), glucose, low density lipoprotein (LDL) cholesterol, lipase, potassium, and sodium, total bilirubin (TBIL) and triglycerides were evaluated. Toxicity was graded according to Division of Acquired Immunodeficiency Syndrome (DAIDS) grading criteria, where Grade 1-mild, Grade 2-moderate, Grade 3-severe, Grade 4-potentially life-threatening. Data presented includes all post-baseline treatment emergent Induction Period and MP toxicities, as well as LTFP toxicities for those participants who did not enter the extension period. Number of participants with any time post-baseline maximum emergent toxicities in any of the chemistry parameters have been presented.

End point type	Primary

End point timeframe:

Up to an average of 59 weeks

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was descriptive, hence no statistical analysis was performed.

End point values	CAB LA 600 mg+RPV LA 900 mg IM-Q8W (Maintenance and Extension)	CAB LA 400 mg+RPV LA 600 mg IM-Q4W (Maintenance and Extension)	CAB 30 mg+ABC/3TC QD (Induction Period and Maintenance Period)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	115	115	56	
Units: Participants				
Maximum toxicity Grade 1	94	94	44	
Maximum toxicity Grade 2	50	42	16	
Maximum toxicity Grade 3	15	20	10	
Maximum toxicity Grade 4	10	7	2	

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with maximum post-Baseline emergent toxicities for hematology parameters

End point title	Number of participants with maximum post-Baseline emergent toxicities for hematology parameters[6]

End point description:

Hematology parameters hemoglobin, platelet count, total neutrophils and white blood cell count were evaluated. Toxicity was graded according to DAIDS grading criteria, where Grade 1-mild, Grade 2-moderate, Grade 3-severe, Grade 4-potentially life-threatening. Data presented includes all post-baseline treatment emergent Induction Period and MP toxicities, as well as LTFP toxicities for those participants who did not enter the extension period. Number of participants with any time post-baseline maximum emergent toxicities in any of the hematology parameters have been presented.

End point type	Primary

End point timeframe:

Up to an average of 59 weeks

Notes:

[6] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was descriptive, hence no statistical analysis was performed.

End point values	CAB LA 600 mg+RPV LA 900 mg IM-Q8W (Maintenance and Extension)	CAB LA 400 mg+RPV LA 600 mg IM-Q4W (Maintenance and Extension)	CAB 30 mg+ABC/3TC QD (Induction Period and Maintenance Period)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	115	115	56	
Units: Participants				
Maximum toxicity Grade 1	23	17	7	
Maximum toxicity Grade 2	2	4	2	
Maximum toxicity Grade 3	0	0	2	
Maximum toxicity Grade 4	0	3	0	

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with post-Baseline urinalysis dipstick results

End point title	Number of participants with post-Baseline urinalysis dipstick results[7]

End point description:

Urinalysis dipstick included urine occult blood, urine glucose, urine ketones, urine nitrite, urine protein and urine leukocyte. The dipstick test gives results in a semi-quantitative manner and results for urinalysis parameters can be read as positive, trace, 1+, 2+ and 3+ indicating proportional concentrations in the urine sample. Data presented includes all post-baseline dipstick results during Induction and Maintenance Periods, as well as LTFP for those participants who did not enter the extension period.

End point type	Primary

End point timeframe:

Up to an average of 59 weeks

Notes:

[7] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was descriptive, hence no statistical analysis was performed.

End point values	CAB LA 600 mg+RPV LA 900 mg IM-Q8W (Maintenance and Extension)	CAB LA 400 mg+RPV LA 600 mg IM-Q4W (Maintenance and Extension)	CAB 30 mg+ABC/3TC QD (Induction Period and Maintenance Period)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	20	20	10	
Units: Participants				
Urine Occult Blood, Trace, n=10,11,4	5	6	1	
Urine Occult Blood, 1+, n=10,11,4	3	3	2	

Urine Occult Blood, 2+, n=10,11,4	0	0	0	
Urine Occult Blood, 3+, n=10,11,4	2	2	1	
Urine Occult Blood, Positive, n=10,11,4	0	0	0	
Urine Glucose, Trace, n=1,1,1	1	0	0	
Urine Glucose, 1+, n=1,1,1	0	0	1	
Urine Glucose, 2+, n=1,1,1	0	1	0	
Urine Glucose, 3+, n=1,1,1	0	0	0	
Urine Glucose, Positive, n=1,1,1	0	0	0	
Urine Ketones, Trace, n=16,20,10	12	17	8	
Urine Ketones, 1+, n=16,20,10	4	3	2	
Urine Ketones, 2+, n=16,20,10	0	0	0	
Urine Ketones, 3+, n=16,20,10	0	0	0	
Urine Ketones, Positive, n=16,20,10	0	0	0	
Urine Nitrite, Trace, n=1,3,1	0	0	0	
Urine Nitrite, 1+, n=1,3,1	0	0	0	
Urine Nitrite, 2+, n=1,3,1	0	0	0	
Urine Nitrite, 3+, n=1,3,1	0	0	0	
Urine Nitrite, Positive, n=1,3,1	1	3	1	
Urine Protein, Trace, n=17,17,7	15	11	2	
Urine Protein, 1+, n=17,17,7	2	4	5	
Urine Protein, 2+, n=17,17,7	0	2	0	
Urine Protein, 3+, n=17,17,7	0	0	0	
Urine Protein, Positive, n=17,17,7	0	0	0	
Urine Leukocyte, Trace, n=20,20,8	0	0	0	
Urine Leukocyte, 1+, n=20,20,8	7	8	3	
Urine Leukocyte, 2+, n=20,20,8	4	0	1	
Urine Leukocyte, 3+, n=20,20,8	1	2	1	
Urine Leukocyte, Positive, n=20,20,8	0	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with plasma HIV-1 RNA <200 c/mL and <50 c/mL, for oral dose of CAB 30 mg plus ABC/3TC (Induction Period)

End point title	Percentage of participants with plasma HIV-1 RNA <200 c/mL and <50 c/mL, for oral dose of CAB 30 mg plus ABC/3TC (Induction Period)

End point description:

Percentage of participants with HIV-1 RNA <200 c/mL and <50 c/mL for oral dose of CAB 30 mg plus ABC/3TC during Induction Period was obtained using FDA Snapshot algorithm. The algorithm treated all participants without HIV-1 RNA data at the visit of interest (due to missing data or discontinuation of investigational product prior to the visit window) as well as participants who switch their concomitant ART prior to the visit of interest, as non-responders. The Intent-to-Treat Exposed (ITT-E) Population consisted of all randomized participants who received at least one dose of investigational product.

End point type	Secondary

End point timeframe:

Week -20, Week -16, Week -12, Week -8, Week -4, Day 1

End point values	CAB 30 mg+ABC/3TC QD (Induction Period)			
Subject group type	Reporting group			
Number of subjects analysed	309			
Units: Percentage of participants				
HIV-1 RNA<50 c/mL, Week -20	0			
HIV-1 RNA<50 c/mL, Week -16	72			
HIV-1 RNA<50 c/mL, Week -12	90			
HIV-1 RNA<50 c/mL, Week -8	89			
HIV-1 RNA<50 c/mL, Week -4	92			
HIV-1 RNA<50 c/mL, Day 1	91			
HIV-1 RNA<200 c/mL, Week -20	0			
HIV-1 RNA<200 c/mL, Week -16	94			
HIV-1 RNA<200 c/mL, Week -12	97			
HIV-1 RNA<200 c/mL, Week -8	96			
HIV-1 RNA<200 c/mL, Week -4	94			
HIV-1 RNA<200 c/mL, Day 1	94			

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute values of plasma HIV-1 RNA, for oral dose of CAB 30 mg plus ABC/3TC (Induction Period)

End point title	Absolute values of plasma HIV-1 RNA, for oral dose of CAB 30 mg plus ABC/3TC (Induction Period)

End point description:

Plasma samples for quantitative HIV-1 RNA were collected at indicated time points. Log10 values for HIV-1 RNA have been presented.

End point type	Secondary

End point timeframe:

Week -20, Week -16, Week -12, Week -8, Week -4, Day 1

End point values	CAB 30 mg+ABC/3TC QD (Induction Period)			
Subject group type	Reporting group			
Number of subjects analysed	309			
Units: Log10 copies per milliliter				
arithmetic mean (standard deviation)				
Week -20, n=309	4.43 (± 0.672)			
Week -16, n=304	1.71 (± 0.229)			

Week -12, n=302	1.62 (± 0.108)			
Week -8, n=299	1.63 (± 0.281)			
Week -4, n=294	1.61 (± 0.080)			
Day 1, n=291	1.60 (± 0.070)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in plasma HIV-1 RNA, for oral dose of CAB 30 mg plus ABC/3TC (Induction Period)

End point title	Change from Baseline in plasma HIV-1 RNA, for oral dose of CAB 30 mg plus ABC/3TC (Induction Period)

End point description:

Plasma samples for quantitative HIV-1 RNA were collected at indicated time points. Baseline (Week -20) refers to the last available value up to and including the date of first induction period dosing with CAB 30 mg plus ABC/3TC. Change from Baseline was defined as: HIV-1 RNA(log 10) at post-baseline visit minus HIV-1 RNA(log 10) at Baseline.

End point type	Secondary

End point timeframe:

Baseline (Week -20) and Week -16, Week -12, Week -8, Week -4, Day 1

End point values	CAB 30 mg+ABC/3TC QD (Induction Period)			
Subject group type	Reporting group			
Number of subjects analysed	304			
Units: Log10 copies per milliliter				
arithmetic mean (standard deviation)				
Week -16, n=304	-2.72 (± 0.572)			
Week -12, n=302	-2.80 (± 0.640)			
Week -8, n=299	-2.79 (± 0.665)			
Week -4, n=294	-2.81 (± 0.647)			
Day 1, n=291	-2.82 (± 0.645)			

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute values of cluster of differentiation 4+ (CD4+), for oral dose of CAB 30 mg plus ABC/3TC (Induction Period)

End point title	Absolute values of cluster of differentiation 4+ (CD4+), for oral

	dose of CAB 30 mg plus ABC/3TC (Induction Period)

End point description:

Blood samples were collected at specified time points to assess CD4+ using flow cytometry. Mean and standard deviation values for CD4+ are presented.

End point type	Secondary

End point timeframe:

Week -20, Week -16, Week -12, Week -4, Day 1

End point values	CAB 30 mg+ABC/3TC QD (Induction Period)			
Subject group type	Reporting group			
Number of subjects analysed	309			
Units: Cells per cubic millimeter				
arithmetic mean (standard deviation)				
Week -20, n=309	498.9 (± 180.67)			
Week -16, n=304	630.5 (± 235.09)			
Week -12, n=300	664.2 (± 256.57)			
Week -4, n=292	702.3 (± 269.60)			
Day 1, n=291	690.9 (± 261.63)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in CD4+, for oral dose of CAB 30 mg plus ABC/3TC (Induction Period)

End point title	Change from Baseline in CD4+, for oral dose of CAB 30 mg plus ABC/3TC (Induction Period)

End point description:

Blood samples were collected at specified time points to assess CD4+. It was evaluated by flow cytometry. Baseline (Week -20) refers to the last available value up to and including the date of first induction period dosing with CAB 30 mg plus ABC/3TC. Change from Baseline was defined as value at post-baseline visit minus value at Baseline.

End point type	Secondary

End point timeframe:

Baseline (Week -20) and Week -16, Week -12, Week -4, Day 1

End point values	CAB 30 mg+ABC/3TC QD (Induction Period)			
Subject group type	Reporting group			
Number of subjects analysed	304			
Units: Cells per cubic millimeter				
arithmetic mean (standard deviation)				
Week -16, n=304	131.7 (± 172.69)			
Week -12, n=300	164.5 (± 174.61)			
Week -4, n=292	201.5 (± 195.53)			
Day 1, n=291	188.7 (± 186.69)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With AEs by their Severity Grades, for oral dose of CAB 30 mg plus ABC/3TC (Induction Period)

End point title	Number of Participants With AEs by their Severity Grades, for oral dose of CAB 30 mg plus ABC/3TC (Induction Period)

End point description:

An AE is any untoward medical occurrence in a clinical investigation participant, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. Adverse events were evaluated by the investigator and graded according to the DAIDS toxicity grading, where Grade 1=Mild, 2=Moderate, 3=Severe, 4=Potentially life threatening. The higher the grade, the more severe the symptoms. Number of participants with adverse events by maximum grade have been presented.

End point type	Secondary

End point timeframe:

Up to 20 Weeks

End point values	CAB 30 mg+ABC/3TC QD (Induction Period)			
Subject group type	Reporting group			
Number of subjects analysed	56			
Units: Participants				
Maximum toxicity Grade 1	27			
Maximum toxicity Grade 2	15			
Maximum toxicity Grade 3	2			
Maximum toxicity Grade 4	1			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with maximum post-Baseline emergent toxicities for hematology parameters, for oral dose of CAB 30 mg plus ABC/3TC (Induction Period)

End point title	Number of participants with maximum post-Baseline emergent toxicities for hematology parameters, for oral dose of CAB 30 mg plus ABC/3TC (Induction Period)

End point description:

Hematology parameters hemoglobin, platelet count, total neutrophils and white blood cell count were evaluated. Laboratory toxicities were graded according to DAIDS grading criteria, where Grade 1-mild, Grade 2-moderate, Grade 3-severe, Grade 4-potentially life-threatening. Number of participants with any time post-baseline maximum emergent toxicities in any of the hematology parameters have been presented.

End point type	Secondary

End point timeframe:

Up to Week 20

End point values	CAB 30 mg+ABC/3TC QD (Induction Period)			
Subject group type	Reporting group			
Number of subjects analysed	309			
Units: Participants				
Maximum toxicity Grade 1	26			
Maximum toxicity Grade 2	4			
Maximum toxicity Grade 3	1			
Maximum toxicity Grade 4	3			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with maximum post-Baseline emergent toxicities for clinical chemistry parameters, for oral dose of CAB 30 mg plus ABC/3TC (Induction Period)

End point title	Number of participants with maximum post-Baseline emergent toxicities for clinical chemistry parameters, for oral dose of CAB 30 mg plus ABC/3TC (Induction Period)

End point description:

Clinical chemistry parameters AST, ALT, ALP, CO2/HCO3, cholesterol, CK, glucose, LDL cholesterol, lipase, potassium, and sodium, total TBIL and triglycerides were evaluated. Laboratory toxicities were graded according to DAIDS grading criteria, where Grade 1-mild, Grade 2-moderate, Grade 3-severe, Grade 4-potentially life-threatening. Number of participants with any time post-baseline maximum emergent toxicities in any of the chemistry parameters have been presented.

End point type	Secondary

End point timeframe:

Up to 20 weeks

End point values	CAB 30 mg+ABC/3TC QD (Induction Period)			
Subject group type	Reporting group			
Number of subjects analysed	309			
Units: Participants				
Maximum toxicity Grade 1	130			
Maximum toxicity Grade 2	50			
Maximum toxicity Grade 3	16			
Maximum toxicity Grade 4	5			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in clinical chemistry parameters: ALT, ALP, AST and CK (Induction Period)

End point title	Change from Baseline in clinical chemistry parameters: ALT, ALP, AST and CK (Induction Period)

End point description:

Blood samples were collected for the analysis of clinical chemistry parameters including ALT, ALP, AST and CK at indicated time points. Baseline (Week -20) refers to the last available value up to and including the date of first induction period dosing with CAB 30 mg plus ABC/3TC. Change from Baseline was defined as value at post-baseline visit minus value at Baseline.

End point type	Secondary

End point timeframe:

Baseline (Week -20) and Week -16, Week -12, Week -8, Week -4, Day 1

End point values	CAB 30 mg+ABC/3TC QD (Induction Period)			
Subject group type	Reporting group			
Number of subjects analysed	306			
Units: International Units per Liter (IU/L)				
arithmetic mean (standard deviation)				
ALT, Week -16, n=306	0.4 (± 33.1)			
ALT, Week -12, n=301	-1.3 (± 14.1)			
ALT, Week -8, n=297	-0.5 (± 16.6)			
ALT, Week -4, n=292	1.5 (± 50.3)			
ALT, Day 1, n=287	-1.2 (± 18.0)			
ALP, Week -16, n=306	-2.1 (± 12.0)			
ALP, Week -12, n=301	-2.6 (± 11.0)			
ALP, Week -8, n=297	-1.2 (± 13.0)			

ALP, Week -4, n=292	0.1 (± 15.4)			
ALP, Day 1, n=287	0.1 (± 14.1)			
AST, Week -16, n=306	0.3 (± 33.4)			
AST, Week -12, n=301	-2.2 (± 13.1)			
AST, Week -8, n=296	-1.7 (± 15.8)			
AST, Week -4, n=292	-0.0 (± 30.9)			
AST, Day 1, n=286	-1.0 (± 25.9)			
CK, Week -16, n=306	19.0 (± 345.6)			
CK, Week -12, n=301	29.4 (± 485.4)			
CK, Week -8, n=297	26.3 (± 529.6)			
CK, Week -4, n=292	33.2 (± 434.2)			
CK, Day 1, n=287	69.9 (± 1164.7)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in clinical chemistry parameter: Albumin (Induction Period)

End point title	Change from Baseline in clinical chemistry parameter: Albumin (Induction Period)

End point description:

Blood samples were collected for the analysis of clinical chemistry parameter: Albumin at indicated time points. Baseline (Week -20) refers to the last available value up to and including the date of first induction period dosing with CAB 30 mg plus ABC/3TC. Change from Baseline was defined as value at post-baseline visit minus value at Baseline.

End point type	Secondary

End point timeframe:

Baseline (Week -20) and Week -16, Week -12, Week -8, Week -4, Day 1

End point values	CAB 30 mg+ABC/3TC QD (Induction Period)			
Subject group type	Reporting group			
Number of subjects analysed	306			
Units: Grams per Liter (G/L)				
arithmetic mean (standard deviation)				
Week -16, n=306	0.2 (± 2.3)			
Week -12, n=301	0.7 (± 2.3)			
Week -8, n=297	1.4 (± 2.6)			
Week -4, n=292	1.7 (± 2.6)			
Day 1, n=287	1.9 (± 2.8)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in clinical chemistry parameters: Total Bilirubin and Creatinine (Induction Period)

End point title	Change from Baseline in clinical chemistry parameters: Total Bilirubin and Creatinine (Induction Period)

End point description:

Blood samples were collected for the analysis of clinical chemistry parameters including total Bilirubin and Creatinine at indicated time points. Baseline (Week -20) refers to the last available value up to and including the date of first induction period dosing with CAB 30 mg plus ABC/3TC. Change from Baseline was defined as value at post-baseline visit minus value at Baseline.

