



Clinical trial results:

A 24-week, multicenter, randomized, double-blind, parallel-arm, placebo-controlled extension study to assess the safety of CSJ117, when added to existing standard of care asthma therapy in patients 18 years of age

Summary

EudraCT number	2020-002341-42
Trial protocol	CZ HU PL SK IT LV DE BE BG FR
Global end of trial date	08 September 2022

Results information

Result version number	v1 (current)
This version publication date	17 September 2023
First version publication date	17 September 2023

Trial information

Trial identification

Sponsor protocol code	CCSJ117A12201E1
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04946318
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Novartis Pharma AG
Sponsor organisation address	Novartis Campus, Basel, Switzerland,
Public contact	Clinical Disclosure Office, Novartis Pharma AG, 41 613241111, novartis.email@novartis.com
Scientific contact	Clinical Disclosure Office, Novartis Pharma AG, 41 613241111, novartis.email@novartis.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	08 September 2022
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	08 September 2022
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To assess the systemic pharmacokinetic (PK) properties of icenticaftor after a single oral dose of 300 mg in participants with mild, moderate, or severe hepatic impairment (HI) (Child-Pugh classification) as compared to matched healthy control participants with normal hepatic function.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and the International Conference on Harmonization (ICH) Good Clinical Practice (GCP) guidelines. All the local regulatory requirements pertinent to safety of trial subjects were also followed during the conduct of the trial.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	08 September 2021
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Philippines: 4
Country: Number of subjects enrolled	Belgium: 1
Country: Number of subjects enrolled	Bulgaria: 7
Country: Number of subjects enrolled	Czechia: 5
Country: Number of subjects enrolled	Germany: 12
Country: Number of subjects enrolled	Hungary: 6
Country: Number of subjects enrolled	Latvia: 5
Country: Number of subjects enrolled	Poland: 13
Country: Number of subjects enrolled	Russian Federation: 3
Country: Number of subjects enrolled	Slovakia: 1
Country: Number of subjects enrolled	Japan: 48
Country: Number of subjects enrolled	Argentina: 12
Country: Number of subjects enrolled	Canada: 3
Country: Number of subjects enrolled	United States: 16
Worldwide total number of subjects	136
EEA total number of subjects	50

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)	113
From 65 to 84 years	23
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants took part in 59 investigative sites in 14 countries.

Pre-assignment

Screening details:

The screening period of up to 3 days began after the participants had provided written informed consent.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
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Arm title	24 weeks CSJ117 8mg
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Arm description:

Participants who entered the extension study after the last treatment visit (Week 12) of the core study and were treated once daily for 24 weeks with the same dose of CSJ117 they had received in the core study (CSJ117 8 mg)

Arm type	Experimental
Investigational medicinal product name	CSJ117
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Inhalation powder, hard capsule
Routes of administration	Inhalation use

Dosage and administration details:

Once daily dosing of CSJ117 8 mg for 24 weeks.

Arm title	24 weeks CSJ117 4mg
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Arm description:

Participants who entered the extension study after the last treatment visit (Week 12) of the core study and were treated once daily for 24 weeks with the same dose of CSJ117 they had received in the core study (CSJ117 4 mg)

Arm type	Experimental
Investigational medicinal product name	CSJ117
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Inhalation powder, hard capsule
Routes of administration	Inhalation use

Dosage and administration details:

Once daily dosing of CSJ117 4 mg for 24 weeks.

Arm title	24 weeks CSJ117 2mg
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Arm description:

Participants who entered the extension study after the last treatment visit (Week 12) of the core study and were treated once daily for 24 weeks with the same dose of CSJ117 they had received in the core study (CSJ117 2 mg)

Arm type	Experimental
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Investigational medicinal product name	CSJ117
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Inhalation powder, hard capsule
Routes of administration	Inhalation use
Dosage and administration details:	
Once daily dosing of CSJ117 2 mg for 24 weeks.	
Arm title	24 weeks CSJ117 1mg
Arm description:	
Participants who entered the extension study after the last treatment visit (Week 12) of the core study and were treated once daily for 24 weeks with the same dose of CSJ117 they had received in the core study (CSJ117 1 mg)	
Arm type	Experimental
Investigational medicinal product name	CSJ117
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Inhalation powder, hard capsule
Routes of administration	Inhalation use
Dosage and administration details:	
Once daily dosing of CSJ117 1 mg for 24 weeks.	
Arm title	24-weeks CSJ117 0.5mg
Arm description:	
Participants who entered the extension study after the last treatment visit (Week 12) of the core study and were treated once daily for 24 weeks with the same dose of CSJ117 they had received in the core study (CSJ117 0.5 mg)	
Arm type	Experimental
Investigational medicinal product name	CSJ117
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Inhalation powder, hard capsule
Routes of administration	Inhalation use
Dosage and administration details:	
Once daily dosing of CSJ117 0.5 mg for 24 weeks.	
Arm title	24-weeks Placebo
Arm description:	
Participants who entered the extension study after the last treatment visit (Week 12) of the core study and were treated once daily for 24 weeks with Placebo	
Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Inhalation powder, hard capsule
Routes of administration	Inhalation use
Dosage and administration details:	
Once daily dosing of Placebo for 24 weeks.	
Arm title	12 weeks wash-out + 12 weeks CSJ117 8mg
Arm description:	
Participants who entered the extension study after the last treatment visit (Week 12) of the core study and received Placebo inhaled once daily for 12 weeks "washout period" and then they were treated once daily for 12 weeks with the same dose of CSJ117 they had received in the core study (CSJ117 8 mg)	
Arm type	Experimental

Investigational medicinal product name	CSJ117
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Inhalation powder, hard capsule
Routes of administration	Inhalation use

Dosage and administration details:

Placebo inhaled once daily for 12 weeks "washout period". Once daily dosing of CSJ117 8 mg for 12 weeks.

Arm title	12 weeks wash-out + 12 weeks CSJ117 4mg
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Arm description:

Participants who entered the extension study after the last treatment visit (Week 12) of the core study and received Placebo inhaled once daily for 12 weeks "washout period" and then they were treated once daily for 12 weeks with the same dose of CSJ117 they had received in the core study (CSJ117 4 mg)

Arm type	Experimental
Investigational medicinal product name	CSJ117
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Inhalation powder, hard capsule
Routes of administration	Inhalation use

Dosage and administration details:

Placebo inhaled once daily for 12 weeks "washout period". Once daily dosing of CSJ117 4 mg for 12 weeks.

Arm title	12 weeks wash-out + 12 weeks CSJ117 2mg
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Arm description:

Participants who entered the extension study after the last treatment visit (Week 12) of the core study and received Placebo inhaled once daily for 12 weeks "washout period" and then they were treated once daily for 12 weeks with the same dose of CSJ117 they had received in the core study (CSJ117 2 mg)

Arm type	Experimental
Investigational medicinal product name	CSJ117
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Inhalation powder, hard capsule
Routes of administration	Inhalation use

Dosage and administration details:

Placebo inhaled once daily for 12 weeks "washout period". Once daily dosing of CSJ117 2 mg for 12 weeks.