End point type	Secondary

End point timeframe:

Baseline (Week -20) and Week -16, Week -12, Week -8, Week -4, Day 1

End point values	CAB 30 mg+ABC/3TC QD (Induction Period)			
Subject group type	Reporting group			
Number of subjects analysed	306			
Units: Micromoles per Liter (umol/L)				
arithmetic mean (standard deviation)				
Total Bilirubin, Week -16, n=305	-0.6 (± 4.5)			
Total Bilirubin, Week -12, n=301	-0.9 (± 4.0)			
Total Bilirubin, Week -8, n=297	-1.0 (± 4.1)			
Total Bilirubin, Week -4, n=292	-0.5 (± 4.1)			
Total Bilirubin, Day 1, n=287	-0.3 (± 4.0)			
Creatinine, Week -16, n=306	2.6 (± 7.6)			
Creatinine, Week -12, n=301	1.5 (± 7.8)			
Creatinine, Week -8, n=297	1.6 (± 7.8)			
Creatinine, Week -4, n=292	3.5 (± 8.7)			
Creatinine, Day 1, n=287	4.6 (± 9.1)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in clinical chemistry parameters: CO2, Chloride, Cholesterol, Glucose, Potassium, Sodium, Triglyceride and Urea (Induction Period)

End point title	Change from Baseline in clinical chemistry parameters: CO2, Chloride, Cholesterol, Glucose, Potassium, Sodium, Triglyceride and Urea (Induction Period)

End point description:

Blood samples were collected for the analysis of clinical chemistry parameters including total CO2, chloride, cholesterol, glucose, potassium, sodium, triglyceride and urea at indicated time points. Baseline (Week -20) refers to the last available value up to and including the date of first induction period dosing with CAB 30 mg plus ABC/3TC. Change from Baseline was defined as value at post-baseline visit minus value at Baseline.

End point type	Secondary

End point timeframe:
Baseline (Week -20) and Week -16, Week -12, Week -8, Week -4, Day 1

End point values	CAB 30 mg+ABC/3TC QD (Induction Period)			
Subject group type	Reporting group			
Number of subjects analysed	306			
Units: Millimoles per Liter (mmol/L)				
arithmetic mean (standard deviation)				
CO2, Week -16, n=306	0.2 (± 2.4)			
CO2, Week -12, n=301	0.3 (± 2.3)			
CO2, Week -8, n=296	0.4 (± 2.3)			
CO2, Week -4, n=292	0.1 (± 2.3)			
CO2, Day 1, n=286	-0.8 (± 2.6)			
Chloride, Week -16, n=306	0.2 (± 2.3)			
Chloride, Week -12, n=301	0.5 (± 2.2)			
Chloride, Week -8, n=297	0.6 (± 2.3)			
Chloride, Week -4, n=292	0.2 (± 2.3)			
Chloride, Day 1, n=287	0.2 (± 2.3)			
Cholesterol, Week -16, n=255	0.21 (± 0.6)			
Cholesterol, Week -12, n=236	0.19 (± 0.5)			
Cholesterol, Week -8, n=235	0.27 (± 0.5)			
Cholesterol, Week -4, n=282	0.34 (± 0.5)			
Cholesterol, Day 1, n=285	0.34 (± 0.6)			
Glucose, Week -16, n=255	0.07 (± 0.7)			
Glucose, Week -12, n=236	0.16 (± 0.7)			
Glucose, Week -8, n=235	0.08 (± 0.7)			
Glucose, Week -4, n=281	0.06 (± 0.7)			
Glucose, Day 1, n=282	-0.01 (± 0.7)			
Potassium, Week -16, n=306	-0.05 (± 0.2)			
Potassium, Week -12, n=301	-0.03 (± 0.3)			
Potassium, Week -8, n=296	0.03 (± 0.3)			
Potassium, Week -4, n=292	0.03 (± 0.3)			
Potassium, Day 1, n=286	0.03 (± 0.3)			
Sodium, Week -16, n=306	-0.1 (± 1.8)			
Sodium, Week -12, n=301	0.1 (± 1.8)			
Sodium, Week -8, n=297	0.2 (± 1.9)			
Sodium, Week -4, n=292	0.4 (± 2.0)			
Sodium, Day 1, n=287	0.3 (± 1.9)			
Triglyceride, Week -16, n=3	-0.69 (± 0.1)			
Triglyceride, Week -12, n=2	-0.37 (± 0.1)			
Triglyceride, Week -8, n=2	0.29 (± 0.4)			
Triglyceride, Week -4, n=278	0.20 (± 0.9)			
Triglyceride, Day 1, n=278	-0.00 (± 0.7)			
Urea, Week -16, n=306	-0.06 (± 1.2)			
Urea, Week -12, n=301	-0.08 (± 1.2)			
Urea, Week -8, n=297	-0.09 (± 1.1)			
Urea, Week -4, n=292	-0.12 (± 1.3)			

Urea, Day 1, n=287	0.00 (± 1.2)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in clinical chemistry parameter: Lipase (Induction Period)

End point title	Change from Baseline in clinical chemistry parameter: Lipase (Induction Period)

End point description:

Blood samples were collected for the analysis of clinical chemistry parameter: Lipase at indicated time points. Baseline (Week -20) refers to the last available value up to and including the date of first induction period dosing with CAB 30 mg plus ABC/3TC. Change from Baseline was defined as value at post-baseline visit minus value at Baseline.

End point type	Secondary

End point timeframe:

Baseline (Week -20) and Week -16, Week -12, Week -8, Week -4, Day 1

End point values	CAB 30 mg+ABC/3TC QD (Induction Period)			
Subject group type	Reporting group			
Number of subjects analysed	306			
Units: Units per Liter (U/L)				
arithmetic mean (standard deviation)				
Week -16, n=306	3.3 (± 20.0)			
Week -12, n=301	0.8 (± 15.3)			
Week -8, n=297	2.8 (± 24.3)			
Week -4, n=292	2.1 (± 23.8)			
Day 1, n=288	-1.2 (± 17.7)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in hematology parameters: Basophil, Eosinophils, Lymphocytes, Total Neutrophils, Monocytes, Platelets count and White Blood Cells (WBC) count (Induction Period)

End point title	Change from Baseline in hematology parameters: Basophil, Eosinophils, Lymphocytes, Total Neutrophils, Monocytes, Platelets count and White Blood Cells (WBC) count (Induction Period)

End point description:

Blood samples were collected for the analysis of hematology parameters: Basophil, Eosinophils, Lymphocytes, Total Neutrophils, Monocytes, Platelets count and WBC at indicated time points. Baseline (Week -20) refers to the last available value up to and including the date of first induction period dosing with CAB 30 mg plus ABC/3TC. Change from Baseline was defined as value at post-baseline visit minus value at Baseline.

End point type	Secondary

End point timeframe:

Baseline (Week -20) and Week -16, Week -12, Week -8, Week -4, Day 1

End point values	CAB 30 mg+ABC/3TC QD (Induction Period)			
Subject group type	Reporting group			
Number of subjects analysed	303			
Units: Giga cells per Liter				
arithmetic mean (standard deviation)				
Basophils, Week -16, n=303	0.00 (± 0.016)			
Basophils, Week -12, n=298	0.00 (± 0.019)			
Basophils, Week -8, n=297	0.00 (± 0.015)			
Basophils, Week -4, n=290	0.00 (± 0.016)			
Basophils, Day 1, n=290	0.00 (± 0.019)			
Eosinophils, Week -16, n=303	0.01 (± 0.131)			
Eosinophils, Week -12, n=298	0.01 (± 0.123)			
Eosinophils, Week -8, n=297	0.02 (± 0.127)			
Eosinophils, Week -4, n=290	0.02 (± 0.136)			
Eosinophils, Day 1, n=290	0.03 (± 0.161)			
Lymphocytes, Week -16, n=303	0.24 (± 0.541)			
Lymphocytes, Week -12, n=298	0.28 (± 0.573)			
Lymphocytes, Week -8, n=297	0.30 (± 0.541)			
Lymphocytes, Week -4, n=290	0.30 (± 0.574)			
Lymphocytes, Day 1, n=290	0.14 (± 0.565)			
Monocytes, Week -16, n=303	-0.00 (± 0.129)			
Monocytes, Week -12, n=298	0.00 (± 0.139)			
Monocytes, Week -8, n=297	-0.00 (± 0.135)			
Monocytes, Week -4, n=290	-0.00 (± 0.132)			
Monocytes, Day 1, n=290	0.00 (± 0.143)			
Platelet count, Week -16, n=302	14.4 (± 31.56)			
Platelet count, Week -12, n=300	18.2 (± 32.53)			
Platelet count, Week -8, n=297	21.1 (± 37.00)			
Platelet count, Week -4, n=290	23.0 (± 35.02)			
Platelet count, Day 1, n=290	22.2 (± 35.32)			
Total Neutrophils, Week -16, n=303	0.04 (± 1.185)			
Total Neutrophils, Week -12, n=298	0.22 (± 1.391)			
Total Neutrophils, Week -8, n=297	0.20 (± 1.286)			
Total Neutrophils, Week -4, n=290	0.31 (± 1.429)			
Total Neutrophils, Day 1, n=290	0.38 (± 1.515)			
WBC, Week -16, n=303	0.31 (± 1.318)			

WBC, Week -12, n=298	0.52 (± 1.522)			
WBC, Week -8, n=297	0.54 (± 1.460)			
WBC, Week -4, n=290	0.64 (± 1.594)			
WBC, Day 1, n=290	0.57 (± 1.713)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in hematology parameter: Hematocrit (Induction Period)

End point title	Change from Baseline in hematology parameter: Hematocrit (Induction Period)

End point description:

Blood samples were collected for the analysis of hematology parameter: Hematocrit at indicated time points. Baseline (Week -20) refers to the last available value up to and including the date of first induction period dosing with CAB 30 mg plus ABC/3TC. Change from Baseline was defined as value at post-baseline visit minus value at Baseline.

End point type	Secondary

End point timeframe:

Baseline (Week -20) and Week -16, Week -12, Week -8, Week -4, Day 1

End point values	CAB 30 mg+ABC/3TC QD (Induction Period)			
Subject group type	Reporting group			
Number of subjects analysed	304			
Units: Proportion of red blood cells in blood				
arithmetic mean (standard deviation)				
Week -16, n=304	0.00 (± 0.022)			
Week -12, n=302	0.00 (± 0.023)			
Week -8, n=298	0.00 (± 0.024)			
Week -4, n=290	0.00 (± 0.025)			
Day 1, n=290	0.00 (± 0.025)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in hematology parameter: Hemoglobin (Induction Period)

End point title	Change from Baseline in hematology parameter: Hemoglobin (Induction Period)

End point description:

Blood samples were collected for the analysis of hematology parameter: Hemoglobin at indicated time

points. Baseline (Week -20) refers to the last available value up to and including the date of first induction period dosing with CAB 30 mg plus ABC/3TC. Change from Baseline was defined as value at post-baseline visit minus value at Baseline.

End point type	Secondary

End point timeframe:

Baseline (Week -20) and Week -16, Week -12, Week -8, Week -4, Day 1

End point values	CAB 30 mg+ABC/3TC QD (Induction Period)			
Subject group type	Reporting group			
Number of subjects analysed	304			
Units: Grams per Liter				
arithmetic mean (standard deviation)				
Week -16, n=304	0.8 (± 6.94)			
Week -12, n=302	2.0 (± 7.07)			
Week -8, n=298	2.5 (± 7.42)			
Week -4, n=290	3.3 (± 7.95)			
Day 1, n=290	3.1 (± 7.96)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in hematology parameter: Mean Corpuscle Volume (Induction Period)

End point title	Change from Baseline in hematology parameter: Mean Corpuscle Volume (Induction Period)

End point description:

Blood samples were collected for the analysis of hematology parameter: Mean Corpuscle Volume at indicated time points. Baseline (Week -20) refers to the last available value up to and including the date of first induction period dosing with CAB 30 mg plus ABC/3TC. Change from Baseline was defined as value at post-baseline visit minus value at Baseline.

End point type	Secondary

End point timeframe:

Baseline (Week -20) and Week -16, Week -12, Week -8, Week -4, Day 1

End point values	CAB 30 mg+ABC/3TC QD (Induction Period)			
Subject group type	Reporting group			
Number of subjects analysed	304			
Units: Femtoliters				
arithmetic mean (standard deviation)				
Week -16, n=304	1.0 (± 1.52)			

Week -12, n=302	2.1 (± 1.90)			
Week -8, n=298	3.1 (± 2.49)			
Week -4, n=290	4.0 (± 2.47)			
Day 1, n=290	4.4 (± 2.57)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in hematology parameter: Red Blood Cell count (Induction Period)

End point title	Change from Baseline in hematology parameter: Red Blood Cell count (Induction Period)

End point description:

Blood samples were collected for the analysis of hematology parameter: Red Blood Cell count at indicated time points. Baseline (Week -20) refers to the last available value up to and including the date of first induction period dosing with CAB 30 mg plus ABC/3TC. Change from Baseline was defined as value at post-baseline visit minus value at Baseline.

End point type	Secondary

End point timeframe:

Baseline (Week -20) and Week -16, Week -12, Week -8, Week -4, Day 1

End point values	CAB 30 mg+ABC/3TC QD (Induction Period)			
Subject group type	Reporting group			
Number of subjects analysed	304			
Units: 10^12 cells per Liter				
arithmetic mean (standard deviation)				
Week -16, n=304	-0.05 (± 0.242)			
Week -12, n=302	-0.07 (± 0.254)			
Week -8, n=298	-0.10 (± 0.266)			
Week -4, n=290	-0.10 (± 0.284)			
Day 1, n=290	-0.14 (± 0.289)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with plasma HIV-1 RNA level <50 c/mL and <200 c/mL over Week 96 (Maintenance Period)

End point title	Percentage of participants with plasma HIV-1 RNA level <50

	c/mL and <200 c/mL over Week 96 (Maintenance Period)

End point description:

Percentage of participants with HIV-1 RNA <50 c/mL and <200 c/mL was obtained using FDA Snapshot algorithm. The algorithm treated all participants without HIV-1 RNA data at the visit of interest (due to missing data or discontinuation of investigational product prior to the visit window) as well as participants who switch their concomitant ART prior to the visit of interest, as non-responders.

End point type	Secondary

End point timeframe:

From Day 1 up to Week 96

End point values	CAB LA 600 mg+RPV LA 900 mg IM-Q8W (Maintenance and Extension)	CAB LA 400 mg+RPV LA 600 mg IM-Q4W (Maintenance and Extension)	CAB 30 mg+ABC/3TC QD (Induction Period and Maintenance Period)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	115	115	56	
Units: Percentage of participants				
HIV-1 RNA<50 c/mL, Day 1	95	99	98	
HIV-1 RNA<50 c/mL, Week 4	97	98	93	
HIV-1 RNA<50 c/mL, Week 8	98	97	95	
HIV-1 RNA<50 c/mL, Week 12	96	7	98	
HIV-1 RNA<50 c/mL, Week 16	97	96	89	
HIV-1 RNA<50 c/mL, Week 20	97	97	91	
HIV-1 RNA<50 c/mL, Week 24	96	94	91	
HIV-1 RNA<50 c/mL, Week 28	90	92	86	
HIV-1 RNA<50 c/mL, Week 32	95	94	91	
HIV-1 RNA<50 c/mL, Week 36	95	90	88	
HIV-1 RNA<50 c/mL, Week 40	92	91	86	
HIV-1 RNA<50 c/mL, Week 44	93	90	88	
HIV-1 RNA<50 c/mL, Week 48	92	91	89	
HIV-1 RNA<50 c/mL, Week 56	94	90	84	
HIV-1 RNA<50 c/mL, Week 64	95	90	86	
HIV-1 RNA<50 c/mL, Week 72	95	90	88	
HIV-1 RNA<50 c/mL, Week 80	95	87	84	
HIV-1 RNA<50 c/mL, Week 88	95	86	84	
HIV-1 RNA<50 c/mL, Week 96	94	87	84	
HIV-1 RNA<200 c/mL, Day 1	100	100	98	
HIV-1 RNA<200 c/mL, Week 4	99	100	96	
HIV-1 RNA<200 c/mL, Week 8	99	99	95	
HIV-1 RNA<200 c/mL, Week 12	97	98	98	
HIV-1 RNA<200 c/mL, Week 16	98	98	93	
HIV-1 RNA<200 c/mL, Week 20	98	97	93	
HIV-1 RNA<200 c/mL, Week 24	97	96	93	
HIV-1 RNA<200 c/mL, Week 28	94	95	91	
HIV-1 RNA<200 c/mL, Week 32	97	95	91	
HIV-1 RNA<200 c/mL, Week 36	97	93	89	
HIV-1 RNA<200 c/mL, Week 40	97	92	86	
HIV-1 RNA<200 c/mL, Week 44	95	91	89	
HIV-1 RNA<200 c/mL, Week 48	97	92	89	

HIV-1 RNA<200 c/mL, Week 56	96	90	86	
HIV-1 RNA<200 c/mL, Week 64	96	90	88	
HIV-1 RNA<200 c/mL, Week 72	96	90	88	
HIV-1 RNA<200 c/mL, Week 80	96	88	84	
HIV-1 RNA<200 c/mL, Week 88	96	86	84	
HIV-1 RNA<200 c/mL, Week 96	96	87	84	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with protocol defined virologic failure at Week 32 and Week 48 (Maintenance Period)

End point title	Number of participants with protocol defined virologic failure at Week 32 and Week 48 (Maintenance Period)

End point description:

Virologic failure was defined as any of the following: (1) Non-response as indicated by a less than a 1.0 log10 c/mL decrease in plasma HIV-1 RNA after 4 weeks of starting the Induction Period, which is subsequently confirmed, unless the plasma HIV-1 RNA is < 400 c/mL; (2) Rebound as indicated by two consecutive plasma HIV-1 RNA levels >=200 c/mL after prior suppression to < 200 c/mL; (3) Rebound as indicated by two consecutive plasma HIV-1 RNA that are > 0.5 log10 c/mL increase in plasma HIV-1 RNA from the nadir value on study, where the lowest HIV-1 RNA value is >=200 c/mL.