Arm title	12 weeks wash-out + 12 weeks CSJ117 1mg
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Arm description:

Participants who entered the extension study after the last treatment visit (Week 12) of the core study and received Placebo inhaled once daily for 12 weeks "washout period" and then they were treated once daily for 12 weeks with the same dose of CSJ117 they had received in the core study (CSJ117 1 mg)

Arm type	Experimental
Investigational medicinal product name	CSJ117
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Inhalation powder, hard capsule
Routes of administration	Inhalation use

Dosage and administration details:

Placebo inhaled once daily for 12 weeks "washout period". Once daily dosing of CSJ117 1 mg for 12 weeks.

Arm title	12 weeks wash-out + 12 weeks CSJ117 0.5mg
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Arm description:

Participants who entered the extension study after the last treatment visit (Week 12) of the core study and received Placebo inhaled once daily for 12 weeks "washout period" and then they were treated once

daily for 12 weeks with the same dose of CSJ117 they had received in the core study (CSJ117 0.5 mg)

Arm type	Experimental
Investigational medicinal product name	CSJ117
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Inhalation powder, hard capsule
Routes of administration	Inhalation use

Dosage and administration details:

Placebo inhaled once daily for 12 weeks "washout period". Once daily dosing of CSJ117 0.5 mg for 12 weeks.

Arm title	12 weeks wash-out + 12 weeks Placebo
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Arm description:

Participants who entered the extension study after the last treatment visit (Week 12) of the core study and received Placebo inhaled once daily for 12 weeks "washout period" and then they were treated once daily for 12 weeks with Placebo

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Inhalation powder, hard capsule
Routes of administration	Inhalation use

Dosage and administration details:

Placebo inhaled once daily for 12 weeks "washout period". Once daily dosing of Placebo for 12 weeks.

Arm title	12 weeks drug-free + 12 weeks CSJ117 8mg
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Arm description:

Participants who entered the extension study after the last follow-up visit (Week 24) of the core study, therefore after a 12-week drug-free period, and were treated in the extension once daily for 12 weeks with the same dose of CSJ117 they had received in the core study (CSJ117 8 mg)

Arm type	Experimental
Investigational medicinal product name	CSJ117
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Inhalation powder, hard capsule
Routes of administration	Inhalation use

Dosage and administration details:

Drug-free period (12 weeks). Once daily dosing of CSJ117 8 mg for 12 weeks.

Arm title	12 weeks drug-free + 12 weeks CSJ117 4mg
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Arm description:

Participants who entered the extension study after the last follow-up visit (Week 24) of the core study, therefore after a 12-week drug-free period, and were treated in the extension once daily for 12 weeks with the same dose of CSJ117 they had received in the core study (CSJ117 4 mg)

Arm type	Experimental
Investigational medicinal product name	CSJ117
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Inhalation powder, hard capsule
Routes of administration	Inhalation use

Dosage and administration details:

Drug-free period (12 weeks). Once daily dosing of CSJ117 4 mg for 12 weeks.

Arm title	12 weeks drug-free + 12 weeks CSJ117 2mg
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Arm description:

Participants who entered the extension study after the last follow-up visit (Week 24) of the core study, therefore after a 12-week drug-free period, and were treated in the extension once daily for 12 weeks

with the same dose of CSJ117 they had received in the core study (CSJ117 2 mg)

Arm type	Experimental
Investigational medicinal product name	CSJ117
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Inhalation powder, hard capsule
Routes of administration	Inhalation use
Dosage and administration details:	
Drug-free period (12 weeks). Once daily dosing of CSJ117 2 mg for 12 weeks.	
Arm title	12 weeks drug-free + 12 weeks CSJ117 1mg

Arm description:

Participants who entered the extension study after the last follow-up visit (Week 24) of the core study, therefore after a 12-week drug-free period, and were treated in the extension once daily for 12 weeks with the same dose of CSJ117 they had received in the core study (CSJ117 1 mg)

Arm type	Experimental
Investigational medicinal product name	CSJ117
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Inhalation powder, hard capsule
Routes of administration	Inhalation use
Dosage and administration details:	
Drug-free period (12 weeks). Once daily dosing of CSJ117 1 mg for 12 weeks.	
Arm title	12 weeks drug-free + 12 weeks CSJ117 0.5mg

Arm description:

Participants who entered the extension study after the last follow-up visit (Week 24) of the core study, therefore after a 12-week drug-free period, and were treated in the extension once daily for 12 weeks with the same dose of CSJ117 they had received in the core study (CSJ117 0.5 mg)

Arm type	Experimental
Investigational medicinal product name	CSJ117
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Inhalation powder, hard capsule
Routes of administration	Inhalation use
Dosage and administration details:	
Drug-free period (12 weeks). Once daily dosing of CSJ117 0.5 mg for 12 weeks.	
Arm title	12 weeks drug-free + 12 weeks Placebo

Arm description:

Participants who entered the extension study after the last follow-up visit (Week 24) of the core study, therefore after a 12-week drug-free period, and were treated in the extension once daily for 12 weeks with Placebo

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Inhalation powder, hard capsule
Routes of administration	Inhalation use
Dosage and administration details:	
Drug-free period (12 weeks). Once daily dosing of Placebo for 12 weeks.	

Number of subjects in period 1	24 weeks CSJ117 8mg	24 weeks CSJ117 4mg	24 weeks CSJ117 2mg
Started	8	5	3
Completed	6	5	2
Not completed	2	0	1
Consent withdrawn by subject	-	-	-
Adverse Event	-	-	-
Study terminated by sponsor	2	-	1

Number of subjects in period 1	24 weeks CSJ117 1mg	24-weeks CSJ117 0.5mg	24-weeks Placebo
Started	3	5	6
Completed	1	5	2
Not completed	2	0	4
Consent withdrawn by subject	-	-	-
Adverse Event	-	-	1
Study terminated by sponsor	2	-	3

Number of subjects in period 1	12 weeks wash-out + 12 weeks CSJ117 8mg	12 weeks wash-out + 12 weeks CSJ117 4mg	12 weeks wash-out + 12 weeks CSJ117 2mg
Started	7	3	2
Completed	4	2	0
Not completed	3	1	2
Consent withdrawn by subject	-	-	-
Adverse Event	-	-	-
Study terminated by sponsor	3	1	2

Number of subjects in period 1	12 weeks wash-out + 12 weeks CSJ117 1mg	12 weeks wash-out + 12 weeks CSJ117 0.5mg	12 weeks wash-out + 12 weeks Placebo
Started	3	1	4
Completed	1	0	3
Not completed	2	1	1
Consent withdrawn by subject	-	-	-
Adverse Event	-	-	-
Study terminated by sponsor	2	1	1

Number of subjects in period 1	12 weeks drug-free + 12 weeks CSJ117 8mg	12 weeks drug-free + 12 weeks CSJ117 4mg	12 weeks drug-free + 12 weeks CSJ117 2mg
Started	18	24	10
Completed	16	22	8
Not completed	2	2	2
Consent withdrawn by subject	-	1	-
Adverse Event	-	-	-
Study terminated by sponsor	2	1	2

Number of subjects in period 1	12 weeks drug-free + 12 weeks CSJ117 1mg	12 weeks drug-free + 12 weeks CSJ117 0.5mg	12 weeks drug-free + 12 weeks Placebo
Started	7	9	18
Completed	7	9	15
Not completed	0	0	3
Consent withdrawn by subject	-	-	1
Adverse Event	-	-	-
Study terminated by sponsor	-	-	2

Baseline characteristics

Reporting groups

Reporting group title	24 weeks CSJ117 8mg
Reporting group description: Participants who entered the extension study after the last treatment visit (Week 12) of the core study and were treated once daily for 24 weeks with the same dose of CSJ117 they had received in the core study (CSJ117 8 mg)	
Reporting group title	24 weeks CSJ117 4mg
Reporting group description: Participants who entered the extension study after the last treatment visit (Week 12) of the core study and were treated once daily for 24 weeks with the same dose of CSJ117 they had received in the core study (CSJ117 4 mg)	
Reporting group title	24 weeks CSJ117 2mg
Reporting group description: Participants who entered the extension study after the last treatment visit (Week 12) of the core study and were treated once daily for 24 weeks with the same dose of CSJ117 they had received in the core study (CSJ117 2 mg)	
Reporting group title	24 weeks CSJ117 1mg
Reporting group description: Participants who entered the extension study after the last treatment visit (Week 12) of the core study and were treated once daily for 24 weeks with the same dose of CSJ117 they had received in the core study (CSJ117 1 mg)	
Reporting group title	24-weeks CSJ117 0.5mg
Reporting group description: Participants who entered the extension study after the last treatment visit (Week 12) of the core study and were treated once daily for 24 weeks with the same dose of CSJ117 they had received in the core study (CSJ117 0.5 mg)	
Reporting group title	24-weeks Placebo
Reporting group description: Participants who entered the extension study after the last treatment visit (Week 12) of the core study and were treated once daily for 24 weeks with Placebo	
Reporting group title	12 weeks wash-out + 12 weeks CSJ117 8mg
Reporting group description: Participants who entered the extension study after the last treatment visit (Week 12) of the core study and received Placebo inhaled once daily for 12 weeks "washout period" and then they were treated once daily for 12 weeks with the same dose of CSJ117 they had received in the core study (CSJ117 8 mg)	
Reporting group title	12 weeks wash-out + 12 weeks CSJ117 4mg
Reporting group description: Participants who entered the extension study after the last treatment visit (Week 12) of the core study and received Placebo inhaled once daily for 12 weeks "washout period" and then they were treated once daily for 12 weeks with the same dose of CSJ117 they had received in the core study (CSJ117 4 mg)	
Reporting group title	12 weeks wash-out + 12 weeks CSJ117 2mg
Reporting group description: Participants who entered the extension study after the last treatment visit (Week 12) of the core study and received Placebo inhaled once daily for 12 weeks "washout period" and then they were treated once daily for 12 weeks with the same dose of CSJ117 they had received in the core study (CSJ117 2 mg)	
Reporting group title	12 weeks wash-out + 12 weeks CSJ117 1mg
Reporting group description: Participants who entered the extension study after the last treatment visit (Week 12) of the core study and received Placebo inhaled once daily for 12 weeks "washout period" and then they were treated once daily for 12 weeks with the same dose of CSJ117 they had received in the core study (CSJ117 1 mg)	
Reporting group title	12 weeks wash-out + 12 weeks CSJ117 0.5mg
Reporting group description: Participants who entered the extension study after the last treatment visit (Week 12) of the core study and received Placebo inhaled once daily for 12 weeks "washout period" and then they were treated once daily for 12 weeks with the same dose of CSJ117 they had received in the core study (CSJ117 0.5 mg)	

Reporting group title	12 weeks wash-out + 12 weeks Placebo
Reporting group description: Participants who entered the extension study after the last treatment visit (Week 12) of the core study and received Placebo inhaled once daily for 12 weeks "washout period" and then they were treated once daily for 12 weeks with Placebo	
Reporting group title	12 weeks drug-free + 12 weeks CSJ117 8mg
Reporting group description: Participants who entered the extension study after the last follow-up visit (Week 24) of the core study, therefore after a 12-week drug-free period, and were treated in the extension once daily for 12 weeks with the same dose of CSJ117 they had received in the core study (CSJ117 8 mg)	
Reporting group title	12 weeks drug-free + 12 weeks CSJ117 4mg
Reporting group description: Participants who entered the extension study after the last follow-up visit (Week 24) of the core study, therefore after a 12-week drug-free period, and were treated in the extension once daily for 12 weeks with the same dose of CSJ117 they had received in the core study (CSJ117 4 mg)	
Reporting group title	12 weeks drug-free + 12 weeks CSJ117 2mg
Reporting group description: Participants who entered the extension study after the last follow-up visit (Week 24) of the core study, therefore after a 12-week drug-free period, and were treated in the extension once daily for 12 weeks with the same dose of CSJ117 they had received in the core study (CSJ117 2 mg)	
Reporting group title	12 weeks drug-free + 12 weeks CSJ117 1mg
Reporting group description: Participants who entered the extension study after the last follow-up visit (Week 24) of the core study, therefore after a 12-week drug-free period, and were treated in the extension once daily for 12 weeks with the same dose of CSJ117 they had received in the core study (CSJ117 1 mg)	
Reporting group title	12 weeks drug-free + 12 weeks CSJ117 0.5mg
Reporting group description: Participants who entered the extension study after the last follow-up visit (Week 24) of the core study, therefore after a 12-week drug-free period, and were treated in the extension once daily for 12 weeks with the same dose of CSJ117 they had received in the core study (CSJ117 0.5 mg)	
Reporting group title	12 weeks drug-free + 12 weeks Placebo
Reporting group description: Participants who entered the extension study after the last follow-up visit (Week 24) of the core study, therefore after a 12-week drug-free period, and were treated in the extension once daily for 12 weeks with Placebo	

Reporting group values	24 weeks CSJ117 8mg	24 weeks CSJ117 4mg	24 weeks CSJ117 2mg
Number of subjects	8	5	3
Age Categorical Units: Participants			
18 - <40 years	0	2	1
40 - <65 years	7	3	1
≥65 years	1	0	1
Age continuous Units: years			
arithmetic mean	53.4	44.6	50.7
standard deviation	± 10.64	± 16.43	± 24.91
Sex: Female, Male Units: Participants			
Female	5	3	0
Male	3	2	3

Race/Ethnicity, Customized Units: Subjects			
Asian	5	4	1
Black or African American	0	0	0
White	3	1	2

Reporting group values	24 weeks CSJ117 1mg	24-weeks CSJ117 0.5mg	24-weeks Placebo
Number of subjects	3	5	6
Age Categorical Units: Participants			
18 - <40 years	0	2	2
40 - <65 years	2	3	4
≥65 years	1	0	0
Age continuous Units: years			
arithmetic mean	63.0	44.0	47.5
standard deviation	± 10.58	± 11.60	± 12.63
Sex: Female, Male Units: Participants			
Female	2	3	3
Male	1	2	3
Race/Ethnicity, Customized Units: Subjects			
Asian	2	3	3
Black or African American	0	0	0
White	1	2	3