End point type	Secondary

End point timeframe:

At Week 32 and Week 48

End point values	CAB LA 600 mg+RPV LA 900 mg IM-Q8W (Maintenance and Extension)	CAB LA 400 mg+RPV LA 600 mg IM-Q4W (Maintenance and Extension)	CAB 30 mg+ABC/3TC QD (Induction Period and Maintenance Period)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	115	115	56	
Units: Participants				
Week 32	1	0	1	
Week 48	2	0	1	

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute value of plasma HIV-1 RNA at Week 32 and Week 96 (Maintenance Period)

End point title	Absolute value of plasma HIV-1 RNA at Week 32 and Week 96 (Maintenance Period)

End point description:

Plasma samples for quantitative HIV-1 RNA analysis were collected at indicated time points during

Maintenance Period. Log10 values for HIV-1 RNA have been presented. SD=0.000 is defined as following: if participants analyzed at a specific timepoint have resulted same values, then SD is considered equal with 0.000.

End point type	Secondary

End point timeframe:

At Week 32 and Week 96

End point values	CAB LA 600 mg+RPV LA 900 mg IM-Q8W (Maintenance and Extension)	CAB LA 400 mg+RPV LA 600 mg IM-Q4W (Maintenance and Extension)	CAB 30 mg+ABC/3TC QD (Induction Period and Maintenance Period)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	111	108	50	
Units: Log10 copies per milliliter				
arithmetic mean (standard deviation)				
Week 32	1.60 (± 0.044)	1.59 (± 0.025)	1.61 (± 0.112)	
Week 96	1.60 (± 0.056)	1.59 (± 0.000)	1.59 (± 0.000)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in plasma HIV-1 RNA at Week 32 and Week 96 (Maintenance Period)

End point title	Change from Baseline in plasma HIV-1 RNA at Week 32 and Week 96 (Maintenance Period)

End point description:

Plasma samples for quantitative HIV-1 RNA analysis were collected at indicated time points during Maintenance Period. Baseline (Week -20) refers to the last available value up to and including the date of first induction period dosing with CAB 30 mg plus ABC/3TC. Change from Baseline was defined as: HIV-1 RNA(log 10) at post-baseline visit minus HIV-1 RNA(log 10) at Baseline.

End point type	Secondary

End point timeframe:

At Week 32 and Week 96 (compared with Baseline [Week -20])

End point values	CAB LA 600 mg+RPV LA 900 mg IM-Q8W (Maintenance and Extension)	CAB LA 400 mg+RPV LA 600 mg IM-Q4W (Maintenance and Extension)	CAB 30 mg+ABC/3TC QD (Induction Period and Maintenance Period)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	111	108	50	
Units: Log10 copies per milliliter				
arithmetic mean (standard deviation)				

Week 32	-2.78 (± 0.610)	-2.88 (± 0.709)	-2.73 (± 0.561)	
Week 96	-2.77 (± 0.602)	-2.89 (± 0.713)	-2.77 (± 0.582)	

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute value of CD4+ at Week 32 and Week 96 (Maintenance Period)

End point title	Absolute value of CD4+ at Week 32 and Week 96 (Maintenance Period)

End point description:

Blood samples were collected at specified time points to assess CD4+. It was evaluated by flow cytometry.

End point type	Secondary

End point timeframe:

At Week 32 and Week 96

End point values	CAB LA 600 mg+RPV LA 900 mg IM-Q8W (Maintenance and Extension)	CAB LA 400 mg+RPV LA 600 mg IM-Q4W (Maintenance and Extension)	CAB 30 mg+ABC/3TC QD (Induction Period and Maintenance Period)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	112	108	50	
Units: Cells per cubic millimeter				
arithmetic mean (standard deviation)				
Week 32	752.3 (± 318.02)	761.3 (± 293.07)	891.3 (± 273.32)	
Week 96	748.6 (± 253.41)	750.0 (± 271.11)	906.8 (± 288.77)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in CD4+ at Week 32 and Week 96 (Maintenance Period)

End point title	Change from Baseline in CD4+ at Week 32 and Week 96 (Maintenance Period)

End point description:

Blood samples were collected at specified time points to assess CD4+. It was evaluated by flow cytometry. Baseline (Week -20) refers to the last available value up to and including the date of first induction period dosing with CAB 30 mg plus ABC/3TC. Change from Baseline was defined as post-baseline value minus Baseline value.

End point type	Secondary

End point timeframe:

At Week 32 and Week 96 (compared with Baseline [Week -20])

End point values	CAB LA 600 mg+RPV LA 900 mg IM-Q8W (Maintenance and Extension)	CAB LA 400 mg+RPV LA 600 mg IM-Q4W (Maintenance and Extension)	CAB 30 mg+ABC/3TC QD (Induction Period and Maintenance Period)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	112	108	50	
Units: Cells per cubic millimeter				
arithmetic mean (standard deviation)				
Week 32	264.4 (± 247.84)	263.7 (± 217.74)	346.1 (± 219.59)	
Week 96	257.5 (± 192.25)	270.6 (± 210.99)	369.9 (± 226.60)	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With HIV-1 Disease Progression over Week 32 and Week 96 (Maintenance Period)

End point title	Number of Participants With HIV-1 Disease Progression over Week 32 and Week 96 (Maintenance Period)

End point description:

HIV-associated conditions were recorded during the study and was assessed according to the Centers for Disease Control and Prevention (CDC) Classification System for HIV Infection in Adults. The clinical categories of HIV infection as per CDC system are class A=Asymptomatic HIV infection or lymphadenopathy or acute HIV infection; class B=symptomatic non-acquired immunodeficiency syndrome (AIDS) conditions and class C=AIDS indicator conditions. Number of participants experiencing disease progression is presented, where disease progression is defined as the progression from Baseline HIV disease status as follows: CDC class A at Baseline to CDC class C event; CDC Class B at Baseline to CDC Class C event; CDC Class C at Baseline to new CDC Class C event; and CDC class A, B or C at Baseline to death.

End point type	Secondary

End point timeframe:

At Week 32 and Week 96

End point values	CAB LA 600 mg+RPV LA 900 mg IM-Q8W (Maintenance and Extension)	CAB LA 400 mg+RPV LA 600 mg IM-Q4W (Maintenance and Extension)	CAB 30 mg+ABC/3TC QD (Induction Period and Maintenance Period)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	115	115	56	
Units: Participants				

From CDC Stage 1 to CDC Stage 3 Event, Week 32	1	0	0	
From CDC Stage 2 to CDC Stage 3 Event, Week 32	0	0	0	
From CDC Stage 3 to New CDC Stage 3 Event, Week 32	0	0	0	
From CDC Stage 1, 2 or 3 to Death, Week 32	0	1	0	
From CDC Stage 1 to CDC Stage 3 Event, Week 96	4	0	0	
From CDC Stage 2 to CDC Stage 3 Event, Week 96	0	0	0	
From CDC Stage 3 to New CDC Stage 3 Event, Week 96	0	0	0	
From CDC Stage 1, 2 or 3 to Death, Week 96	0	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With AEs by their Severity Grades over Week 96 (Maintenance Period)

End point title	Number of Participants With AEs by their Severity Grades over Week 96 (Maintenance Period)

End point description:

An AE is any untoward medical occurrence in a clinical investigation participant, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. Adverse events were evaluated by the investigator and graded according to the DAIDS toxicity grading, where Grade 1=Mild, 2=Moderate, 3=Severe, 4=Potentially life threatening). The higher the grade, the more severe the symptoms. Number of participants with adverse events by maximum grade have been presented.

End point type	Secondary

End point timeframe:

Up to Week 96

End point values	CAB LA 600 mg+RPV LA 900 mg IM-Q8W (Maintenance and Extension)	CAB LA 400 mg+RPV LA 600 mg IM-Q4W (Maintenance and Extension)	CAB 30 mg+ABC/3TC QD (Induction Period and Maintenance Period)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	115	115	56	
Units: Participants				
Grade 1	23	21	24	
Grade 2	71	74	26	
Grade 3	19	18	4	
Grade 4	2	2	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With AEs by their Severity Grades over Week 32 (Maintenance Period)

End point title	Number of Participants With AEs by their Severity Grades over Week 32 (Maintenance Period)

End point description:

An AE is any untoward medical occurrence in a clinical investigation participant, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. Adverse events were evaluated by the investigator and graded according to the DAIDS toxicity grading, where Grade 1=Mild, 2=Moderate, 3=Severe, 4=Potentially life threatening). The higher the grade, the more severe the symptoms. Number of participants with adverse events by maximum grade have been presented.

End point type	Secondary

End point timeframe:

Up to Week 32

End point values	CAB LA 600 mg+RPV LA 900 mg IM-Q8W (Maintenance and Extension)	CAB LA 400 mg+RPV LA 600 mg IM-Q4W (Maintenance and Extension)	CAB 30 mg+ABC/3TC QD (Induction Period and Maintenance Period)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	115	115	56	
Units: Participants				
Grade 1	35	29	23	
Grade 2	65	69	22	
Grade 3	14	13	11	
Grade 4	1	2	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in clinical chemistry parameters: ALT, ALP, AST and CK at Week 32 and Week 96 (Maintenance Period)

End point title	Change from Baseline in clinical chemistry parameters: ALT, ALP, AST and CK at Week 32 and Week 96 (Maintenance Period)

End point description:

Blood samples were collected for the analysis of clinical chemistry parameters including ALT, ALP, AST and CK at indicated time points. Baseline (Week -20) refers to the last available value up to and including the date of first induction period dosing with CAB 30 mg plus ABC/3TC. Change from Baseline was defined as value at post-baseline visit minus value at Baseline.

End point type	Secondary

End point timeframe:

At Week 32 and Week 96 (compared with Baseline [Week -20])

End point values	CAB LA 600 mg+RPV LA 900 mg IM-Q8W (Maintenance and Extension)	CAB LA 400 mg+RPV LA 600 mg IM-Q4W (Maintenance and Extension)	CAB 30 mg+ABC/3TC QD (Induction Period and Maintenance Period)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	115	115	56	
Units: International Units per Liter				
arithmetic mean (standard deviation)				
ALT, Week 32	-2.4 (± 13.4)	-2.7 (± 13.5)	-5.0 (± 19.5)	
ALP, Week 32	-1.2 (± 14.6)	-3.8 (± 15.0)	-1.3 (± 11.6)	
AST, Week 32	-2.8 (± 12.5)	-2.2 (± 14.5)	-8.3 (± 30.6)	
CK, Week 32	51.4 (± 651.0)	93.4 (± 446.9)	38.8 (± 394.9)	
ALT, Week 96	1.8 (± 19.19)	-2.2 (± 14.42)	-2.7 (± 22.17)	
ALP, Week 96	-3.1 (± 15.59)	-3.4 (± 15.64)	-2.8 (± 12.34)	
AST, Week 96	-1.0 (± 15.45)	-4.0 (± 9.31)	-8.8 (± 32.57)	
CK, Week 96	21.1 (± 490.00)	13.7 (± 153.92)	-13.9 (± 227.98)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in clinical chemistry parameter: Albumin at Week 32 and Week 96 (Maintenance Period)

End point title	Change from Baseline in clinical chemistry parameter: Albumin at Week 32 and Week 96 (Maintenance Period)

End point description:

Blood samples were collected for the analysis of clinical chemistry parameters including Albumin at indicated time points. Baseline (Week -20) refers to the last available value up to and including the date of first induction period dosing with CAB 30 mg plus ABC/3TC. Change from Baseline was defined as value at post-baseline visit minus value at Baseline.

End point type	Secondary

End point timeframe:

At Week 32 and Week 96 (compared with Baseline [Week -20])

End point values	CAB LA 600 mg+RPV LA 900 mg IM-Q8W (Maintenance and Extension)	CAB LA 400 mg+RPV LA 600 mg IM-Q4W (Maintenance and Extension)	CAB 30 mg+ABC/3TC QD (Induction Period and Maintenance Period)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	112	108	50	
Units: Grams per Liter				
arithmetic mean (standard deviation)				

Week 32	1.4 (± 3.0)	0.9 (± 2.9)	1.1 (± 2.8)	
Week 96	1.0 (± 2.76)	0.9 (± 2.87)	0.2 (± 0.2)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in clinical chemistry parameters: Total Bilirubin and Creatinine at Week 32 and Week 96 (Maintenance Period)

End point title	Change from Baseline in clinical chemistry parameters: Total Bilirubin and Creatinine at Week 32 and Week 96 (Maintenance Period)

End point description:

Blood samples were collected for the analysis of clinical chemistry parameters including Total Bilirubin and Creatinine at indicated time points. Baseline (Week -20) refers to the last available value up to and including the date of first induction period dosing with CAB 30 mg plus ABC/3TC. Change from Baseline was defined as value at post-baseline visit minus value at Baseline.

End point type	Secondary

End point timeframe:

At Week 32 and Week 96 (compared with Baseline [Week -20])

End point values	CAB LA 600 mg+RPV LA 900 mg IM-Q8W (Maintenance and Extension)	CAB LA 400 mg+RPV LA 600 mg IM-Q4W (Maintenance and Extension)	CAB 30 mg+ABC/3TC QD (Induction Period and Maintenance Period)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	112	108	50	
Units: Micromoles per Liter				
arithmetic mean (standard deviation)				
Total Bilirubin, Week 32	0.8 (± 4.4)	0.4 (± 3.6)	-0.6 (± 4.4)	
Creatinine, Week 32	2.7 (± 8.5)	3.8 (± 8.7)	2.7 (± 6.1)	
Total Bilirubin, Week 96	0.0 (± 3.78)	-0.3 (± 4.11)	-1.1 (± 4.25)	
Creatinine, Week 96	3.11 (± 8.515)	4.27 (± 8.730)	4.42 (± 6.105)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in clinical chemistry parameters: Total CO2, chloride, cholesterol, glucose, potassium, sodium, triglyceride and urea at Week 32 and Week 96 (Maintenance Period)

End point title	Change from Baseline in clinical chemistry parameters: Total CO2, chloride, cholesterol, glucose, potassium, sodium, triglyceride and urea at Week 32 and Week 96 (Maintenance Period)

End point description:

Blood samples were collected for the analysis of clinical chemistry parameters including total CO2, chloride, cholesterol, glucose, potassium, sodium, triglyceride and urea at indicated time points. Baseline (Week -20) refers to the last available value up to and including the date of first induction period dosing with CAB 30 mg plus ABC/3TC. Change from Baseline was defined as value at post-baseline visit minus value at Baseline.

End point type	Secondary

End point timeframe:

At Week 32 and Week 96 (compared with Baseline [Week -20])

End point values	CAB LA 600 mg+RPV LA 900 mg IM-Q8W (Maintenance and Extension)	CAB LA 400 mg+RPV LA 600 mg IM-Q4W (Maintenance and Extension)	CAB 30 mg+ABC/3TC QD (Induction Period and Maintenance Period)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	112	108	50	
Units: Millimoles per Liter				
arithmetic mean (standard deviation)				
Total CO2, Week 32	-0.8 (± 2.1)	-1.5 (± 2.4)	-1.1 (± 2.4)	
Chloride, Week 32	-0.2 (± 0.3)	2.4 (± 0.1)	2.1 (± 0.2)	
Cholesterol, Week 32	0.37 (± 0.6)	0.47 (± 0.7)	0.25 (± 0.5)	
Glucose, Week 32	0.13 (± 1.0)	0.03 (± 0.7)	-0.05 (± 0.6)	
Potassium, Week 32	0.01 (± 0.3)	-0.05 (± 0.3)	-0.04 (± 0.2)	
Sodium, Week 32	0.4 (± 2.0)	-0.1 (± 1.8)	0.0 (± 1.7)	
Triglycerides, Week 32	0.08 (± 0.9)	-0.00 (± 1.7)	0.06 (± 0.7)	
Urea, Week 32	0.15 (± 1.3)	0.23 (± 1.4)	-0.01 (± 1.4)	
Total CO2, Week 96	-0.8 (± 2.88)	-1.1 (± 2.64)	-0.1 (± 2.47)	
Chloride, Week 96	-0.1 (± 2.32)	-0.4 (± 2.53)	0.3 (± 2.12)	
Cholesterol, Week 96	0.554 (± 0.6724)	0.731 (± 0.7380)	0.348 (± 0.6490)	
Glucose, Week 96	0.12 (± 0.729)	0.11 (± 0.667)	0.02 (± 0.745)	
Potassium, Week 96	0.11 (± 0.378)	-0.04 (± 0.408)	-0.03 (± 0.314)	
Sodium, Week 96	-0.1 (± 1.85)	-0.4 (± 2.07)	-0.4 (± 1.96)	
Triglycerides, Week 96	0.084 (± 0.9000)	0.080 (± 1.4964)	0.197 (± 0.4972)	
Urea, Week 96	0.09 (± 1.393)	-0.01 (± 1.230)	0.12 (± 1.461)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in clinical chemistry parameter: Lipase at Week 32 and Week 96 (Maintenance Period)

End point title	Change from Baseline in clinical chemistry parameter: Lipase at Week 32 and Week 96 (Maintenance Period)

End point description:

Blood samples were collected for the analysis of clinical chemistry parameters including Lipase at

indicated time points. Baseline (Week -20) refers to the last available value up to and including the date of first induction period dosing with CAB 30 mg plus ABC/3TC. Change from Baseline was defined as value at post-baseline visit minus value at Baseline.

End point type	Secondary

End point timeframe:

At Week 32 and Week 96 (compared with Baseline [Week -20])

End point values	CAB LA 600 mg+RPV LA 900 mg IM-Q8W (Maintenance and Extension)	CAB LA 400 mg+RPV LA 600 mg IM-Q4W (Maintenance and Extension)	CAB 30 mg+ABC/3TC QD (Induction Period and Maintenance Period)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	115	115	56	
Units: Units per Liter				
arithmetic mean (standard deviation)				
Week 32	-1.2 (± 33.2)	-4.4 (± 15.4)	-3.9 (± 14.7)	
Week 96	3.5 (± 22.00)	-0.8 (± 14.73)	-2.3 (± 14.21)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in hematology parameters: Basophil, Eosinophils, Lymphocytes, Total Neutrophils, Monocytes, Platelet count and WBC count at Week 32 and Week 96 (Maintenance Period)

End point title	Change from Baseline in hematology parameters: Basophil, Eosinophils, Lymphocytes, Total Neutrophils, Monocytes, Platelet count and WBC count at Week 32 and Week 96 (Maintenance Period)

End point description:

Blood samples were collected for the analysis of hematology parameters including Basophil, Eosinophils, Lymphocytes, Total Neutrophils, Monocytes, Platelet count and WBC count at indicated time points. Baseline (Week -20) refers to the last available value up to and including the date of first induction period dosing with CAB 30 mg plus ABC/3TC. Change from Baseline was defined as value at post-baseline visit minus value at Baseline.