Reporting group values	12 weeks wash-out + 12 weeks CSJ117 8mg	12 weeks wash-out + 12 weeks CSJ117 4mg	12 weeks wash-out + 12 weeks CSJ117 2mg
Number of subjects	7	3	2
Age Categorical Units: Participants			
18 - <40 years	1	0	0
40 - <65 years	4	3	2
≥65 years	2	0	0
Age continuous Units: years			
arithmetic mean	54.4	50.7	55.5
standard deviation	± 15.33	± 9.29	± 4.95
Sex: Female, Male Units: Participants			
Female	4	0	1
Male	3	3	1
Race/Ethnicity, Customized Units: Subjects			
Asian	2	2	1
Black or African American	2	0	0
White	3	1	1

Reporting group values	12 weeks wash-out + 12 weeks CSJ117	12 weeks wash-out + 12 weeks CSJ117	12 weeks wash-out + 12 weeks Placebo
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	1mg	0.5mg	
Number of subjects	3	1	4
Age Categorical			
Units: Participants			
18 - <40 years	0	0	0
40 - <65 years	3	1	4
≥65 years	0	0	0
Age continuous			
Units: years			
arithmetic mean	44.7	56.0	50.3
standard deviation	± 3.21	± 0	± 6.65
Sex: Female, Male			
Units: Participants			
Female	2	1	3
Male	1	0	1
Race/Ethnicity, Customized			
Units: Subjects			
Asian	1	1	3
Black or African American	0	0	0
White	2	0	1

Reporting group values	12 weeks drug-free + 12 weeks CSJ117 8mg	12 weeks drug-free + 12 weeks CSJ117 4mg	12 weeks drug-free + 12 weeks CSJ117 2mg
Number of subjects	18	24	10
Age Categorical			
Units: Participants			
18 - <40 years	2	6	3
40 - <65 years	12	13	6
≥65 years	4	5	1
Age continuous			
Units: years			
arithmetic mean	53.3	50.4	49.1
standard deviation	± 12.18	± 13.69	± 14.76
Sex: Female, Male			
Units: Participants			
Female	14	15	7
Male	4	9	3
Race/Ethnicity, Customized			
Units: Subjects			
Asian	3	8	4
Black or African American	1	1	0
White	14	15	6

Reporting group values	12 weeks drug-free + 12 weeks CSJ117 1mg	12 weeks drug-free + 12 weeks CSJ117 0.5mg	12 weeks drug-free + 12 weeks Placebo
Number of subjects	7	9	18
Age Categorical			
Units: Participants			
18 - <40 years	1	1	5
40 - <65 years	5	5	9
≥65 years	1	3	4

Age continuous Units: years arithmetic mean standard deviation	50.4 ± 14.21	57.0 ± 12.40	51.0 ± 14.79
Sex: Female, Male Units: Participants			
Female	4	7	11
Male	3	2	7
Race/Ethnicity, Customized Units: Subjects			
Asian	2	3	5
Black or African American	0	0	0
White	5	6	13

Reporting group values	Total		
Number of subjects	136		
Age Categorical Units: Participants			
18 - <40 years	26		
40 - <65 years	87		
≥65 years	23		
Age continuous Units: years arithmetic mean standard deviation	-		
Sex: Female, Male Units: Participants			
Female	85		
Male	51		
Race/Ethnicity, Customized Units: Subjects			
Asian	53		
Black or African American	4		
White	79		

End points

End points reporting groups

Reporting group title	24 weeks CSJ117 8mg
Reporting group description: Participants who entered the extension study after the last treatment visit (Week 12) of the core study and were treated once daily for 24 weeks with the same dose of CSJ117 they had received in the core study (CSJ117 8 mg)	
Reporting group title	24 weeks CSJ117 4mg
Reporting group description: Participants who entered the extension study after the last treatment visit (Week 12) of the core study and were treated once daily for 24 weeks with the same dose of CSJ117 they had received in the core study (CSJ117 4 mg)	
Reporting group title	24 weeks CSJ117 2mg
Reporting group description: Participants who entered the extension study after the last treatment visit (Week 12) of the core study and were treated once daily for 24 weeks with the same dose of CSJ117 they had received in the core study (CSJ117 2 mg)	
Reporting group title	24 weeks CSJ117 1mg
Reporting group description: Participants who entered the extension study after the last treatment visit (Week 12) of the core study and were treated once daily for 24 weeks with the same dose of CSJ117 they had received in the core study (CSJ117 1 mg)	
Reporting group title	24-weeks CSJ117 0.5mg
Reporting group description: Participants who entered the extension study after the last treatment visit (Week 12) of the core study and were treated once daily for 24 weeks with the same dose of CSJ117 they had received in the core study (CSJ117 0.5 mg)	
Reporting group title	24-weeks Placebo
Reporting group description: Participants who entered the extension study after the last treatment visit (Week 12) of the core study and were treated once daily for 24 weeks with Placebo	
Reporting group title	12 weeks wash-out + 12 weeks CSJ117 8mg
Reporting group description: Participants who entered the extension study after the last treatment visit (Week 12) of the core study and received Placebo inhaled once daily for 12 weeks "washout period" and then they were treated once daily for 12 weeks with the same dose of CSJ117 they had received in the core study (CSJ117 8 mg)	
Reporting group title	12 weeks wash-out + 12 weeks CSJ117 4mg
Reporting group description: Participants who entered the extension study after the last treatment visit (Week 12) of the core study and received Placebo inhaled once daily for 12 weeks "washout period" and then they were treated once daily for 12 weeks with the same dose of CSJ117 they had received in the core study (CSJ117 4 mg)	
Reporting group title	12 weeks wash-out + 12 weeks CSJ117 2mg
Reporting group description: Participants who entered the extension study after the last treatment visit (Week 12) of the core study and received Placebo inhaled once daily for 12 weeks "washout period" and then they were treated once daily for 12 weeks with the same dose of CSJ117 they had received in the core study (CSJ117 2 mg)	
Reporting group title	12 weeks wash-out + 12 weeks CSJ117 1mg
Reporting group description: Participants who entered the extension study after the last treatment visit (Week 12) of the core study and received Placebo inhaled once daily for 12 weeks "washout period" and then they were treated once daily for 12 weeks with the same dose of CSJ117 they had received in the core study (CSJ117 1 mg)	
Reporting group title	12 weeks wash-out + 12 weeks CSJ117 0.5mg
Reporting group description: Participants who entered the extension study after the last treatment visit (Week 12) of the core study and received Placebo inhaled once daily for 12 weeks "washout period" and then they were treated once daily for 12 weeks with the same dose of CSJ117 they had received in the core study (CSJ117 0.5 mg)	

Reporting group title	12 weeks wash-out + 12 weeks Placebo
Reporting group description: Participants who entered the extension study after the last treatment visit (Week 12) of the core study and received Placebo inhaled once daily for 12 weeks "washout period" and then they were treated once daily for 12 weeks with Placebo	
Reporting group title	12 weeks drug-free + 12 weeks CSJ117 8mg
Reporting group description: Participants who entered the extension study after the last follow-up visit (Week 24) of the core study, therefore after a 12-week drug-free period, and were treated in the extension once daily for 12 weeks with the same dose of CSJ117 they had received in the core study (CSJ117 8 mg)	
Reporting group title	12 weeks drug-free + 12 weeks CSJ117 4mg
Reporting group description: Participants who entered the extension study after the last follow-up visit (Week 24) of the core study, therefore after a 12-week drug-free period, and were treated in the extension once daily for 12 weeks with the same dose of CSJ117 they had received in the core study (CSJ117 4 mg)	
Reporting group title	12 weeks drug-free + 12 weeks CSJ117 2mg
Reporting group description: Participants who entered the extension study after the last follow-up visit (Week 24) of the core study, therefore after a 12-week drug-free period, and were treated in the extension once daily for 12 weeks with the same dose of CSJ117 they had received in the core study (CSJ117 2 mg)	
Reporting group title	12 weeks drug-free + 12 weeks CSJ117 1mg
Reporting group description: Participants who entered the extension study after the last follow-up visit (Week 24) of the core study, therefore after a 12-week drug-free period, and were treated in the extension once daily for 12 weeks with the same dose of CSJ117 they had received in the core study (CSJ117 1 mg)	
Reporting group title	12 weeks drug-free + 12 weeks CSJ117 0.5mg
Reporting group description: Participants who entered the extension study after the last follow-up visit (Week 24) of the core study, therefore after a 12-week drug-free period, and were treated in the extension once daily for 12 weeks with the same dose of CSJ117 they had received in the core study (CSJ117 0.5 mg)	
Reporting group title	12 weeks drug-free + 12 weeks Placebo
Reporting group description: Participants who entered the extension study after the last follow-up visit (Week 24) of the core study, therefore after a 12-week drug-free period, and were treated in the extension once daily for 12 weeks with Placebo	
Subject analysis set title	FAS 12 weeks CSJ117 8mg
Subject analysis set type	Full analysis
Subject analysis set description: FAS 12 weeks CSJ117 8mg	
Subject analysis set title	FAS 12 weeks CSJ117 4mg
Subject analysis set type	Full analysis
Subject analysis set description: FAS 12 weeks CSJ117 4mg	
Subject analysis set title	FAS 12 weeks CSJ117 2mg
Subject analysis set type	Full analysis
Subject analysis set description: FAS 12 weeks CSJ117 2mg	
Subject analysis set title	FAS 12weeks CSJ117 1mg
Subject analysis set type	Full analysis
Subject analysis set description: FAS 12 weeks CSJ117 1mg	
Subject analysis set title	FAS 12 weeks CSJ117 0.5mg
Subject analysis set type	Full analysis
Subject analysis set description: FAS 12 weeks CSJ117 0.5mg	
Subject analysis set title	FAS Placebo

Subject analysis set type	Full analysis
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Subject analysis set description:

FAS Placebo

Primary: Number of participants with treatment emergent adverse events (AEs) and serious adverse events (SAEs)

End point title	Number of participants with treatment emergent adverse events (AEs) and serious adverse events (SAEs) ^[1]
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End point description:

Number of participants with treatment emergent AEs, AEs led to study treatment discontinuation, SAEs and SAEs led to study treatment discontinuation.

The Number of Subjects Analyzed differs as stated on the comment field for each column, in case of difference from Number of subjects that started the Arm.

Treatment emergent AEs and SAEs were counted from first day of treatment of the core study (CCSJ117A12201C) and until 30 days after last day of treatment in the extension study. For participants who entered the extension study after the last follow-up visit (week 24) of the core study, AEs (if any) occurred from week 4 to week 12 of the drug free follow-up period were not counted as treatment emergent AEs.

End point type	Primary
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End point timeframe:

From start of treatment in the core study until 30 days after end of treatment in the extension study. Up to 48 weeks.

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: No statistical analysis conducted for this endpoint.

End point values	24 weeks CSJ117 8mg	24 weeks CSJ117 4mg	24 weeks CSJ117 2mg	24 weeks CSJ117 1mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	5	3 ^[2]	3 ^[3]
Units: Participants				
At least one AE (0 to 12 weeks)	2	1	2	1
At least one AE (week 12 to week 24)	2	0	2	2
At least one AE (week 24 to week 36)	2	0	1	0
At least one AE (week 36 to week 48)	1	1	0	0
At least one SAE (0 to 12 weeks)	0	0	0	0
At least one SAE (week 12 to week 24)	0	0	0	0
At least one SAE (week 24 to week 36)	0	0	0	0
At least one SAE (week 36 to week 48)	0	0	0	0
AE leading to discontinuation (week 0 to week 48)	0	0	0	0
SAE leading to discontinuation (week 0 to week 48)	0	0	0	0

Notes:

[2] - n=2 (week 24 to week 36); n=0 (week 36 to week 48)

[3] - n=0 (week 24 to week 36); n=0 (week 36 to week 48)

End point values	24-weeks CSJ117 0.5mg	24-weeks Placebo	12 weeks wash-out + 12 weeks CSJ117 8mg	12 weeks wash-out + 12 weeks CSJ117 4mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5 ^[4]	6 ^[5]	7 ^[6]	3 ^[7]
Units: Participants				
At least one AE (0 to 12 weeks)	0	1	2	1

At least one AE (week 12 to week 24)	1	1	2	0
At least one AE (week 24 to week 36)	1	1	2	0
At least one AE (week 36 to week 48)	0	0	0	0
At least one SAE (0 to 12 weeks)	0	0	0	0
At least one SAE (week 12 to week 24)	0	0	0	0
At least one SAE (week 24 to week 36)	0	0	0	0
At least one SAE (week 36 to week 48)	0	0	0	0
AE leading to discontinuation (week 0 to week 48)	0	1	0	0
SAE leading to discontinuation (week 0 to week 48)	0	0	0	0

Notes:

[4] - n=0 (week 36 to week 48)

[5] - n=5 (week 24 to week 36); n=0 (week 36 to week 48)

[6] - n=6 (week 24 to week 36); n=0 (week 36 to week 48)

[7] - n=0 (week 12 to week 24); n=0 (week 24 to week 36); n=0 (week 36 to week 48)

End point values	12 weeks wash-out + 12 weeks CSJ117 2mg	12 weeks wash-out + 12 weeks CSJ117 1mg	12 weeks wash-out + 12 weeks CSJ117 0.5mg	12 weeks wash-out + 12 weeks Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2 ^[8]	3 ^[9]	1 ^[10]	4 ^[11]
Units: Participants				
At least one AE (0 to 12 weeks)	0	1	0	1
At least one AE (week 12 to week 24)	1	1	0	1
At least one AE (week 24 to week 36)	0	0	0	2
At least one AE (week 36 to week 48)	0	0	0	0
At least one SAE (0 to 12 weeks)	0	0	0	0
At least one SAE (week 12 to week 24)	0	0	0	0
At least one SAE (week 24 to week 36)	0	0	0	0
At least one SAE (week 36 to week 48)	0	0	0	0
AE leading to discontinuation (week 0 to week 48)	0	0	0	0
SAE leading to discontinuation (week 0 to week 48)	0	0	0	0