End point type	Secondary

End point timeframe:

At Week 32 and Week 96 (compared with Baseline [Week -20])

End point values	CAB LA 600 mg+RPV LA 900 mg IM-Q8W (Maintenance and Extension)	CAB LA 400 mg+RPV LA 600 mg IM-Q4W (Maintenance and Extension)	CAB 30 mg+ABC/3TC QD (Induction Period and Maintenance Period)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	110	107	48	

Units: 10^9 cells per Liter				
arithmetic mean (standard deviation)				
Basophils, Week 32	0.00 (± 0.012)	0.00 (± 0.022)	0.00 (± 0.010)	
Eosinophils, Week 32	0.01 (± 0.146)	0.23 (± 1.985)	-0.01 (± 0.143)	
Lymphocytes, Week 32	0.34 (± 0.661)	0.26 (± 0.694)	0.48 (± 0.635)	
Monocytes, Week 32	-0.02 (± 0.152)	-0.03 (± 0.144)	0.00 (± 0.144)	
Platelet count, Week 32	18.7 (± 38.28)	20.6 (± 44.93)	11.6 (± 33.33)	
Total Neutrophils, Week 32	0.59 (± 1.505)	0.34 (± 1.489)	0.94 (± 1.365)	
WBC count, Week 32	0.93 (± 1.670)	0.81 (± 2.881)	1.41 (± 1.529)	
Basophils, Week 96	0.004 (± 0.0139)	0.000 (± 0.0204)	0.006 (± 0.0157)	
Eosinophils, Week 96	0.015 (± 0.1461)	0.021 (± 0.1013)	-0.013 (± 0.1528)	
Lymphocytes, Week 96	0.325 (± 0.6356)	0.290 (± 0.6793)	0.534 (± 0.5408)	
Monocytes, Week 96	-0.009 (± 0.1685)	-0.014 (± 0.1781)	-0.005 (± 0.1443)	
Platelet count, Week 96	21.9 (± 40.07)	21.1 (± 41.49)	15.3 (± 39.28)	
Total Neutrophils, Week 96	0.381 (± 1.3060)	0.515 (± 1.6200)	0.783 (± 1.0747)	
WBC count, Week 96	0.72 (± 1.545)	0.82 (± 1.786)	1.31 (± 1.144)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in hematology parameter: Hematocrit at Week 32 and Week 96 (Maintenance Period)

End point title	Change from Baseline in hematology parameter: Hematocrit at Week 32 and Week 96 (Maintenance Period)

End point description:

Blood samples were collected for the analysis of hematology parameters including Hematocrit at indicated time points. Baseline (Week -20) refers to the last available value up to and including the date of first induction period dosing with CAB 30 mg plus ABC/3TC. Change from Baseline was defined as value at post-baseline visit minus value at Baseline.

End point type	Secondary

End point timeframe:

At Week 32 and Week 96 (compared with Baseline [Week -20])

End point values	CAB LA 600 mg+RPV LA 900 mg IM-Q8W (Maintenance and Extension)	CAB LA 400 mg+RPV LA 600 mg IM-Q4W (Maintenance and Extension)	CAB 30 mg+ABC/3TC QD (Induction Period and Maintenance Period)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	111	107	48	
Units: Proportion of red blood cells in blood				
arithmetic mean (standard deviation)				

Week 32	0.01 (± 0.026)	0.01 (± 0.027)	0.01 (± 0.027)	
Week 96	0.0114 (± 0.02880)	0.0134 (± 0.03125)	0.0124 (± 0.02748)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in hematology parameter: Hemoglobin at Week 32 and Week 96 (Maintenance Period)

End point title	Change from Baseline in hematology parameter: Hemoglobin at Week 32 and Week 96 (Maintenance Period)

End point description:

Blood samples were collected for the analysis of hematology parameters including Hemoglobin at indicated time points. Baseline (Week -20) refers to the last available value up to and including the date of first induction period dosing with CAB 30 mg plus ABC/3TC. Change from Baseline was defined as value at post-baseline visit minus value at Baseline.

End point type	Secondary

End point timeframe:

At Week 32 and Week 96 (compared with Baseline [Week -20])

End point values	CAB LA 600 mg+RPV LA 900 mg IM-Q8W (Maintenance and Extension)	CAB LA 400 mg+RPV LA 600 mg IM-Q4W (Maintenance and Extension)	CAB 30 mg+ABC/3TC QD (Induction Period and Maintenance Period)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	111	107	48	
Units: Grams per Liter				
arithmetic mean (standard deviation)				
Week 32	2.0 (± 8.56)	0.8 (± 8.45)	1.7 (± 8.38)	
Week 96	3.9 (± 8.95)	4.3 (± 9.92)	4.1 (± 8.11)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in hematology parameter: Mean Corpuscle Volume at Week 32 and Week 96 (Maintenance Period)

End point title	Change from Baseline in hematology parameter: Mean Corpuscle Volume at Week 32 and Week 96 (Maintenance Period)

End point description:

Blood samples were collected for the analysis of hematology parameters including Mean Corpuscle Volume at indicated time points. Baseline (Week -20) refers to the last available value up to and including the date of first induction period dosing with CAB 30 mg plus ABC/3TC. Change from Baseline was defined as value at post-baseline visit minus value at Baseline.

End point type	Secondary

End point timeframe:

At Week 32 and Week 96 (compared with Baseline [Week -20])

End point values	CAB LA 600 mg+RPV LA 900 mg IM-Q8W (Maintenance and Extension)	CAB LA 400 mg+RPV LA 600 mg IM-Q4W (Maintenance and Extension)	CAB 30 mg+ABC/3TC QD (Induction Period and Maintenance Period)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	111	107	48	
Units: Femtoliters				
arithmetic mean (standard deviation)				
Week 32	2.5 (± 1.97)	2.3 (± 2.54)	7.1 (± 2.88)	
Week 96	0.1 (± 2.99)	0.3 (± 2.54)	5.3 (± 3.14)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in hematology parameter: Red Blood Cell count at Week 32 and Week 96 (Maintenance Period)

End point title	Change from Baseline in hematology parameter: Red Blood Cell count at Week 32 and Week 96 (Maintenance Period)

End point description:

Blood samples were collected for the analysis of hematology parameters including Red Blood Cell count at indicated time points. Baseline (Week -20) refers to the last available value up to and including the date of first induction period dosing with CAB 30 mg plus ABC/3TC. Change from Baseline was defined as value at post-baseline visit minus value at Baseline.

End point type	Secondary

End point timeframe:

At Week 32 and Week 96 (compared with Baseline [Week -20])

End point values	CAB LA 600 mg+RPV LA 900 mg IM-Q8W (Maintenance and Extension)	CAB LA 400 mg+RPV LA 600 mg IM-Q4W (Maintenance and Extension)	CAB 30 mg+ABC/3TC QD (Induction Period and Maintenance Period)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	111	107	48	
Units: 10^12 cells per Liter				
arithmetic mean (standard deviation)				
Week 32	0.03 (± 0.286)	0.02 (± 0.278)	-0.20 (± 0.296)	
Week 96	0.12 (± 0.294)	0.14 (± 0.310)	-0.13 (± 0.293)	

Statistical analyses

No statistical analyses for this end point

Secondary: Average initial concentration (C0) and Maximum Plasma Concentration (Cmax) of CAB LA (Q4W IM and Q8W IM dosing) (Maintenance Period)

End point title	Average initial concentration (C0) and Maximum Plasma Concentration (Cmax) of CAB LA (Q4W IM and Q8W IM dosing) (Maintenance Period)

End point description:

Blood samples were collected at indicated time points for pharmacokinetic (PK) analysis of CAB LA. The PK Concentration Population included all participants who received CAB LA and/or RPV LA and underwent PK sampling during the study, and provided available CAB LA and/or RPV LA plasma concentration data.

End point type	Secondary

End point timeframe:

Up to Week 32

End point values	CAB LA 600 mg+RPV LA 900 mg IM-Q8W (Maintenance and Extension)	CAB LA 400 mg+RPV LA 600 mg IM-Q4W (Maintenance and Extension)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	115	115		
Units: Micrograms per milliliter				
geometric mean (geometric coefficient of variation)				
C0	1.43 (± 54)	2.35 (± 32)		
Cmax	3.55 (± 56)	3.50 (± 39)		

Statistical analyses

No statistical analyses for this end point

Secondary: Trough concentration (Ctrough) of CAB LA (Q8W IM dosing) used for assessment of steady state (Maintenance Period)

End point title	Trough concentration (Ctrough) of CAB LA (Q8W IM dosing) used for assessment of steady state (Maintenance Period)

End point description:

Blood samples were collected at indicated time points for PK analysis of CAB LA. Ctrough is the lowest concentration reached by a drug before the next dose is administered. Ctrough for CAB LA (Q8W IM dosing) which were considered for the assessment of steady state are presented.

End point type	Secondary
End point timeframe: Pre-dose on Weeks 16, 24 and 32	

End point values	CAB LA 600 mg+RPV LA 900 mg IM-Q8W (Maintenance and Extension)			
Subject group type	Reporting group			
Number of subjects analysed	87			
Units: Micrograms per milliliter				
arithmetic mean (standard deviation)				
Week 16, n=87	1.6902 (± 0.80471)			
Week 24, n=86	1.6051 (± 0.78254)			
Week 32, n=84	1.5330 (± 0.70822)			

Statistical analyses

No statistical analyses for this end point

Secondary: Average initial concentration (C0) and Cmax of RPV LA (Q4W IM and Q8W IM dosing) (Maintenance Period)

End point title	Average initial concentration (C0) and Cmax of RPV LA (Q4W IM and Q8W IM dosing) (Maintenance Period)
End point description: Blood samples were collected at indicated time points for PK analysis of RPV LA. C0 and Cmax of RPV LA (Q4W IM and Q8W IM dosing) was evaluated.	
End point type	Secondary
End point timeframe: Up to Week 32	

End point values	CAB LA 600 mg+RPV LA 900 mg IM-Q8W (Maintenance and Extension)	CAB LA 400 mg+RPV LA 600 mg IM-Q4W (Maintenance and Extension)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	115	115		
Units: Nanograms per milliliter				
geometric mean (geometric coefficient of variation)				
C0	49.3 (± 41)	77.2 (± 35)		

Cmax	104 (± 47)	111 (± 40)		

Statistical analyses

No statistical analyses for this end point

Secondary: Ctrough of CAB LA (Q4W IM dosing) used for assessment of steady state (Maintenance Period)

End point title	Ctrough of CAB LA (Q4W IM dosing) used for assessment of steady state (Maintenance Period)

End point description:

Blood samples were collected at indicated time points for PK analysis of CAB LA. Ctrough is the lowest concentration reached by a drug before the next dose is administered. Ctrough for CAB LA (Q4W IM dosing) which were considered for the assessment of steady state are presented.

End point type	Secondary

End point timeframe:

Pre-dose on Weeks 16, 20, 24, 28 and 32

End point values	CAB LA 400 mg+RPV LA 600 mg IM-Q4W (Maintenance and Extension)			
Subject group type	Reporting group			
Number of subjects analysed	85			
Units: Micrograms per milliliter				
arithmetic mean (standard deviation)				
Week 16, n=78	2.2703 (± 0.92102)			
Week 20, n=77	2.3861 (± 0.76176)			
Week 24, n=78	2.6342 (± 1.29093)			
Week 28, n=82	2.4365 (± 0.86420)			
Week 32, n=85	2.4715 (± 0.89893)			

Statistical analyses

No statistical analyses for this end point

Secondary: Ctrough of RPV LA (Q8W IM dosing) used for assessment of steady state (Maintenance Period)

End point title	Ctrough of RPV LA (Q8W IM dosing) used for assessment of

	steady state (Maintenance Period)

End point description:

Blood samples were collected at indicated time points for PK analysis of RPV LA. Ctrough is the lowest concentration reached by a drug before the next dose is administered. Ctrough for RPV LA (Q8W IM dosing) which were considered for the assessment of steady state are presented.

End point type	Secondary

End point timeframe:

Pre-dose on Weeks 16, 24 and 32

End point values	CAB LA 600 mg+RPV LA 900 mg IM-Q8W (Maintenance and Extension)			
Subject group type	Reporting group			
Number of subjects analysed	87			
Units: Nanograms per milliliter				
arithmetic mean (standard deviation)				
Week 16, n=87	41.94 (± 17.575)			
Week 24, n=85	47.97 (± 22.341)			
Week 32, n=83	57.24 (± 22.926)			

Statistical analyses

No statistical analyses for this end point

Secondary: Ctrough of RPV LA (Q4W IM dosing) used for assessment of steady state (Maintenance Period)

End point title	Ctrough of RPV LA (Q4W IM dosing) used for assessment of steady state (Maintenance Period)

End point description:

Blood samples were collected at indicated time points for PK analysis of RPV LA. Ctrough is the lowest concentration reached by a drug before the next dose is administered. Ctrough for RPV LA (Q4W IM dosing) which were considered for the assessment of steady state are presented.

End point type	Secondary

End point timeframe:

Pre-dose on Weeks 16, 20, 24, 28 and 32

End point values	CAB LA 400 mg+RPV LA 600 mg IM-Q4W (Maintenance and Extension)			
Subject group type	Reporting group			
Number of subjects analysed	85			
Units: Nanograms per milliliter				
arithmetic mean (standard deviation)				
Week 16, n=78	66.92 (± 25.986)			
Week 20, n=77	74.55 (± 29.156)			
Week 24, n=78	76.84 (± 27.976)			
Week 28, n=83	80.84 (± 31.297)			
Week 32, n=85	90.34 (± 34.549)			

Statistical analyses

No statistical analyses for this end point

Secondary: Pharmacodynamic Response (HIV-1 RNA<50 c/mL) in relation with PK parameter (AUC[0-tau]) of CAB LA and RPV LA at Week 32 (Maintenance Period)

End point title	Pharmacodynamic Response (HIV-1 RNA<50 c/mL) in relation with PK parameter (AUC[0-tau]) of CAB LA and RPV LA at Week 32 (Maintenance Period)

End point description:

Logistic regression was used to examine the correlation between pharmacodynamics response (HIV-1 RNA<50 c/mL) at Week 32 and plasma PK parameter: area under plasma concentration-time curve from time zero to the end of dosing interval (AUC [0-tau]) of CAB LA and RPV LA per arm using MSDF (Missing, Switch or Discontinuation = Failure) algorithm. Estimates were obtained from logistic statistical model where the dependent variable is "HIV-1 RNA<50 c/mL" (success) and the independent variable is PK parameter (AUC [0-tau]). Slopes and standard error are presented. Estimated effect represents the change in log odds for a one-unit increase in the PK parameter AUC (0-tau). Standard Error (SE)=0.000 is defined as following: if for all participants was resulted same value for the specific timepoint, then SE is equal with 0.000.

End point type	Secondary

End point timeframe:

Up to Week 32

End point values	CAB LA 600 mg+RPV LA 900 mg IM-Q8W (Maintenance and Extension)	CAB LA 400 mg+RPV LA 600 mg IM-Q4W (Maintenance and Extension)	CAB 30 mg+ABC/3TC QD (Induction Period and Maintenance Period)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	86	84	0[8]	
Units: Change in log odds				
arithmetic mean (standard error)				

CAB LA	0.00 (± 0.001)	0.00 (± 0.002)	()	
RPV LA	0.00 (± 0.000)	0.00 (± 0.000)	()	

Notes:

[8] - No participants in this group were included in this analysis.

Statistical analyses

No statistical analyses for this end point

Secondary: Pharmacodynamic Response (HIV-1 RNA<50 c/mL) in relation with PK parameter (Average C0) of CAB LA and RPV LA at Week 32 (Maintenance Period)

End point title	Pharmacodynamic Response (HIV-1 RNA<50 c/mL) in relation with PK parameter (Average C0) of CAB LA and RPV LA at Week 32 (Maintenance Period)

End point description:

Logistic regression was used to examine the correlation between pharmacodynamics response (HIV-1 RNA<50 c/mL) at Week 32 and plasma PK parameter: Average C0 of CAB LA and RPV LA per arm using MSDF (Missing, Switch or Discontinuation = Failure) algorithm. Estimates were obtained from logistic statistical model where the dependent variable is "HIV-1 RNA<50 c/mL" (success) and the independent variable is PK parameter (Average C0). Slopes and standard error are presented. Estimated effect represents the change in log odds for a one-unit increase in the PK parameter Average C0.

End point type	Secondary

End point timeframe:

Up to Week 32

End point values	CAB LA 600 mg+RPV LA 900 mg IM-Q8W (Maintenance and Extension)	CAB LA 400 mg+RPV LA 600 mg IM-Q4W (Maintenance and Extension)	CAB 30 mg+ABC/3TC QD (Induction Period and Maintenance Period)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	101	108	50	
Units: Change in log odds				
arithmetic mean (standard error)				
CAB LA, n=100,108, 50	0.64 (± 0.837)	2.39 (± 1.903)	0.39 (± 0.528)	
RPV LA, n=101,104,49	0.00 (± 0.025)	0.01 (± 0.039)	-0.01 (± 0.020)	

Statistical analyses

No statistical analyses for this end point

Secondary: Pharmacodynamic Response (HIV-1 RNA<50 c/mL) in relation with PK parameter (Cmax) of CAB LA and RPV LA at Week 32 (Maintenance Period)

End point title	Pharmacodynamic Response (HIV-1 RNA<50 c/mL) in relation with PK parameter (Cmax) of CAB LA and RPV LA at Week 32 (Maintenance Period)

End point description:

Logistic regression was used to examine the correlation between pharmacodynamics response (HIV-1 RNA<50 c/mL) at Week 32 and plasma PK parameter: Cmax of CAB LA and RPV LA per arm using MSDF (Missing, Switch or Discontinuation = Failure) algorithm. Estimates were obtained from logistic statistical model where the dependent variable is "HIV-1 RNA<50 c/mL" (success) and the independent variable is PK parameter (Cmax). Slopes and standard error are presented. Estimated effect represents the change in log odds for a one-unit increase in the PK parameter Cmax.