Notes:

[8] - n=0 (week 24 to week 36); n=0 (week 36 to week 48)

[9] - n=0 (week 24 to week 36); n=0 (week 36 to week 48)

[10] - n=0 (week 24 to week 36); n=0 (week 36 to week 48)

[11] - n=3 (week 24 to week 36); n=0 (week 36 to week 48)

End point values	12 weeks drug-free + 12 weeks CSJ117 8mg	12 weeks drug-free + 12 weeks CSJ117 4mg	12 weeks drug-free + 12 weeks CSJ117 2mg	12 weeks drug-free + 12 weeks CSJ117 1mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	24	10	7 ^[12]
Units: Participants				
At least one AE (0 to 12 weeks)	6	6	3	2
At least one AE (week 12 to week 24)	1	1	1	2
At least one AE (week 24 to week 36)	6	10	4	4
At least one AE (week 36 to week 48)	3	2	2	0
At least one SAE (0 to 12 weeks)	0	0	0	0
At least one SAE (week 12 to week 24)	0	0	0	0

At least one SAE (week 24 to week 36)	0	1	0	0
At least one SAE (week 36 to week 48)	0	0	0	0
AE leading to discontinuation (week 0 to week 48)	0	0	0	0
SAE leading to discontinuation (week 0 to week 48)	0	0	0	0

Notes:

[12] - n=0 (week 36 to week 48)

End point values	12 weeks drug-free + 12 weeks CSJ117 0.5mg	12 weeks drug-free + 12 weeks Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9 ^[13]	18		
Units: Participants				
At least one AE (0 to 12 weeks)	4	9		
At least one AE (week 12 to week 24)	2	2		
At least one AE (week 24 to week 36)	2	4		
At least one AE (week 36 to week 48)	0	3		
At least one SAE (0 to 12 weeks)	0	0		
At least one SAE (week 12 to week 24)	0	0		
At least one SAE (week 24 to week 36)	0	0		
At least one SAE (week 36 to week 48)	0	0		
AE leading to discontinuation (week 0 to week 48)	0	0		
SAE leading to discontinuation (week 0 to week 48)	0	0		

Notes:

[13] - n= 0 (week 36 to week 48)

Statistical analyses

No statistical analyses for this end point

Primary: Number of treatment emergent participant deaths and participant hospitalizations

End point title	Number of treatment emergent participant deaths and participant hospitalizations ^[14]
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End point description:

Number of treatment emergent participant deaths and participant hospitalizations (any visit to the hospital that required an overnight stay or an emergency room visit greater than 24 hours).

Treatment emergent participant deaths and participant hospitalizations were counted from first day of treatment of the core study (CCSJ117A12201C) and until 30 days after last day of treatment in the extension study. For participants who entered the extension study after the last follow-up visit (week 24) of the core study, participant deaths and hospitalizations (if any) occurred from week 4 to week 12 of the drug free follow-up period were not counted as treatment emergent participant deaths and hospitalizations.

End point type	Primary
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End point timeframe:

From start of treatment in the core study until 30 days after end of treatment in the extension study. Up to 48 weeks.

Notes:

[14] - 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: No statistical analysis conducted for this endpoint.

End point values	24 weeks CSJ117 8mg	24 weeks CSJ117 4mg	24 weeks CSJ117 2mg	24 weeks CSJ117 1mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	5	3	3
Units: Participants				
Deaths	0	0	0	0
Hospitalizations	0	0	0	0

End point values	24-weeks CSJ117 0.5mg	24-weeks Placebo	12 weeks wash-out + 12 weeks CSJ117 8mg	12 weeks wash-out + 12 weeks CSJ117 4mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	6	7	3
Units: Participants				
Deaths	0	0	0	0
Hospitalizations	0	0	0	0

End point values	12 weeks wash-out + 12 weeks CSJ117 2mg	12 weeks wash-out + 12 weeks CSJ117 1mg	12 weeks wash-out + 12 weeks CSJ117 0.5mg	12 weeks wash-out + 12 weeks Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	3	1	4
Units: Participants				
Deaths	0	0	0	0
Hospitalizations	0	0	0	0

End point values	12 weeks drug- free + 12 weeks CSJ117 8mg	12 weeks drug- free + 12 weeks CSJ117 4mg	12 weeks drug- free + 12 weeks CSJ117 2mg	12 weeks drug- free + 12 weeks CSJ117 1mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18	24	10	7
Units: Participants				
Deaths	0	0	0	0
Hospitalizations	0	1	0	0

End point values	12 weeks drug- free + 12	12 weeks drug- free + 12		
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	weeks CSJ117 0.5mg	weeks Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9	18		
Units: Participants				
Deaths	0	0		
Hospitalizations	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in fractional exhaled Nitric Oxide (FeNO) levels (CSJ117 continuous treatment and placebo)

End point title	Change from baseline in fractional exhaled Nitric Oxide (FeNO) levels (CSJ117 continuous treatment and placebo) ^[15]
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End point description:

Fractional exhaled Nitric Oxide (FeNO) pre-dose measurements were done at the investigational sites prior to spirometry assessments. FeNO is defined as the mean of two serial measurements. The measurement of exhaled nitric oxide is widely accepted as a non-invasive marker of airway inflammation (inflammation leads to elevation of FeNO). The baseline FeNO pre-dose measurements were taken at the end of the run-in period of the core study. A negative average change from baseline in FeNO is considered a favourable outcome.

Due to EudraCT system limitations, data fields in the table cannot contain letters (eg. NA indicating 'not applicable'). Therefore, not applicable values are indicated as '999'.

The Number of Subjects Analyzed differs as stated on the comment field for each column, in case of difference from Number of subjects that started the Arm.

End point type	Secondary
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End point timeframe:

Baseline (from core study), Weeks 2, 4, 8, 12, 14, 16, 20, 24, 26, 28, 32, 36, 38, 40 and 48.

Notes:

[15] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: No statistical analysis conducted for this endpoint.