End point type	Secondary

End point timeframe:

Up to Week 32

End point values	CAB LA 600 mg+RPV LA 900 mg IM-Q8W (Maintenance and Extension)	CAB LA 400 mg+RPV LA 600 mg IM-Q4W (Maintenance and Extension)	CAB 30 mg+ABC/3TC QD (Induction Period and Maintenance Period)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	98	97	0[9]	
Units: Change in log odds				
arithmetic mean (standard error)				
CAB LA, n=98, 97,0	-0.01 (± 0.174)	1.64 (± 1.707)	()	
RPV LA, n=97,96,0	0.00 (± 0.010)	0.01 (± 0.027)	()	

Notes:

[9] - No participants in this group were included in this analysis.

Statistical analyses

No statistical analyses for this end point

Secondary: Virologic Failure (from MSDF algorithm) in relation with PK parameter (AUC[0-tau]) of CAB LA and RPV LA at Week 32 (Maintenance Period)

End point title	Virologic Failure (from MSDF algorithm) in relation with PK parameter (AUC[0-tau]) of CAB LA and RPV LA at Week 32 (Maintenance Period)

End point description:

Logistic regression was used to examine the correlation between virologic failure at Week 32 and plasma PK parameter: AUC (0-tau) of CAB LA and RPV LA per arm using MSDF (Missing, Switch or Discontinuation = Failure) algorithm. Estimates were obtained from logistic statistical model where the dependent variable is "virologic failure" and the independent variable is PK parameter (AUC [0-tau]). Slopes and standard error are presented. Estimated effect represents the change in log odds for a one-unit increase in the PK parameter AUC (0-tau). SE=0.000 is defined as following: if for all participants was resulted same value for the specific timepoint, then SE is equal with 0.000.

End point type	Secondary

End point timeframe:

Up to Week 32

End point values	CAB LA 600 mg+RPV LA 900 mg IM-Q8W (Maintenance and Extension)	CAB LA 400 mg+RPV LA 600 mg IM-Q4W (Maintenance and Extension)	CAB 30 mg+ABC/3TC QD (Induction Period and Maintenance Period)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	86	84	0[10]	
Units: Change in log odds				
arithmetic mean (standard error)				
CAB LA	0.00 (± 0.001)	0.00 (± 0.002)	()	
RPV LA	0.00 (± 0.000)	0.00 (± 0.000)	()	

Notes:

[10] - No participants in this group were included in this analysis.

Statistical analyses

No statistical analyses for this end point

Secondary: Virologic Failure (from MSDF algorithm) in relation with PK parameter (Average C0) of CAB LA and RPV LA at Week 32 (Maintenance Period)

End point title	Virologic Failure (from MSDF algorithm) in relation with PK parameter (Average C0) of CAB LA and RPV LA at Week 32 (Maintenance Period)

End point description:

Logistic regression was used to examine the correlation between virologic failure at Week 32 and plasma PK parameter: Average C0 of CAB LA and RPV LA per arm using MSDF (Missing, Switch or Discontinuation = Failure) algorithm. Estimates were obtained from logistic statistical model where the dependent variable is "virologic failure" and the independent variable is PK parameter (Average C0). Slopes and standard error are presented. Estimated effect represents the change in log odds for a one-unit increase in the PK parameter Average C0.

End point type	Secondary

End point timeframe:

Up to Week 32

End point values	CAB LA 600 mg+RPV LA 900 mg IM-Q8W (Maintenance and Extension)	CAB LA 400 mg+RPV LA 600 mg IM-Q4W (Maintenance and Extension)	CAB 30 mg+ABC/3TC QD (Induction Period and Maintenance Period)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	101	108	50	
Units: Change in log odds				
arithmetic mean (standard error)				
CAB LA, n=100,108, 50	-1.01 (± 1.014)	-2.39 (± 1.903)	-0.53 (± 0.796)	
RPV LA, n=101,104,49	0.00 (± 0.027)	-0.01 (± 0.039)	-0.01 (± 0.038)	

Statistical analyses

No statistical analyses for this end point

Secondary: Virologic Failure (from MSDF algorithm) in relation with PK parameter (Cmax) of CAB LA and RPV LA at Week 32 (Maintenance Period)

End point title	Virologic Failure (from MSDF algorithm) in relation with PK parameter (Cmax) of CAB LA and RPV LA at Week 32 (Maintenance Period)

End point description:

Logistic regression was used to examine the correlation between virologic failure at Week 32 and plasma PK parameter: Cmax of CAB LA and RPV LA per arm using MSDF (Missing, Switch or Discontinuation = Failure) algorithm. Estimates were obtained from logistic statistical model where the dependent variable is "virologic failure" and the independent variable is PK parameter (Cmax). Slopes and standard error are presented. Estimated effect represents the change in log odds for a one-unit increase in the PK parameter Cmax.

End point type	Secondary

End point timeframe:

Up to Week 32

End point values	CAB LA 600 mg+RPV LA 900 mg IM-Q8W (Maintenance and Extension)	CAB LA 400 mg+RPV LA 600 mg IM-Q4W (Maintenance and Extension)	CAB 30 mg+ABC/3TC QD (Induction Period and Maintenance Period)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	98	97	0[11]	
Units: Change in log odds				
arithmetic mean (standard error)				
CAB LA, n=98, 97,0	-0.45 (± 0.509)	-1.64 (± 1.707)	()	
RPV LA, n=97,96,0	0.00 (± 0.012)	-0.01 (± 0.027)	()	

Notes:

[11] - No participants in this group were included in this analysis.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Treatment-emergent Genotypic Resistance

End point title	Number of Participants With Treatment-emergent Genotypic Resistance

End point description:

Plasma samples were collected to assess treatment emergent Genotypic Resistance for participants who had confirmed virologic failure. Number of participants who had any Integrase Inhibitor (INI) mutations or major mutations of other classes (Nucleoside reverse transcriptase inhibitor [NRTI], Non-nucleoside reverse transcriptase inhibitor [NNRTI], protease inhibitor [PI])are presented.

End point type	Secondary

End point timeframe:

Up to Week 32

End point values	CAB LA 600 mg+RPV LA 900 mg IM-Q8W (Maintenance and Extension)	CAB LA 400 mg+RPV LA 600 mg IM-Q4W (Maintenance and Extension)	CAB 30 mg+ABC/3TC QD (Induction Period and Maintenance Period)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	1	0[12]	1	
Units: Participants				
INI mutations	0		0	
Major mutations of other classes	0		0	

Notes:

[12] - No participants in this group were included in this analysis.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Treatment-emergent Phenotypic Resistance

End point title	Number of Participants With Treatment-emergent Phenotypic Resistance

End point description:

Plasma samples were collected for drug resistance testing. Number of participants, with treatment emergent phenotypic resistance to INI, NNRTI, NRTI and/or PI were summarized. Overall susceptibility of the drug was categorized as sensitive, partially sensitive and resistant.

End point type	Secondary

End point timeframe:

Up to Week 32

End point values	CAB LA 600 mg+RPV LA 900 mg IM-Q8W (Maintenance and Extension)	CAB LA 400 mg+RPV LA 600 mg IM-Q4W (Maintenance and Extension)	CAB 30 mg+ABC/3TC QD (Induction Period and Maintenance Period)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	1	0[13]	1	
Units: Participants				
INI, Sensitive	1		1	
INI, Partially sensitive	0		0	
INI, Resistant	0		0	
NNRTI, Sensitive	1		1	
NNRTI, Partially sensitive	0		0	
NNRTI, Resistant	0		0	
NRTI, Sensitive	1		1	
NRTI, Partially sensitive	0		0	
NRTI, Resistant	0		0	

PI, Sensitive	1		1	
PI, Partially sensitive	0		0	
PI, Resistant	0		0	

Notes:

[13] - No participants in this group were included in this analysis.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with plasma HIV-1 RNA level <50 c/mL over Week 32 by subgroups (Maintenance Period)

End point title	Percentage of participants with plasma HIV-1 RNA level <50 c/mL over Week 32 by subgroups (Maintenance Period)

End point description:

Percentage of participants with HIV-1 RNA<50 c/mL was obtained using FDA Snapshot algorithm. The algorithm treated all participants without HIV-1 RNA data at the visit of interest (due to missing data or discontinuation of investigational product prior to the visit window) as well as participants who switch their concomitant ART prior to the visit of interest, as non-responders. Data is presented for following subgroups: Baseline plasma HIV-1 RNA levels, Baseline CD4+ cell count, Race and HIV Risk factor (Homosexual contact [HC] and not injectable drug user).

End point type	Secondary

End point timeframe:

Up to Week 32

End point values	CAB LA 600 mg+RPV LA 900 mg IM-Q8W (Maintenance and Extension)	CAB LA 400 mg+RPV LA 600 mg IM-Q4W (Maintenance and Extension)	CAB 30 mg+ABC/3TC QD (Induction Period and Maintenance Period)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	99	94	49	
Units: Percentage of participants				
Baseline HIV-1 RNA<100000 c/mL, n=99,87,49	96	92	94	
Baseline HIV-1 RNA>=100000 c/mL, n=16,28,7	88	100	71	
Baseline HIV-1 RNA<1000 c/mL, n=0,3,1	0	100	100	
Baseline HIV-1 RNA 1000 to<10000c/mL, n=26,25,13	100	84	92	
Baseline HIV-1 RNA 1000 to <50000c/mL, n=50,42,25	49	39	24	
Baseline HIV-1 RNA 50000 to<100000c/mL,n=23,17,10	87	100	90	
Baseline HIV-1 RNA>=100000 to<200000c/mL,n=9,13,2	89	100	50	
Baseline plasma HIV-1 RNA >=200000 c/mL, n=7,15,5	86	100	80	
Baseline CD4+ cell count <200 cells/mm^3, n=3,2,0	100	100	0	
Baseline CD4+ count 200 to<350cells/mm^3,n=30,23,8	97	100	88	

Baseline CD4+ count >=350 cells/mm^3, n=82,90,48	94	92	92	
Race-White, n=93,94,39	95	94	95	
Race-Non-White, n=22,21,17	95	95	82	
HC and not injectable drug user, n=98,90,40	96	94	90	
No HC and not injectable drug user, n=17,25,16	88	92	94	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with protocol defined virologic failure (PDVF) at Week 32 by subgroups(Maintenance Period)

End point title	Percentage of participants with protocol defined virologic failure (PDVF) at Week 32 by subgroups(Maintenance Period)

End point description:

Virologic failure was defined as any of the following: (1) Non-response as indicated by a less than a 1.0 log10 c/mL decrease in plasma HIV-1 RNA after 4 weeks of starting the Induction Period, which is subsequently confirmed, unless the plasma HIV-1 RNA is < 400 c/mL; (2) Rebound as indicated by two consecutive plasma HIV-1 RNA levels >=200 c/mL after prior suppression to <200 c/mL; (3) Rebound as indicated by two consecutive plasma HIV-1 RNA that are > 0.5 log10 c/mL increase in plasma HIV-1 RNA from the nadir value on study, where the lowest HIV-1 RNA value is >=200 c/mL. Data is presented for following subgroups: Baseline plasma HIV-1 RNA levels, Baseline CD4+ cell count, Race and HIV Risk factor (Homosexual contact [HC] and not injectable drug user).

End point type	Secondary

End point timeframe:

Up to Week 32

End point values	CAB LA 600 mg+RPV LA 900 mg IM-Q8W (Maintenance and Extension)	CAB LA 400 mg+RPV LA 600 mg IM-Q4W (Maintenance and Extension)	CAB 30 mg+ABC/3TC QD (Induction Period and Maintenance Period)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	99	94	49	
Units: Percentage of participants				
Baseline HIV-1 RNA<100000 c/mL, n=99,87,49	3	1	0	
Baseline HIV-1 RNA>=100000 c/mL, n=16,28,7	13	0	29	
Baseline HIV-1 RNA<1000 c/mL, n=0,3,1	0	0	0	
Baseline HIV-1 RNA 1000 to<10000c/mL, n=26,25,13	0	4	0	
Baseline HIV-1 RNA 1000 to <50000c/mL, n=50,42,25	2	0	0	
Baseline HIV-1 RNA 50000 to<100000c/mL,n=23,17,10	0	0	0	
Baseline HIV-1 RNA>=100000 to<200000c/mL,n=9,13,2	11	0	50	

Baseline plasma HIV-1 RNA >=200000 c/mL, n=7,15,5	14	0	20	
Baseline CD4+ cell count <200 cells/mm^3, n=3,2,0	0	0	0	
Baseline CD4+ count 200 to<350cells/mm^3,n=30,23,8	0	0	13	
Baseline CD4+ count >=350 cells/mm^3, n=82,90,48	6	1	2	
Race-White, n=93,94,39	4	1	0	
Race-Non-White, n=22,21,17	5	0	12	
HC and not injectable drug user, n=98,90,40	3	1	5	
No HC and not injectable drug user, n=17,25,16	12	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: HIV treatment satisfaction questionnaire - status version (HIVTSQ[s]) Total Score at Week 32 and Week 96 (Maintenance Period)

End point title	HIV treatment satisfaction questionnaire - status version (HIVTSQ[s]) Total Score at Week 32 and Week 96 (Maintenance Period)

End point description:

The HIVTSQ(s) was developed to evaluate treatments for HIV and participant satisfaction. It has total 14 items and each items are scored from 6 (very satisfied) to 0 (very dissatisfied). Items 1 to 12 are summed to produce the Total Treatment Satisfaction Score with a possible range of 0 to 72. Higher scores represent greater treatment satisfaction as compared to the past few weeks.

End point type	Secondary

End point timeframe:

At Week 32 and Week 96

End point values	CAB LA 600 mg+RPV LA 900 mg IM-Q8W (Maintenance and Extension)	CAB LA 400 mg+RPV LA 600 mg IM-Q4W (Maintenance and Extension)	CAB 30 mg+ABC/3TC QD (Induction Period and Maintenance Period)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	109	106	50	
Units: Scores on a scale				
arithmetic mean (standard deviation)				
Week 32	68.4 (± 4.48)	66.6 (± 6.47)	65.1 (± 5.83)	
Week 96	68.4 (± 4.34)	67.0 (± 5.20)	63.5 (± 9.75)	

Statistical analyses

No statistical analyses for this end point

Secondary: HIV treatment satisfaction questionnaire - change version (HIVTSQ[c]) Total Score at Week 32 (Maintenance Period)

End point title	HIV treatment satisfaction questionnaire - change version (HIVTSQ[c]) Total Score at Week 32 (Maintenance Period)

End point description:

The HIVTSQ(c) was developed to evaluate treatments for HIV and participant satisfaction. It has total 14 items and each items are scored from +3 ('much more satisfied', 'much more convenient', 'much more flexible', etc.) to -3 ('much less satisfied', 'much less convenient', 'much less flexible', etc.). Items 1 to 12 (excluding Items 7b and 9b) are summed to produce a Total Treatment Satisfaction Score (change) with a possible range of -33 to +33. The higher the score, the greater the improvement in satisfaction with treatment; the lower the score, the greater the deterioration in satisfaction with treatment.

End point type	Secondary

End point timeframe:

Week 32

End point values	CAB LA 600 mg+RPV LA 900 mg IM-Q8W (Maintenance and Extension)	CAB LA 400 mg+RPV LA 600 mg IM-Q4W (Maintenance and Extension)	CAB 30 mg+ABC/3TC QD (Induction Period and Maintenance Period)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	106	100	49	
Units: Scores on a scale				
arithmetic mean (standard deviation)	30.9 (± 7.56)	28.9 (± 8.53)	20.5 (± 14.09)	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with HIV Medication Questionnaire (HIVMQ) Item E and F Scores at Week 32 (Maintenance Period)

End point title	Number of participants with HIV Medication Questionnaire (HIVMQ) Item E and F Scores at Week 32 (Maintenance Period)

End point description:

The HIVMQ was developed to assess participant reported medication adherence. It has 6 items (a, b, c, d, e, f). Item E (How often do you find it inconvenient or difficult to take/receive medication as recommended?) and Item F (How much pain/discomfort have experienced with this medication?). Each of these 2 items are scored from 0 (none of the time) to 6 (all of the time). The higher the score, the greater the adherence to medication. Number of participants with HIVMQ Item E and F Scores at Week 32 by their score categories (0: none of the time to 6: all of the time) are presented.

End point type	Secondary

End point timeframe:

Week 32

End point values	CAB LA 600 mg+RPV LA 900 mg IM-Q8W (Maintenance and Extension)	CAB LA 400 mg+RPV LA 600 mg IM-Q4W (Maintenance and Extension)	CAB 30 mg+ABC/3TC QD (Induction Period and Maintenance Period)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	109	106	50	
Units: Participants				
Item E, score 0	80	73	16	
Item E, score 1	12	14	13	
Item E, score 2	3	2	2	
Item E, score 3	2	6	3	
Item E, score 4	0	1	1	
Item E, score 5	2	4	12	
Item E, score 6	10	6	3	
Item F, Score 0	40	33	29	
Item F, Score 1	35	43	12	
Item F, Score 2	17	16	2	
Item F, Score 3	6	5	2	
Item F, Score 4	7	3	2	
Item F, Score 5	4	4	0	
Item F, Score 6	0	2	2	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with HIV Medication Questionnaire (HIVMQ) Item E and F Scores at Week 96 (Maintenance Period)

End point title	Number of participants with HIV Medication Questionnaire (HIVMQ) Item E and F Scores at Week 96 (Maintenance Period)

End point description:

The HIVMQ was developed to assess participant reported medication adherence. It has 6 items (a, b, c, d, e, f). Item E (How often do you find it inconvenient or difficult to take/receive medication as recommended?) and Item F (How much pain/discomfort have experienced with this medication?). Each of these 2 items are scored from 0 (none of the time) to 6 (all of the time). The higher the score, the greater the adherence to medication. Number of participants with HIVMQ Item E and F Scores at Week 96 by their score categories (0: none of the time to 6: all of the time) are presented. Analysis was performed on the participants that received exclusively an oral regimen during the 96-weeks period [CAB 30mg+ABC/3TC QD (Induction Period and Maintenance Period) group], as pre-specified in Protocol.

End point type	Secondary

End point timeframe:

Week 96

End point values	CAB 30 mg+ABC/3TC QD (Induction Period and Maintenance Period)			
Subject group type	Reporting group			
Number of subjects analysed	46			
Units: Participants				
Item E, score 0	18			
Item E, score 1	10			
Item E, score 2	3			
Item E, score 3	32			
Item E, score 4	1			
Item E, score 5	9			
Item E, score 6	3			
Item F, Score 0	3			
Item F, Score 1	8			
Item F, Score 2	4			
Item F, Score 3	1			
Item F, Score 4	0			
Item F, Score 5	1			
Item F, Score 6	1			

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

All-cause mortality, SAEs and non-SAEs were collected from start of the study treatment up to end of Extension and LTFU Periods (up to approximately 468 weeks).