End point values	24 weeks CSJ117 8mg	24 weeks CSJ117 4mg	24 weeks CSJ117 2mg	24 weeks CSJ117 1mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7 ^[16]	2 ^[17]	2 ^[18]	2 ^[19]
Units: parts per billion (ppb)				
arithmetic mean (standard deviation)				
Week 2	-5.1 (± 10.76)	-16.0 (± 8.49)	-22.5 (± 37.48)	-52.0 (± 999)
Week 4	-6.9 (± 12.51)	-13.5 (± 17.68)	-24.0 (± 32.53)	-57.0 (± 999)
Week 8	-1.6 (± 18.25)	-13.0 (± 2.83)	-27.0 (± 42.43)	-53.0 (± 999)
Week 12	-1.3 (± 14.58)	-8.5 (± 19.09)	-24.5 (± 43.13)	-50.0 (± 999)
Week 14	-2.9 (± 14.72)	-13.0 (± 7.07)	-47.0 (± 60.81)	-64.0 (± 999)
Week 16	-3.6 (± 16.25)	-20.0 (± 12.73)	-33.5 (± 58.69)	999 (± 999)
Week 20	-2.3 (± 13.60)	-23.5 (± 24.75)	-32.0 (± 52.33)	-63.0 (± 999)

Week 24	-4.0 (± 10.58)	-27.5 (± 20.51)	-89.0 (± 999)	-61.0 (± 999)
Week 26	-4.0 (± 7.51)	-34.0 (± 15.56)	-76.0 (± 999)	999 (± 999)
Week 28	1.2 (± 7.55)	-28.5 (± 7.78)	-69.0 (± 999)	999 (± 999)
Week 32	-1.3 (± 9.56)	-13.5 (± 0.71)	-80.0 (± 999)	999 (± 999)
Week 36	-5.0 (± 5.96)	2.5 (± 20.51)	-72.0 (± 999)	999 (± 999)
Week 38	-1.5 (± 11.56)	11.5 (± 26.16)	999 (± 999)	999 (± 999)
Week 40	-4.3 (± 10.40)	-16.0 (± 999)	999 (± 999)	999 (± 999)
Week 48	-3.0 (± 999)	-21.0 (± 999)	999 (± 999)	999 (± 999)

Notes:

[16] - n=6 (weeks 24, 26, 28, 32);

n=5 (week 36);

n=4 (weeks 38, 40);

n=1 (week 48)

[17] - n=1 (weeks 40, 48)

[18] - n=1 (weeks 24, 26, 28, 32, 36);

n=0 (weeks 38, 40, 48)

[19] - n=1 (weeks 2, 4, 8, 12, 14, 20, 24);

n=0 (weeks 16, 26, 28, 32, 36, 38, 40, 48)

End point values	24-weeks CSJ117 0.5mg	FAS Placebo		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	1	28 ^[20]		
Units: parts per billion (ppb)				
arithmetic mean (standard deviation)				
Week 2	5.0 (± 999)	-2.1 (± 6.4)		
Week 4	6.0 (± 999)	0.6 (± 8.65)		
Week 8	3.0 (± 999)	0.3 (± 7.72)		
Week 12	7.0 (± 999)	-1.3 (± 12.23)		
Week 14	8.0 (± 999)	-2.7 (± 13.29)		
Week 16	4.0 (± 999)	0.6 (± 12.34)		
Week 20	-1.0 (± 999)	-0.7 (± 9.99)		
Week 24	-5.0 (± 999)	0.6 (± 14.35)		
Week 26	16.0 (± 999)	-1.9 (± 8.73)		
Week 28	8.0 (± 999)	-2.0 (± 13.05)		
Week 32	-1.0 (± 999)	-1.2 (± 10.48)		
Week 36	4.0 (± 999)	-2.3 (± 23.85)		
Week 38	0.0 (± 999)	-2.6 (± 11.41)		
Week 40	1.0 (± 999)	-3.5 (± 20.83)		
Week 48	0.0 (± 999)	2.5 (± 19.59)		

Notes:

[20] - n=26(weeks2,16,24)

n=24(weeks20,26,28)

n=22(week32)n=20(week36)

n=17(week38)n=16(week40)n=10(week48)

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in fractional exhaled Nitric Oxide (FeNO) levels (CSJ117 interrupted treatment and placebo)

End point title	Change from baseline in fractional exhaled Nitric Oxide (FeNO) levels (CSJ117 interrupted treatment and placebo)
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End point description:

Fractional exhaled Nitric Oxide (FeNO) pre-dose measurements were done at the investigational sites prior to spirometry assessments. FeNO is defined as the mean of two serial measurements. The measurement of exhaled nitric oxide is widely accepted as a non-invasive marker of airway inflammation (inflammation leads to elevation of FeNO). The baseline FeNO pre-dose measurements were taken at the end of the run-in period of the core study. A negative average change from baseline in FeNO is considered a favourable outcome.

The Number of Subjects Analyzed differs as stated on the comment field for each column, in case of difference from Number of subjects that started the Arm.

End point type Secondary

End point timeframe:

Baseline (from core study), Weeks 2, 4, 8, 12, 14, 16, 20, 24, 26, 28, 32, 36, 38, 40 and 48.

End point values	FAS 12 weeks CSJ117 8mg	FAS 12 weeks CSJ117 4mg	FAS 12 weeks CSJ117 2mg	FAS 12weeks CSJ117 1mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	26 ^[21]	30 ^[22]	13 ^[23]	11 ^[24]
Units: parts per billion (ppb)				
arithmetic mean (standard deviation)				
Week 2	-2.7 (± 8.99)	-4.9 (± 13.85)	-10.4 (± 15.59)	-4.5 (± 9.83)
Week 4	-1.5 (± 8.36)	-2.5 (± 7.59)	-12.2 (± 19.69)	-1.5 (± 6.92)
Week 8	3.3 (± 9.46)	-2.5 (± 9.39)	-8.5 (± 15.76)	-3.4 (± 7.47)
Week 12	0.5 (± 9.51)	1.7 (± 17.12)	-3.5 (± 17.25)	-2.5 (± 10.02)
Week 14	-0.7 (± 9.08)	0.6 (± 14.80)	-9.8 (± 16.43)	-5.5 (± 8.58)
Week 16	-0.3 (± 9.03)	0.4 (± 13.49)	-11.6 (± 16.48)	-2.4 (± 12.30)
Week 20	0.5 (± 12.58)	-0.2 (± 19.14)	-10.7 (± 16.69)	-2.1 (± 8.17)
Week 24	0.5 (± 8.86)	-1.4 (± 12.80)	-8.9 (± 17.03)	-3.5 (± 14.88)
Week 26	3.7 (± 14.48)	2.4 (± 9.81)	-10.5 (± 18.28)	-6.0 (± 9.53)
Week 28	1.1 (± 11.89)	0.8 (± 17.41)	-14.0 (± 21.80)	-7.4 (± 10.38)
Week 32	-2.2 (± 10.44)	-2.6 (± 11.50)	-13.3 (± 18.62)	-4.0 (± 8.31)
Week 36	-1.3 (± 11.25)	-0.5 (± 14.89)	-15.6 (± 23.62)	-7.1 (± 9.52)
Week 38	-0.5 (± 10.17)	-3.6 (± 10.18)	-10.1 (± 21.01)	-7.0 (± 9.73)
Week 40	1.3 (± 7.69)	-1.1 (± 9.28)	-9.6 (± 21.23)	-8.6 (± 10.60)
Week 48	5.0 (± 11.82)	-4.9 (± 13.66)	-17.3 (± 21.04)	-6.6 (± 11.76)

Notes:

[21] - n=24(Wk8,16)n=23(Wk2,4,12,14,20,24,26)n=22(Wk28)n=19(Wk32)n=18(Wk36,38)n=17(Wk40)n=12(Wk48)

[22] - n=29(Wk2,4)n=28(Wk8,14,20,24)n=27(Wk12,16,28)n=26(Wk26,36)n=23(Wk32)n=20(Wk38)n=18(Wk40)n=14(Wk48)

[23] - n=12(weeks 2,4,8,14,16,20,24,) n=11 (week12) n=10(weeks 26,28,32) n=8 (weeks 36,38,40) n=6 (week 48)

[24] - n=10 (weeks 2,26,28);n=9 (week 36) n=7 (weeks 32,38,40);n=5 (week 48)

End point values	FAS 12 weeks CSJ117 0.5mg	FAS Placebo		
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Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	14 ^[25]	28 ^[26]		
Units: parts per billion (ppb)				
arithmetic mean (standard deviation)				
Week 2	-4.3 (± 12.59)	-2.1 (± 6.4)		
Week 4	-0.1 (± 8.45)	0.6 (± 8.65)		
Week 8	2.3 (± 9.16)	0.3 (± 7.72)		
Week 12	-5.9 (± 14.86)	-1.3 (± 12.23)		
Week 14	-3.7 (± 21.54)	-2.7 (± 13.29)		
Week 16	-5.1 (± 14.17)	0.6 (± 12.34)		
Week 20	-6.1 (± 14.83)	-0.7 (± 9.99)		
Week 24	0.3 (± 26.83)	0.6 (± 14.35)		
Week 26	0.8 (± 13.57)	-1.9 (± 8.73)		
Week 28	-2.4 (± 5.12)	-2.0 (± 13.05)		
Week 32	-1.8 (± 8.81)	-1.2 (± 10.48)		
Week 36	-1.2 (± 5.33)	-2.3 (± 23.85)		
Week 38	-4.7 (± 5.02)	-2.6 (± 11.41)		
Week 40	-3.9 (± 6.60)	-3.5 (± 20.83)		
Week 48	-4.1 (± 6.52)	2.5 (± 19.59)		

Notes:

[25] - n=13(weeks 20,24);n=12(weeks 8,16) n=11(weeks 26,28);n=9(weeks 36,38,40);n=8(week 32);n=7(week 48)

[26] - n=26(weeks2,16,24)n=24(weeks20,26,28)n=22(week32)n=20(week36)n=17(week38)n=16(week40)n=10(week48)

Statistical analyses

No statistical analyses for this end point

Secondary: Terminal Elimination half-life (T1/2) at Steady State

End point title	Terminal Elimination half-life (T1/2) at Steady State ^[27]
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End point description:

Terminal elimination half-life (T1/2) of CSJ117 calculated by non-compartmental methods based on CSJ117 serum concentrations.

The PK sampling planned and executed was not sufficient to support the calculation of T1/2. The maximum numbers of samples collected on any day were 3 samples, including the predose sample, and majority of those samples were below the limit of quantification (BLQ). The insufficient PK sampling scheme coupled with the early termination of studies did not allow us to calculate T1/2.

End point type	Secondary
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End point timeframe:

Day 1 and Week 12(extension) (Weeks 12 and 24 overall):pre-dose, 2 and 4 hours post-dose; Weeks 2, 4, 8(extension) (Weeks 14, 16 and 20 overall):pre-dose and 4 hours post-dose; Weeks 14, 16, 20 and 24(extension) (Weeks 26, 28, 32 and 36 overall):pre-dose

Notes:

[27] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: No statistical analysis conducted for this endpoint.

End point values	24 weeks CSJ117 8mg	24 weeks CSJ117 4mg	24 weeks CSJ117 2mg	24 weeks CSJ117 1mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[28]	0 ^[29]	0 ^[30]	0 ^[31]
Units: Days				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

- [28] - The insufficient PK sampling scheme did not allow to calculate T1/2.
 [29] - The insufficient PK sampling scheme did not allow to calculate T1/2.
 [30] - The insufficient PK sampling scheme did not allow to calculate T1/2.
 [31] - The insufficient PK sampling scheme did not allow to calculate T1/2.

End point values	24-weeks CSJ117 0.5mg	12 weeks wash-out + 12 weeks CSJ117 8mg	12 weeks wash-out + 12 weeks CSJ117 4mg	12 weeks wash-out + 12 weeks CSJ117 2mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[32]	0 ^[33]	0 ^[34]	0 ^[35]
Units: Days				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

- [32] - The insufficient PK sampling scheme did not allow to calculate T1/2.
 [33] - The insufficient PK sampling scheme did not allow to calculate T1/2.
 [34] - The insufficient PK sampling scheme did not allow to calculate T1/2.
 [35] - The insufficient PK sampling scheme did not allow to calculate T1/2.

End point values	12 weeks wash-out + 12 weeks CSJ117 1mg	12 weeks wash-out + 12 weeks CSJ117 0.5mg	12 weeks drug-free + 12 weeks CSJ117 8mg	12 weeks drug-free + 12 weeks CSJ117 4mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[36]	0 ^[37]	0 ^[38]	0 ^[39]
Units: Days				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

- [36] - The insufficient PK sampling scheme did not allow to calculate T1/2.
 [37] - The insufficient PK sampling scheme did not allow to calculate T1/2.
 [38] - The insufficient PK sampling scheme did not allow to calculate T1/2.
 [39] - The insufficient PK sampling scheme did not allow to calculate T1/2.

End point values	12 weeks drug-free + 12 weeks CSJ117 2mg	12 weeks drug-free + 12 weeks CSJ117 1mg	12 weeks drug-free + 12 weeks CSJ117 0.5mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0 ^[40]	0 ^[41]	0 ^[42]	
Units: Days				
arithmetic mean (standard deviation)	()	()	()	

Notes:

- [40] - The insufficient PK sampling scheme did not allow to calculate T1/2.
 [41] - The insufficient PK sampling scheme did not allow to calculate T1/2.
 [42] - The insufficient PK sampling scheme did not allow to calculate T1/2.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with anti-CSJ117 antibodies

End point title	Number of participants with anti-CSJ117 antibodies
End point description:	
Immunogenicity (antibody formation against CSJ117) was evaluated in serum by a validated bridging	

electrochemiluminescence immunoassay (ECLIA).

The Number of Subjects Analyzed differs as stated on the comment field for each column, in case of difference from Number of subjects that started the Arm.

End point type	Secondary
End point timeframe:	
Day 1, Week 2, 4, 8, 12, 14, 16, 20, 24, 26, 28, 32, 36, 38, 40 and 48	

End point values	24 weeks CSJ117 8mg	24 weeks CSJ117 4mg	24 weeks CSJ117 2mg	24 weeks CSJ117 1mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8 ^[43]	5 ^[44]	3 ^[45]	3 ^[46]
Units: Participants				
Day 1 Negative	6	5	2	3
Week 2 Negative	7	5	2	2
Week4 Negative	5	5	2	2
Week 8 Negative	1	2	0	0
Week 12 Negative	0	2	0	0
Week 14 Negative	0	2	0	