Adverse event reporting additional description:

Safety population included all randomized participants who received at least one dose of study drug, based on the study phase they were included in.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	18.1

Reporting groups

Reporting group title	Long-Term Follow-Up Group

Reporting group description:

This group included participants that were withdrawn from CAB LA+RPV LA IM regimens based on protocol criteria and were required to access Highly Active Antiretroviral Therapy (HAART) of choice. Participants were followed up for approximately 52 weeks.

Reporting group title	CAB 30 mg+ABC/3TC QD (Induction Period)

Reporting group description:

In induction period, all participants received an oral regimen of cabotegravir (CAB) 30 milligrams (mg) once daily (QD) plus abacavir/lamivudine (ABC/3TC) 600/300 mg QD for 20 weeks. They also received an oral dose of Rilpivirine (RPV) 25 mg tablet once daily in the last 4 weeks of the Induction Period.

Reporting group title	CAB LA 400 mg+RPV LA 600 mg IM-Q4W (Maintenance and Extension)

Reporting group description:

On Day 1 of the Maintenance period, participants who successfully completed the Induction period, were randomized to receive following intramuscular (IM) doses: Day 1 only: CAB long acting (LA) 800 mg (loading dose delivered as two 400 mg IM injections) + RPV LA 900 mg IM; Week 4 only: CAB LA 600 mg IM (second loading dose, no RPV); and from Week 8: CAB LA 600 mg IM +RPV LA 900 mg IM every 8 Weeks (Q8W) for 96 weeks. Eligible participants had the option to continue study participation in the Extension Period.

Reporting group title	Optimized CAB LA 400 mg+RPV LA 600 mg IM-Q4W (Extension)

Reporting group description:

Participants who completed 96 weeks of CAB 30 mg + ABC/3TC QD regimen in Maintenance Period transitioned to Extension Period and received an optimized loading dose of CAB LA 400 mg+RPV LA 900 mg IM at Week 100 followed by CAB LA 400 mg+RPV LA 900 mg IM-Q8W in the Extension Phase. Participants were followed up until end of Extension Period.

Reporting group title	CAB 30 mg+ABC/3TC QD (Induction and Maintenance)

Reporting group description:

On Day 1 of the Maintenance period, participants who successfully completed the Induction period, were randomized to receive CAB and ABC/3TC QD for 96 weeks. Eligible participants had the option to continue study participation in Extension Period by switching to an optimized IM CAB LA+ RPV LA regimen of their choice (Q8W or Q4W).

Reporting group title	Optimized CAB LA 600 mg+RPV LA 900 mg IM-Q8W (Extension)

Reporting group description:

Participants who completed 96 weeks of CAB 30 mg + ABC/3TC QD regimen in Maintenance Period transitioned to Extension Period and received an optimized loading dose of CAB LA 600 mg+RPV LA 900 mg IM at Week 100 and Week 104 followed by CAB LA 600 mg+RPV LA 900 mg IM-Q8W in the Extension Phase. Participants were followed up until end of Extension Period.

Reporting group title	CAB LA 400 mg+RPV LA 600 mg IM-Q4W (Maintenance and Extension)

Reporting group description:

On Day 1 of the Maintenance period, participants who successfully completed the Induction period, were

randomized to receive following IM doses: Day 1 only: CAB LA 800 mg (loading dose delivered as two 400 mg IM injections) + RPV LA 600 mg IM; and from Week 4: CAB LA 400 mg IM + RPV LA 600 mg IM every 4 Weeks (Q4W) for 96 weeks. Eligible participants had the option to continue study participation in the Extension Period.

Serious adverse events	Long-Term Follow-Up Group	CAB 30 mg+ABC/3TC QD (Induction Period)	CAB LA 400 mg+RPV LA 600 mg IM-Q4W (Maintenance and Extension)
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 43 (16.28%)	8 / 309 (2.59%)	31 / 115 (26.96%)
number of deaths (all causes)	0	1	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Anogenital warts			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningioma			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm prostate			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	0 / 115 (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
Squamous cell carcinoma of lung			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	0 / 115 (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
Anal neoplasm			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	0 / 115 (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			
Hypertension			

subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic dilatation			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Flushing			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	0 / 115 (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
Haematoma			
subjects affected / exposed	1 / 43 (2.33%)	0 / 309 (0.00%)	0 / 115 (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
General disorders and administration site conditions			
Hernia			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	0 / 115 (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
Chest pain			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	0 / 115 (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
Pyrexia			
subjects affected / exposed	1 / 43 (2.33%)	0 / 309 (0.00%)	0 / 115 (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
Immune system disorders			
Eosinophilic granulomatosis with polyangiitis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	0 / 115 (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

Reproductive system and breast disorders			
Ovarian cyst			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	0 / 115 (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
Benign prostatic hyperplasia			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	0 / 115 (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
Prostatitis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	0 / 115 (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
Pelvic prolapse			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	0 / 115 (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			
Acute pulmonary oedema			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	0 / 115 (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
Asthmatic crisis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasal septum deviation			

subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	0 / 115 (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 embolism			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	0 / 115 (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			
Suicide attempt			
subjects affected / exposed	2 / 43 (4.65%)	0 / 309 (0.00%)	2 / 115 (1.74%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Substance abuse			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	0 / 115 (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
Drug abuse			
subjects affected / exposed	1 / 43 (2.33%)	0 / 309 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adjustment disorder			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	0 / 115 (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
Alcohol withdrawal syndrome			
subjects affected / exposed	1 / 43 (2.33%)	0 / 309 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bipolar I disorder			

subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bipolar disorder			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	0 / 115 (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
Delirium			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delusion			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	1 / 115 (0.87%)
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	0 / 43 (0.00%)	0 / 309 (0.00%)	1 / 115 (0.87%)
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 suicidal			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Major depression			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dissociation			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	0 / 115 (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
Mania			

subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal ideation			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	0 / 115 (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
Psychotic behaviour			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric decompensation			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aggression			
subjects affected / exposed	1 / 43 (2.33%)	0 / 309 (0.00%)	0 / 115 (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
Injury, poisoning and procedural complications			
Overdose			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	0 / 115 (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
Rib fracture			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	0 / 115 (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
Epicondylitis			
subjects affected / exposed	0 / 43 (0.00%)	1 / 309 (0.32%)	0 / 115 (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
Road traffic accident			

subjects affected / exposed	0 / 43 (0.00%)	1 / 309 (0.32%)	0 / 115 (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
Multiple injuries			
subjects affected / exposed	0 / 43 (0.00%)	1 / 309 (0.32%)	0 / 115 (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
Uterine perforation			
subjects affected / exposed	0 / 43 (0.00%)	1 / 309 (0.32%)	0 / 115 (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
Toxicity to various agents			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	0 / 115 (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
Accidental overdose			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alcohol poisoning			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carbon monoxide poisoning			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	0 / 115 (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
Fibula fracture			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament rupture			

subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radius fracture			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	0 / 115 (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
Tendon injury			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypobarism			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	0 / 115 (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
Tendon rupture			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	0 / 115 (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
Facial bones fracture			
subjects affected / exposed	1 / 43 (2.33%)	0 / 309 (0.00%)	0 / 115 (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
Head injury			
subjects affected / exposed	1 / 43 (2.33%)	0 / 309 (0.00%)	0 / 115 (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
Jaw fracture			
subjects affected / exposed	1 / 43 (2.33%)	0 / 309 (0.00%)	0 / 115 (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
Congenital, familial and genetic disorders			
Hydrocele			

subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	0 / 115 (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
Buried penis syndrome			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Myocardial infarction			
subjects affected / exposed	0 / 43 (0.00%)	1 / 309 (0.32%)	0 / 115 (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
Acute myocardial infarction			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	0 / 115 (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
Cardiogenic shock			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina unstable			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	0 / 115 (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 / 43 (0.00%)	0 / 309 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Epilepsy			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	0 / 115 (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
Headache			

subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine			
subjects affected / exposed	0 / 43 (0.00%)	1 / 309 (0.32%)	0 / 115 (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
Nerve root compression			
subjects affected / exposed	0 / 43 (0.00%)	1 / 309 (0.32%)	0 / 115 (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
Syncope			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	2 / 115 (1.74%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cognitive disorder			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	0 / 115 (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
Coma			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	0 / 115 (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
Dizziness			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	0 / 115 (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
Leukoencephalopathy			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	0 / 115 (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
Motor neurone disease			

subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	0 / 115 (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
Polyneuropathy alcoholic			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sciatica			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VIth nerve paralysis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	0 / 115 (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
Seizure			
subjects affected / exposed	1 / 43 (2.33%)	0 / 309 (0.00%)	0 / 115 (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
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coagulopathy			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Splenic vein thrombosis			
subjects affected / exposed	1 / 43 (2.33%)	0 / 309 (0.00%)	0 / 115 (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
Lymphadenopathy			

subjects affected / exposed	1 / 43 (2.33%)	0 / 309 (0.00%)	0 / 115 (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
Eye disorders			
Blindness			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	1 / 115 (0.87%)
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			
Gastritis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	0 / 115 (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
Umbilical hernia			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal hernia			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	0 / 115 (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
Abdominal pain			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	0 / 115 (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
Anal fissure			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum intestinal			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	0 / 115 (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
Duodenal ulcer			

subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mesenteric vein thrombosis			
subjects affected / exposed	1 / 43 (2.33%)	0 / 309 (0.00%)	0 / 115 (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
Gastric ulcer perforation			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal food impaction			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	0 / 115 (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
Diarrhoea			
subjects affected / exposed	1 / 43 (2.33%)	0 / 309 (0.00%)	0 / 115 (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			
Drug-induced liver injury			
subjects affected / exposed	0 / 43 (0.00%)	1 / 309 (0.32%)	0 / 115 (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
Hepatic failure			

subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Portal vein thrombosis			
subjects affected / exposed	1 / 43 (2.33%)	0 / 309 (0.00%)	0 / 115 (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
Ischaemic hepatitis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis alcoholic			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	0 / 115 (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
Skin and subcutaneous tissue disorders			
Toxic skin eruption			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	0 / 115 (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			
Nephrolithiasis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	1 / 115 (0.87%)
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 kidney injury			
subjects affected / exposed	1 / 43 (2.33%)	0 / 309 (0.00%)	2 / 115 (1.74%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			

subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Neck pain			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc protrusion			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	0 / 115 (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
Osteoarthritis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhabdomyolysis			
subjects affected / exposed	1 / 43 (2.33%)	0 / 309 (0.00%)	0 / 115 (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
Rotator cuff syndrome			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	0 / 115 (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			

Abscess limb			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal abscess			
subjects affected / exposed	0 / 43 (0.00%)	1 / 309 (0.32%)	0 / 115 (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
Epididymitis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orchitis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	1 / 115 (0.87%)
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			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	0 / 115 (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 / 43 (0.00%)	0 / 309 (0.00%)	0 / 115 (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 / 43 (0.00%)	1 / 309 (0.32%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis infective			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			

subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	1 / 115 (0.87%)
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 / 43 (0.00%)	0 / 309 (0.00%)	2 / 115 (1.74%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	0 / 115 (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
Herpes zoster			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	0 / 115 (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
Localised infection			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	0 / 115 (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
Malaria			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	1 / 115 (0.87%)
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 aspiration			

subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	0 / 115 (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
Pyelonephritis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	1 / 43 (2.33%)	0 / 309 (0.00%)	0 / 115 (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
Septic shock			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Shigella infection			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	0 / 115 (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 / 43 (0.00%)	0 / 309 (0.00%)	0 / 115 (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
Meningitis aseptic			

subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	0 / 115 (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			
Obesity			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic acidosis			
subjects affected / exposed	1 / 43 (2.33%)	0 / 309 (0.00%)	0 / 115 (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
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	1 / 115 (0.87%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Optimized CAB LA 400 mg+RPV LA 600 mg IM-Q4W (Extension)	CAB 30 mg+ABC/3TC QD (Induction and Maintenance)	Optimized CAB LA 600 mg+RPV LA 900 mg IM-Q8W (Extension)
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 10 (10.00%)	9 / 56 (16.07%)	9 / 34 (26.47%)
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)			
Anogenital warts			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Meningioma			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Neoplasm prostate			

subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Squamous cell carcinoma of lung			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Anal neoplasm			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	1 / 34 (2.94%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Aortic dilatation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Flushing			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Haematoma			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
General disorders and administration site conditions			
Hernia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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

Chest pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Pyrexia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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			
Eosinophilic granulomatosis with polyangiitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Reproductive system and breast disorders			
Ovarian cyst			
subjects affected / exposed	0 / 10 (0.00%)	1 / 56 (1.79%)	0 / 34 (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
Benign prostatic hyperplasia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Prostatitis			
subjects affected / exposed	0 / 10 (0.00%)	1 / 56 (1.79%)	0 / 34 (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
Pelvic prolapse			
subjects affected / exposed	0 / 10 (0.00%)	1 / 56 (1.79%)	0 / 34 (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			
Acute pulmonary oedema			

subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Dyspnoea			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Asthmatic crisis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Nasal septum deviation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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 embolism			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Pneumothorax			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	1 / 34 (2.94%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Suicide attempt			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Substance abuse			
subjects affected / exposed	0 / 10 (0.00%)	1 / 56 (1.79%)	0 / 34 (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
Drug abuse			

subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Adjustment disorder			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Alcohol withdrawal syndrome			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Bipolar I disorder			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Bipolar disorder			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Delirium			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Delusion			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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 / 10 (0.00%)	1 / 56 (1.79%)	0 / 34 (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
Depression suicidal			

subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Dissociation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Mania			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Psychotic behaviour			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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 decompensation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Aggression			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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			
Overdose			

subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Rib fracture			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Epicondylitis			
subjects affected / exposed	0 / 10 (0.00%)	1 / 56 (1.79%)	0 / 34 (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
Road traffic accident			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	1 / 34 (2.94%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple injuries			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Uterine perforation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Toxicity to various agents			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Accidental overdose			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Alcohol poisoning			

subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Carbon monoxide poisoning			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Fibula fracture			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Ligament rupture			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Radius fracture			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Tendon injury			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Hypobarism			
subjects affected / exposed	0 / 10 (0.00%)	1 / 56 (1.79%)	0 / 34 (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
Tendon rupture			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	1 / 34 (2.94%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial bones fracture			

subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Head injury			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Jaw fracture			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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			
Hydrocele			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Buried penis syndrome			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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			
Myocardial infarction			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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 myocardial infarction			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Cardiogenic shock			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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			
Epilepsy			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Headache			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Migraine			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Nerve root compression			
subjects affected / exposed	0 / 10 (0.00%)	1 / 56 (1.79%)	0 / 34 (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
Syncope			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Cognitive disorder			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Coma			

subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Dizziness			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Leukoencephalopathy			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Motor neurone disease			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Polyneuropathy alcoholic			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Sciatica			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
VIth nerve paralysis			
subjects affected / exposed	1 / 10 (10.00%)	0 / 56 (0.00%)	0 / 34 (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
Seizure			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	1 / 34 (2.94%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			

subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Coagulopathy			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Splenic vein thrombosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Lymphadenopathy			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Eye disorders			
Blindness			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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			
Gastritis			
subjects affected / exposed	0 / 10 (0.00%)	1 / 56 (1.79%)	0 / 34 (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
Umbilical hernia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Abdominal hernia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Abdominal pain			

subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	1 / 34 (2.94%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal fissure			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Diverticulum intestinal			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Duodenal ulcer			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Mesenteric vein thrombosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Gastric ulcer perforation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Enterocolitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Oesophageal food impaction			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Abdominal pain upper			

subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	1 / 34 (2.94%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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			
Drug-induced liver injury			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Hepatic failure			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Portal vein thrombosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Ischaemic hepatitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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 alcoholic			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Cholelithiasis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	1 / 34 (2.94%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			

Toxic skin eruption			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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			
Nephrolithiasis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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 kidney injury			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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 failure			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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			
Neck pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Muscular weakness			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Pain in extremity			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Intervertebral disc protrusion			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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

Osteoarthritis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Rhabdomyolysis			
subjects affected / exposed	0 / 10 (0.00%)	1 / 56 (1.79%)	0 / 34 (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
Rotator cuff syndrome			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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			
Abscess limb			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Anal abscess			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Epididymitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Orchitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	2 / 34 (5.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonsillar abscess			

subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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 / 10 (0.00%)	1 / 56 (1.79%)	0 / 34 (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
Arthritis infective			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Viral infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Clostridium difficile infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Herpes zoster			

subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Localised infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Malaria			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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 aspiration			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Pyelonephritis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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 tract infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Shigella infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Urosepsis			

subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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 viral			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	1 / 34 (2.94%)
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 / 10 (0.00%)	0 / 56 (0.00%)	1 / 34 (2.94%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis aseptic			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	1 / 34 (2.94%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Obesity			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Metabolic acidosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (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	CAB LA 400 mg+RPV LA 600 mg IM-Q4W (Maintenance and Extension)		
Total subjects affected by serious adverse events			
subjects affected / exposed	31 / 115 (26.96%)		
number of deaths (all causes)	3		

number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Anogenital warts			
subjects affected / exposed	1 / 115 (0.87%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Meningioma			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neoplasm prostate			
subjects affected / exposed	1 / 115 (0.87%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Squamous cell carcinoma of lung			
subjects affected / exposed	1 / 115 (0.87%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Anal neoplasm			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 115 (0.87%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Aortic dilatation			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Flushing			

subjects affected / exposed	1 / 115 (0.87%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Haematoma			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Hernia			
subjects affected / exposed	1 / 115 (0.87%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Chest pain			
subjects affected / exposed	2 / 115 (1.74%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Pyrexia			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Eosinophilic granulomatosis with polyangiitis			
subjects affected / exposed	1 / 115 (0.87%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Ovarian cyst			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Benign prostatic hyperplasia			

subjects affected / exposed	1 / 115 (0.87%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Prostatitis				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pelvic prolapse				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory, thoracic and mediastinal disorders				
Acute pulmonary oedema				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dyspnoea				
subjects affected / exposed	1 / 115 (0.87%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Asthmatic crisis				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nasal septum deviation				
subjects affected / exposed	1 / 115 (0.87%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pulmonary embolism				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumothorax				

subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Suicide attempt			
subjects affected / exposed	1 / 115 (0.87%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Substance abuse			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Drug abuse			
subjects affected / exposed	1 / 115 (0.87%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Adjustment disorder			
subjects affected / exposed	1 / 115 (0.87%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Alcohol withdrawal syndrome			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bipolar I disorder			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bipolar disorder			
subjects affected / exposed	1 / 115 (0.87%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Delirium			

subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Delusion				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Depression				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Depression suicidal				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Major depression				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dissociation				
subjects affected / exposed	1 / 115 (0.87%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Mania				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Suicidal ideation				
subjects affected / exposed	1 / 115 (0.87%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Psychotic behaviour				

subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Psychiatric decompensation				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Aggression				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Injury, poisoning and procedural complications				
Overdose				
subjects affected / exposed	2 / 115 (1.74%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Rib fracture				
subjects affected / exposed	1 / 115 (0.87%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Epicondylitis				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Road traffic accident				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Multiple injuries				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Uterine perforation				

subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Toxicity to various agents				
subjects affected / exposed	2 / 115 (1.74%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 1			
Accidental overdose				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Alcohol poisoning				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Carbon monoxide poisoning				
subjects affected / exposed	1 / 115 (0.87%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Fibula fracture				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ligament rupture				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Radius fracture				
subjects affected / exposed	1 / 115 (0.87%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Tendon injury				

subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypobarism			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tendon rupture			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Facial bones fracture			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Head injury			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Jaw fracture			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Congenital, familial and genetic disorders			
Hydrocele			
subjects affected / exposed	1 / 115 (0.87%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Buried penis syndrome			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			

Myocardial infarction				
subjects affected / exposed	1 / 115 (0.87%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	1 / 1			
Acute myocardial infarction				
subjects affected / exposed	1 / 115 (0.87%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cardiogenic shock				
subjects affected / exposed	1 / 115 (0.87%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Angina unstable				
subjects affected / exposed	1 / 115 (0.87%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Myocardial ischaemia				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nervous system disorders				
Epilepsy				
subjects affected / exposed	1 / 115 (0.87%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Headache				
subjects affected / exposed	1 / 115 (0.87%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Migraine				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nerve root compression				

subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Syncope				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cognitive disorder				
subjects affected / exposed	1 / 115 (0.87%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Coma				
subjects affected / exposed	1 / 115 (0.87%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Dizziness				
subjects affected / exposed	1 / 115 (0.87%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Leukoencephalopathy				
subjects affected / exposed	1 / 115 (0.87%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Motor neurone disease				
subjects affected / exposed	1 / 115 (0.87%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Polyneuropathy alcoholic				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sciatica				

subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
VIth nerve paralysis			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Seizure			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Coagulopathy			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Splenic vein thrombosis			
subjects affected / exposed	1 / 115 (0.87%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lymphadenopathy			
subjects affected / exposed	1 / 115 (0.87%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Eye disorders			
Blindness			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			

Gastritis				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Umbilical hernia				
subjects affected / exposed	1 / 115 (0.87%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Abdominal hernia				
subjects affected / exposed	1 / 115 (0.87%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Abdominal pain				
subjects affected / exposed	1 / 115 (0.87%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Anal fissure				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diverticulum intestinal				
subjects affected / exposed	1 / 115 (0.87%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Duodenal ulcer				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Mesenteric vein thrombosis				
subjects affected / exposed	1 / 115 (0.87%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastric ulcer perforation				

subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Enterocolitis				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oesophageal food impaction				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Abdominal pain upper				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diarrhoea				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatobiliary disorders				
Drug-induced liver injury				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatic failure				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Portal vein thrombosis				
subjects affected / exposed	1 / 115 (0.87%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Ischaemic hepatitis				

subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatitis alcoholic			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cholelithiasis			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Toxic skin eruption			
subjects affected / exposed	1 / 115 (0.87%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Acute kidney injury			
subjects affected / exposed	2 / 115 (1.74%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Renal failure			
subjects affected / exposed	1 / 115 (0.87%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Neck pain			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Muscular weakness				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pain in extremity				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intervertebral disc protrusion				
subjects affected / exposed	2 / 115 (1.74%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Osteoarthritis				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rhabdomyolysis				
subjects affected / exposed	1 / 115 (0.87%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Rotator cuff syndrome				
subjects affected / exposed	1 / 115 (0.87%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
Abscess limb				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Anal abscess				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Epididymitis				

subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Orchitis				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Peritonsillar abscess				
subjects affected / exposed	1 / 115 (0.87%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Arthritis infective				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Viral infection				
subjects affected / exposed	1 / 115 (0.87%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cellulitis				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
COVID-19				

subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Clostridium difficile infection				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diverticulitis				
subjects affected / exposed	1 / 115 (0.87%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Herpes zoster				
subjects affected / exposed	1 / 115 (0.87%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Localised infection				
subjects affected / exposed	1 / 115 (0.87%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Malaria				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia aspiration				
subjects affected / exposed	1 / 115 (0.87%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pyelonephritis				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory tract infection				

subjects affected / exposed	1 / 115 (0.87%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Septic shock				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Shigella infection				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urosepsis				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis viral				
subjects affected / exposed	0 / 115 (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 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Meningitis aseptic				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metabolism and nutrition disorders				
Obesity				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metabolic acidosis				

subjects affected / exposed	1 / 115 (0.87%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 115 (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	Long-Term Follow-Up Group	CAB 30 mg+ABC/3TC QD (Induction Period)	CAB LA 400 mg+RPV LA 600 mg IM-Q4W (Maintenance and Extension)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 43 (16.28%)	145 / 309 (46.93%)	115 / 115 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Anogenital warts			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	11 / 115 (9.57%)
occurrences (all)	0	0	19
Skin papilloma			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	8 / 115 (6.96%)
occurrences (all)	0	0	10
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	10 / 115 (8.70%)
occurrences (all)	0	0	12
General disorders and administration site conditions			
Injection site swelling			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	41 / 115 (35.65%)
occurrences (all)	0	0	209
Injection site pain			
subjects affected / exposed	4 / 43 (9.30%)	0 / 309 (0.00%)	111 / 115 (96.52%)
occurrences (all)	4	0	2749
Injection site bruising			

subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	24 / 115 (20.87%)
occurrences (all)	0	0	65
Injection site warmth			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	32 / 115 (27.83%)
occurrences (all)	0	0	161
Fatigue			
subjects affected / exposed	0 / 43 (0.00%)	19 / 309 (6.15%)	13 / 115 (11.30%)
occurrences (all)	0	19	14
Pyrexia			
subjects affected / exposed	3 / 43 (6.98%)	0 / 309 (0.00%)	23 / 115 (20.00%)
occurrences (all)	3	0	33
Injection site induration			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	32 / 115 (27.83%)
occurrences (all)	0	0	156
Injection site nodule			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	46 / 115 (40.00%)
occurrences (all)	0	0	327
Injection site pruritus			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	40 / 115 (34.78%)
occurrences (all)	0	0	285
Asthenia			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	8 / 115 (6.96%)
occurrences (all)	0	0	14
Injection site erythema			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	20 / 115 (17.39%)
occurrences (all)	0	0	66
Injection site haematoma			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	6 / 115 (5.22%)
occurrences (all)	0	0	11
Injection site discolouration			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	7 / 115 (6.09%)
occurrences (all)	0	0	20
Influenza like illness			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	10 / 115 (8.70%)
occurrences (all)	0	0	11
Immune system disorders			

Seasonal allergy			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	11 / 115 (9.57%)
occurrences (all)	0	0	12
Reproductive system and breast disorders			
Erectile dysfunction			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	0 / 115 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Oropharyngeal pain			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	14 / 115 (12.17%)
occurrences (all)	0	0	17
Cough			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	19 / 115 (16.52%)
occurrences (all)	0	0	26
Rhinitis allergic			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	14 / 115 (12.17%)
occurrences (all)	0	0	20
Catarrh			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	0 / 115 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	0 / 115 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	15 / 115 (13.04%)
occurrences (all)	0	0	19
Anxiety			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	22 / 115 (19.13%)
occurrences (all)	0	0	31
Insomnia			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	19 / 115 (16.52%)
occurrences (all)	0	0	20
Injury, poisoning and procedural complications			

Ligament sprain			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	0 / 115 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	7 / 115 (6.09%)
occurrences (all)	0	0	10
Limb injury			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	6 / 115 (5.22%)
occurrences (all)	0	0	7
Exposure to communicable disease			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	0 / 115 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	9 / 115 (7.83%)
occurrences (all)	0	0	9
Penis injury			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	0 / 115 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 43 (0.00%)	27 / 309 (8.74%)	30 / 115 (26.09%)
occurrences (all)	0	27	51
Dizziness			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	9 / 115 (7.83%)
occurrences (all)	0	0	13
Sciatica			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	7 / 115 (6.09%)
occurrences (all)	0	0	12
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 43 (0.00%)	34 / 309 (11.00%)	39 / 115 (33.91%)
occurrences (all)	0	34	55
Nausea			
subjects affected / exposed	3 / 43 (6.98%)	38 / 309 (12.30%)	9 / 115 (7.83%)
occurrences (all)	3	38	10
Abdominal pain			

subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	14 / 115 (12.17%)
occurrences (all)	0	0	18
Vomiting			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	8 / 115 (6.96%)
occurrences (all)	0	0	9
Dyspepsia			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	13 / 115 (11.30%)
occurrences (all)	0	0	13
Constipation			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	11 / 115 (9.57%)
occurrences (all)	0	0	13
Odynophagia			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	0 / 115 (0.00%)
occurrences (all)	0	0	0
Anogenital dysplasia			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	0 / 115 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	10 / 115 (8.70%)
occurrences (all)	0	0	10
Toothache			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	13 / 115 (11.30%)
occurrences (all)	0	0	17
Gastritis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	0 / 115 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	7 / 115 (6.09%)
occurrences (all)	0	0	9
Haemorrhoids			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	14 / 115 (12.17%)
occurrences (all)	0	0	17
Proctitis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	11 / 115 (9.57%)
occurrences (all)	0	0	14
Skin and subcutaneous tissue disorders			

Eczema			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	7 / 115 (6.09%)
occurrences (all)	0	0	8
Rash			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	9 / 115 (7.83%)
occurrences (all)	0	0	11
Pruritus			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	9 / 115 (7.83%)
occurrences (all)	0	0	11
Musculoskeletal and connective tissue disorders			
Neck pain			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	10 / 115 (8.70%)
occurrences (all)	0	0	13
Pain in extremity			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	10 / 115 (8.70%)
occurrences (all)	0	0	14
Arthralgia			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	27 / 115 (23.48%)
occurrences (all)	0	0	45
Myalgia			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	11 / 115 (9.57%)
occurrences (all)	0	0	14
Back pain			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	27 / 115 (23.48%)
occurrences (all)	0	0	39
Muscle contracture			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	8 / 115 (6.96%)
occurrences (all)	0	0	9
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	0 / 43 (0.00%)	27 / 309 (8.74%)	54 / 115 (46.96%)
occurrences (all)	0	27	129
Upper respiratory tract infection			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	30 / 115 (26.09%)
occurrences (all)	0	0	55
Syphilis			

subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	36 / 115 (31.30%)
occurrences (all)	0	0	61
Pharyngitis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	19 / 115 (16.52%)
occurrences (all)	0	0	25
Bronchitis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	19 / 115 (16.52%)
occurrences (all)	0	0	25
Gastroenteritis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	28 / 115 (24.35%)
occurrences (all)	0	0	43
Influenza			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	21 / 115 (18.26%)
occurrences (all)	0	0	26
Respiratory tract infection			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	8 / 115 (6.96%)
occurrences (all)	0	0	14
Gonorrhoea			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	15 / 115 (13.04%)
occurrences (all)	0	0	25
Conjunctivitis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	15 / 115 (13.04%)
occurrences (all)	0	0	18
Urethritis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	8 / 115 (6.96%)
occurrences (all)	0	0	12
Sinusitis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	10 / 115 (8.70%)
occurrences (all)	0	0	23
Oral herpes			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	7 / 115 (6.09%)
occurrences (all)	0	0	28
Tonsillitis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	8 / 115 (6.96%)
occurrences (all)	0	0	14
Rhinitis			

subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	9 / 115 (7.83%)
occurrences (all)	0	0	9
Chlamydial infection			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	13 / 115 (11.30%)
occurrences (all)	0	0	19
Folliculitis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	9 / 115 (7.83%)
occurrences (all)	0	0	11
Gastroenteritis viral			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	0 / 115 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	1 / 43 (2.33%)	0 / 309 (0.00%)	9 / 115 (7.83%)
occurrences (all)	1	0	11
Tooth infection			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	0 / 115 (0.00%)
occurrences (all)	0	0	0
Subcutaneous abscess			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	7 / 115 (6.09%)
occurrences (all)	0	0	7
Viral infection			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	6 / 115 (5.22%)
occurrences (all)	0	0	6
Ear infection			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	6 / 115 (5.22%)
occurrences (all)	0	0	8
Proctitis chlamydial			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	8 / 115 (6.96%)
occurrences (all)	0	0	18
Tinea versicolour			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	0 / 115 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	11 / 115 (9.57%)
occurrences (all)	0	0	21
Anal chlamydia infection			

subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	8 / 115 (6.96%)
occurrences (all)	0	0	11
Onychomycosis			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	6 / 115 (5.22%)
occurrences (all)	0	0	8
Oropharyngeal gonococcal infection			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	11 / 115 (9.57%)
occurrences (all)	0	0	26
Pneumonia			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	0 / 115 (0.00%)
occurrences (all)	0	0	0
Proctitis gonococcal			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	12 / 115 (10.43%)
occurrences (all)	0	0	29
Urethritis gonococcal			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	8 / 115 (6.96%)
occurrences (all)	0	0	13
COVID-19			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	25 / 115 (21.74%)
occurrences (all)	0	0	29
Suspected COVID-19			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	9 / 115 (7.83%)
occurrences (all)	0	0	13
Metabolism and nutrition disorders			
Hypercholesterolaemia			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	9 / 115 (7.83%)
occurrences (all)	0	0	11
Vitamin D deficiency			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	14 / 115 (12.17%)
occurrences (all)	0	0	15
Dyslipidaemia			
subjects affected / exposed	0 / 43 (0.00%)	0 / 309 (0.00%)	0 / 115 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Optimized CAB LA 400 mg+RPV LA 600 mg IM-Q4W (Extension)	CAB 30 mg+ABC/3TC QD (Induction and Maintenance)	Optimized CAB LA 600 mg+RPV LA 900 mg IM-Q8W (Extension)

Total subjects affected by non-serious adverse events subjects affected / exposed	10 / 10 (100.00%)	52 / 56 (92.86%)	34 / 34 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Anogenital warts			
subjects affected / exposed	2 / 10 (20.00%)	0 / 56 (0.00%)	2 / 34 (5.88%)
occurrences (all)	2	0	2
Skin papilloma			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Injection site swelling			
subjects affected / exposed	3 / 10 (30.00%)	0 / 56 (0.00%)	6 / 34 (17.65%)
occurrences (all)	3	0	9
Injection site pain			
subjects affected / exposed	8 / 10 (80.00%)	0 / 56 (0.00%)	31 / 34 (91.18%)
occurrences (all)	197	0	486
Injection site bruising			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Injection site warmth			
subjects affected / exposed	2 / 10 (20.00%)	0 / 56 (0.00%)	2 / 34 (5.88%)
occurrences (all)	2	0	5
Fatigue			
subjects affected / exposed	1 / 10 (10.00%)	4 / 56 (7.14%)	3 / 34 (8.82%)
occurrences (all)	2	5	3
Pyrexia			
subjects affected / exposed	0 / 10 (0.00%)	3 / 56 (5.36%)	3 / 34 (8.82%)
occurrences (all)	0	3	4
Injection site induration			
subjects affected / exposed	1 / 10 (10.00%)	0 / 56 (0.00%)	4 / 34 (11.76%)
occurrences (all)	1	0	4
Injection site nodule			

subjects affected / exposed	5 / 10 (50.00%)	0 / 56 (0.00%)	12 / 34 (35.29%)
occurrences (all)	14	0	34
Injection site pruritus			
subjects affected / exposed	2 / 10 (20.00%)	0 / 56 (0.00%)	4 / 34 (11.76%)
occurrences (all)	3	0	10
Asthenia			
subjects affected / exposed	1 / 10 (10.00%)	9 / 56 (16.07%)	3 / 34 (8.82%)
occurrences (all)	1	11	4
Injection site erythema			
subjects affected / exposed	1 / 10 (10.00%)	0 / 56 (0.00%)	4 / 34 (11.76%)
occurrences (all)	1	0	5
Injection site haematoma			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	3 / 34 (8.82%)
occurrences (all)	0	0	6
Injection site discolouration			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Erectile dysfunction			
subjects affected / exposed	1 / 10 (10.00%)	0 / 56 (0.00%)	2 / 34 (5.88%)
occurrences (all)	1	0	2
Respiratory, thoracic and mediastinal disorders			
Oropharyngeal pain			
subjects affected / exposed	0 / 10 (0.00%)	3 / 56 (5.36%)	4 / 34 (11.76%)
occurrences (all)	0	4	4
Cough			
subjects affected / exposed	2 / 10 (20.00%)	7 / 56 (12.50%)	4 / 34 (11.76%)
occurrences (all)	5	8	4
Rhinitis allergic			

subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Catarrh			
subjects affected / exposed	0 / 10 (0.00%)	3 / 56 (5.36%)	0 / 34 (0.00%)
occurrences (all)	0	4	0
Rhinorrhoea			
subjects affected / exposed	0 / 10 (0.00%)	3 / 56 (5.36%)	0 / 34 (0.00%)
occurrences (all)	0	3	0
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 10 (0.00%)	5 / 56 (8.93%)	4 / 34 (11.76%)
occurrences (all)	0	6	5
Anxiety			
subjects affected / exposed	1 / 10 (10.00%)	4 / 56 (7.14%)	3 / 34 (8.82%)
occurrences (all)	1	4	3
Insomnia			
subjects affected / exposed	0 / 10 (0.00%)	4 / 56 (7.14%)	4 / 34 (11.76%)
occurrences (all)	0	4	5
Injury, poisoning and procedural complications			
Ligament sprain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	3 / 34 (8.82%)
occurrences (all)	0	0	3
Contusion			
subjects affected / exposed	2 / 10 (20.00%)	0 / 56 (0.00%)	2 / 34 (5.88%)
occurrences (all)	2	0	2
Limb injury			
subjects affected / exposed	1 / 10 (10.00%)	0 / 56 (0.00%)	2 / 34 (5.88%)
occurrences (all)	1	0	2
Exposure to communicable disease			
subjects affected / exposed	1 / 10 (10.00%)	0 / 56 (0.00%)	2 / 34 (5.88%)
occurrences (all)	1	0	3
Skin laceration			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Penis injury			

subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	3 / 34 (8.82%)
occurrences (all)	0	0	3
Nervous system disorders			
Headache			
subjects affected / exposed	1 / 10 (10.00%)	14 / 56 (25.00%)	3 / 34 (8.82%)
occurrences (all)	1	19	6
Dizziness			
subjects affected / exposed	1 / 10 (10.00%)	3 / 56 (5.36%)	2 / 34 (5.88%)
occurrences (all)	1	3	2
Sciatica			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	3 / 34 (8.82%)
occurrences (all)	0	0	3
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	3 / 10 (30.00%)	11 / 56 (19.64%)	4 / 34 (11.76%)
occurrences (all)	3	13	5
Nausea			
subjects affected / exposed	0 / 10 (0.00%)	9 / 56 (16.07%)	0 / 34 (0.00%)
occurrences (all)	0	11	0
Abdominal pain			
subjects affected / exposed	1 / 10 (10.00%)	4 / 56 (7.14%)	3 / 34 (8.82%)
occurrences (all)	1	5	3
Vomiting			
subjects affected / exposed	0 / 10 (0.00%)	4 / 56 (7.14%)	0 / 34 (0.00%)
occurrences (all)	0	5	0
Dyspepsia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Odynophagia			
subjects affected / exposed	0 / 10 (0.00%)	4 / 56 (7.14%)	0 / 34 (0.00%)
occurrences (all)	0	6	0
Anogenital dysplasia			

subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	3 / 34 (8.82%)
occurrences (all)	0	0	6
Abdominal pain upper			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	1 / 10 (10.00%)	0 / 56 (0.00%)	3 / 34 (8.82%)
occurrences (all)	1	0	3
Gastritis			
subjects affected / exposed	0 / 10 (0.00%)	3 / 56 (5.36%)	0 / 34 (0.00%)
occurrences (all)	0	3	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Proctitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Eczema			
subjects affected / exposed	0 / 10 (0.00%)	6 / 56 (10.71%)	0 / 34 (0.00%)
occurrences (all)	0	8	0
Rash			
subjects affected / exposed	2 / 10 (20.00%)	0 / 56 (0.00%)	0 / 34 (0.00%)
occurrences (all)	3	0	0
Pruritus			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Neck pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	4 / 34 (11.76%)
occurrences (all)	0	0	4
Pain in extremity			

subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	3 / 34 (8.82%)
occurrences (all)	0	0	3
Arthralgia			
subjects affected / exposed	3 / 10 (30.00%)	4 / 56 (7.14%)	6 / 34 (17.65%)
occurrences (all)	5	7	9
Myalgia			
subjects affected / exposed	0 / 10 (0.00%)	1 / 56 (1.79%)	0 / 34 (0.00%)
occurrences (all)	0	1	0
Back pain			
subjects affected / exposed	3 / 10 (30.00%)	10 / 56 (17.86%)	8 / 34 (23.53%)
occurrences (all)	4	12	16
Muscle contracture			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	5 / 10 (50.00%)	22 / 56 (39.29%)	8 / 34 (23.53%)
occurrences (all)	13	39	11
Upper respiratory tract infection			
subjects affected / exposed	1 / 10 (10.00%)	7 / 56 (12.50%)	9 / 34 (26.47%)
occurrences (all)	1	9	12
Syphilis			
subjects affected / exposed	3 / 10 (30.00%)	6 / 56 (10.71%)	4 / 34 (11.76%)
occurrences (all)	3	7	5
Pharyngitis			
subjects affected / exposed	0 / 10 (0.00%)	5 / 56 (8.93%)	6 / 34 (17.65%)
occurrences (all)	0	5	8
Bronchitis			
subjects affected / exposed	0 / 10 (0.00%)	6 / 56 (10.71%)	6 / 34 (17.65%)
occurrences (all)	0	6	9
Gastroenteritis			
subjects affected / exposed	0 / 10 (0.00%)	5 / 56 (8.93%)	8 / 34 (23.53%)
occurrences (all)	0	5	10
Influenza			
subjects affected / exposed	3 / 10 (30.00%)	0 / 56 (0.00%)	7 / 34 (20.59%)
occurrences (all)	4	0	10

Respiratory tract infection			
subjects affected / exposed	1 / 10 (10.00%)	6 / 56 (10.71%)	2 / 34 (5.88%)
occurrences (all)	1	8	3
Gonorrhoea			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	1 / 10 (10.00%)	3 / 56 (5.36%)	3 / 34 (8.82%)
occurrences (all)	2	3	3
Urethritis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	1 / 10 (10.00%)	4 / 56 (7.14%)	3 / 34 (8.82%)
occurrences (all)	1	5	3
Oral herpes			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	1 / 10 (10.00%)	4 / 56 (7.14%)	3 / 34 (8.82%)
occurrences (all)	1	4	7
Rhinitis			
subjects affected / exposed	0 / 10 (0.00%)	3 / 56 (5.36%)	0 / 34 (0.00%)
occurrences (all)	0	3	0
Chlamydial infection			
subjects affected / exposed	1 / 10 (10.00%)	0 / 56 (0.00%)	3 / 34 (8.82%)
occurrences (all)	1	0	3
Folliculitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed	2 / 10 (20.00%)	0 / 56 (0.00%)	2 / 34 (5.88%)
occurrences (all)	2	0	2
Herpes zoster			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0

Tooth infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Subcutaneous abscess			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 10 (0.00%)	3 / 56 (5.36%)	3 / 34 (8.82%)
occurrences (all)	0	3	3
Ear infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	3 / 34 (8.82%)
occurrences (all)	0	0	5
Proctitis chlamydial			
subjects affected / exposed	1 / 10 (10.00%)	0 / 56 (0.00%)	2 / 34 (5.88%)
occurrences (all)	1	0	2
Tinea versicolour			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	3 / 34 (8.82%)
occurrences (all)	0	0	4
Urinary tract infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Anal chlamydia infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Onychomycosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal gonococcal infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 56 (0.00%)	2 / 34 (5.88%)
occurrences (all)	1	0	2
Proctitis gonococcal			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0

Urethritis gonococcal			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	2 / 10 (20.00%)	0 / 56 (0.00%)	9 / 34 (26.47%)
occurrences (all)	2	0	9
Suspected COVID-19			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	4 / 34 (11.76%)
occurrences (all)	0	0	4
Metabolism and nutrition disorders			
Hypercholesterolaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	3 / 34 (8.82%)
occurrences (all)	0	0	3
Vitamin D deficiency			
subjects affected / exposed	0 / 10 (0.00%)	0 / 56 (0.00%)	0 / 34 (0.00%)
occurrences (all)	0	0	0
Dyslipidaemia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 56 (0.00%)	4 / 34 (11.76%)
occurrences (all)	1	0	4

Non-serious adverse events	CAB LA 400 mg+RPV LA 600 mg IM-Q4W (Maintenance and Extension)		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	115 / 115 (100.00%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Anogenital warts			
subjects affected / exposed	18 / 115 (15.65%)		
occurrences (all)	22		
Skin papilloma			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences (all)	0		
Vascular disorders			
Hypertension			
subjects affected / exposed	10 / 115 (8.70%)		
occurrences (all)	14		
General disorders and administration			

site conditions				
Injection site swelling				
subjects affected / exposed	43 / 115 (37.39%)			
occurrences (all)	293			
Injection site pain				
subjects affected / exposed	114 / 115 (99.13%)			
occurrences (all)	3533			
Injection site bruising				
subjects affected / exposed	18 / 115 (15.65%)			
occurrences (all)	93			
Injection site warmth				
subjects affected / exposed	29 / 115 (25.22%)			
occurrences (all)	218			
Fatigue				
subjects affected / exposed	19 / 115 (16.52%)			
occurrences (all)	28			
Pyrexia				
subjects affected / exposed	20 / 115 (17.39%)			
occurrences (all)	33			
Injection site induration				
subjects affected / exposed	33 / 115 (28.70%)			
occurrences (all)	263			
Injection site nodule				
subjects affected / exposed	57 / 115 (49.57%)			
occurrences (all)	675			
Injection site pruritus				
subjects affected / exposed	40 / 115 (34.78%)			
occurrences (all)	305			
Asthenia				
subjects affected / exposed	14 / 115 (12.17%)			
occurrences (all)	19			
Injection site erythema				
subjects affected / exposed	23 / 115 (20.00%)			
occurrences (all)	122			
Injection site haematoma				

subjects affected / exposed	13 / 115 (11.30%)		
occurrences (all)	69		
Injection site discolouration			
subjects affected / exposed	8 / 115 (6.96%)		
occurrences (all)	11		
Influenza like illness			
subjects affected / exposed	15 / 115 (13.04%)		
occurrences (all)	27		
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	6 / 115 (5.22%)		
occurrences (all)	6		
Reproductive system and breast disorders			
Erectile dysfunction			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			
Oropharyngeal pain			
subjects affected / exposed	13 / 115 (11.30%)		
occurrences (all)	18		
Cough			
subjects affected / exposed	26 / 115 (22.61%)		
occurrences (all)	39		
Rhinitis allergic			
subjects affected / exposed	10 / 115 (8.70%)		
occurrences (all)	12		
Catarrh			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences (all)	0		
Rhinorrhoea			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences (all)	0		
Psychiatric disorders			
Depression			
subjects affected / exposed	11 / 115 (9.57%)		
occurrences (all)	15		

Anxiety			
subjects affected / exposed	20 / 115 (17.39%)		
occurrences (all)	24		
Insomnia			
subjects affected / exposed	14 / 115 (12.17%)		
occurrences (all)	15		
Injury, poisoning and procedural complications			
Ligament sprain			
subjects affected / exposed	12 / 115 (10.43%)		
occurrences (all)	15		
Contusion			
subjects affected / exposed	13 / 115 (11.30%)		
occurrences (all)	17		
Limb injury			
subjects affected / exposed	6 / 115 (5.22%)		
occurrences (all)	6		
Exposure to communicable disease			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences (all)	0		
Skin laceration			
subjects affected / exposed	7 / 115 (6.09%)		
occurrences (all)	7		
Penis injury			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Headache			
subjects affected / exposed	30 / 115 (26.09%)		
occurrences (all)	56		
Dizziness			
subjects affected / exposed	11 / 115 (9.57%)		
occurrences (all)	16		
Sciatica			
subjects affected / exposed	7 / 115 (6.09%)		
occurrences (all)	10		
Gastrointestinal disorders			

Diarrhoea				
subjects affected / exposed	35 / 115 (30.43%)			
occurrences (all)	59			
Nausea				
subjects affected / exposed	14 / 115 (12.17%)			
occurrences (all)	25			
Abdominal pain				
subjects affected / exposed	14 / 115 (12.17%)			
occurrences (all)	14			
Vomiting				
subjects affected / exposed	8 / 115 (6.96%)			
occurrences (all)	13			
Dyspepsia				
subjects affected / exposed	7 / 115 (6.09%)			
occurrences (all)	10			
Constipation				
subjects affected / exposed	11 / 115 (9.57%)			
occurrences (all)	15			
Odynophagia				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences (all)	0			
Anogenital dysplasia				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences (all)	0			
Abdominal pain upper				
subjects affected / exposed	10 / 115 (8.70%)			
occurrences (all)	11			
Toothache				
subjects affected / exposed	14 / 115 (12.17%)			
occurrences (all)	19			
Gastritis				
subjects affected / exposed	8 / 115 (6.96%)			
occurrences (all)	10			
Gastrooesophageal reflux disease				
subjects affected / exposed	11 / 115 (9.57%)			
occurrences (all)	12			

Haemorrhoids subjects affected / exposed occurrences (all) Proctitis subjects affected / exposed occurrences (all)	12 / 115 (10.43%) 13 7 / 115 (6.09%) 10		
Skin and subcutaneous tissue disorders Eczema subjects affected / exposed occurrences (all) Rash subjects affected / exposed occurrences (all) Pruritus subjects affected / exposed occurrences (all)	 0 / 115 (0.00%) 0 11 / 115 (9.57%) 13 7 / 115 (6.09%) 8		
Musculoskeletal and connective tissue disorders Neck pain subjects affected / exposed occurrences (all) Pain in extremity subjects affected / exposed occurrences (all) Arthralgia subjects affected / exposed occurrences (all) Myalgia subjects affected / exposed occurrences (all) Back pain subjects affected / exposed occurrences (all) Muscle contracture subjects affected / exposed occurrences (all)	 6 / 115 (5.22%) 8 14 / 115 (12.17%) 19 21 / 115 (18.26%) 34 13 / 115 (11.30%) 18 30 / 115 (26.09%) 55 9 / 115 (7.83%) 10		
Infections and infestations			

Nasopharyngitis				
subjects affected / exposed	54 / 115 (46.96%)			
occurrences (all)	146			
Upper respiratory tract infection				
subjects affected / exposed	28 / 115 (24.35%)			
occurrences (all)	42			
Syphilis				
subjects affected / exposed	28 / 115 (24.35%)			
occurrences (all)	46			
Pharyngitis				
subjects affected / exposed	21 / 115 (18.26%)			
occurrences (all)	32			
Bronchitis				
subjects affected / exposed	17 / 115 (14.78%)			
occurrences (all)	26			
Gastroenteritis				
subjects affected / exposed	23 / 115 (20.00%)			
occurrences (all)	36			
Influenza				
subjects affected / exposed	32 / 115 (27.83%)			
occurrences (all)	45			
Respiratory tract infection				
subjects affected / exposed	11 / 115 (9.57%)			
occurrences (all)	17			
Gonorrhoea				
subjects affected / exposed	8 / 115 (6.96%)			
occurrences (all)	10			
Conjunctivitis				
subjects affected / exposed	10 / 115 (8.70%)			
occurrences (all)	11			
Urethritis				
subjects affected / exposed	11 / 115 (9.57%)			
occurrences (all)	16			
Sinusitis				
subjects affected / exposed	12 / 115 (10.43%)			
occurrences (all)	18			

Oral herpes				
subjects affected / exposed	17 / 115 (14.78%)			
occurrences (all)	23			
Tonsillitis				
subjects affected / exposed	11 / 115 (9.57%)			
occurrences (all)	15			
Rhinitis				
subjects affected / exposed	16 / 115 (13.91%)			
occurrences (all)	19			
Chlamydial infection				
subjects affected / exposed	7 / 115 (6.09%)			
occurrences (all)	7			
Folliculitis				
subjects affected / exposed	6 / 115 (5.22%)			
occurrences (all)	7			
Gastroenteritis viral				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences (all)	0			
Herpes zoster				
subjects affected / exposed	12 / 115 (10.43%)			
occurrences (all)	20			
Tooth infection				
subjects affected / exposed	11 / 115 (9.57%)			
occurrences (all)	16			
Subcutaneous abscess				
subjects affected / exposed	9 / 115 (7.83%)			
occurrences (all)	10			
Viral infection				
subjects affected / exposed	9 / 115 (7.83%)			
occurrences (all)	10			
Ear infection				
subjects affected / exposed	9 / 115 (7.83%)			
occurrences (all)	11			
Proctitis chlamydial				
subjects affected / exposed	0 / 115 (0.00%)			
occurrences (all)	0			

Tinea versicolour			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences (all)	0		
Urinary tract infection			
subjects affected / exposed	6 / 115 (5.22%)		
occurrences (all)	9		
Anal chlamydia infection			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences (all)	0		
Onychomycosis			
subjects affected / exposed	6 / 115 (5.22%)		
occurrences (all)	8		
Oropharyngeal gonococcal infection			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences (all)	0		
Pneumonia			
subjects affected / exposed	8 / 115 (6.96%)		
occurrences (all)	10		
Proctitis gonococcal			
subjects affected / exposed	7 / 115 (6.09%)		
occurrences (all)	9		
Urethritis gonococcal			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences (all)	0		
COVID-19			
subjects affected / exposed	28 / 115 (24.35%)		
occurrences (all)	34		
Suspected COVID-19			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences (all)	0		
Metabolism and nutrition disorders			
Hypercholesterolaemia			
subjects affected / exposed	9 / 115 (7.83%)		
occurrences (all)	10		
Vitamin D deficiency			

subjects affected / exposed	0 / 115 (0.00%)		
occurrences (all)	0		
Dyslipidaemia			
subjects affected / exposed	0 / 115 (0.00%)		
occurrences (all)	0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
28 October 2013	Amendment 1: was finalized 28 October 2013, however, was never implemented due to a design change requiring a second amendment. Amendment 1 was prepared to address the following changes: universal changes to naming conventions for the long acting formulation of CAB, simplifying the protocol summary to allow better understanding of the protocol, clarifying the study schematic to increase understanding, clarification the purpose of and analyses to be performed by the Independent Data Monitoring Committee to reflect current plans, clarification of the intent of the Day 1 analysis as a possible analysis if needed, clarification to study treatments including the addition of the ingredients of the long acting formulations of both study treatments, clarification of health outcomes objectives, timings and questionnaires, adding the assessment of exercises habits and intravenous drug use, removing some assessments to simplify study visits, updates and simplification to the time and events tables and additional miscellaneous clarifications.
23 January 2014	Amendment No.02: Primary modifications included, Study design adapted to consolidate the Induction Period into a single 20 Week arm and for the addition of an every 8 week IM regimen into the Maintenance Period. Increased sample size to 265 subjects. Primary endpoint changed from Week 24 to Week 32. Dose rationale updated.
13 June 2014	Amendment No.03: Primary modifications included, ABC/3TC added as Investigational Product beginning at Day 1 of the Maintenance Period; clarification that alternative background therapy (if positive for HLA-B*5701) is not counted as the protocol permitted switch for NRTI; clarification regarding provision of alternative NRTI therapy; change in visit window for subjects on the oral dosing arm; excursion temperatures added for ABC/3TC and RPV oral tablet; text added for ABC/3TC overdose; deleted option for participant informed consent by legal representative; Time and Events Table clarifications. Additional clarifications and typographical corrections throughout.
22 April 2015	Amendment No. 4: Primary modifications included, addition of a 2-hour post dose pharmacokinetic samples and electrocardiogram at Week 32 and Week 48 for subjects receiving intramuscular CAB LA and RPV LA; addition of LAI116482 Week 96 data; addition of maladministration of injection risk; additional clarifications for injection site reaction collection; clarified visit windows.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported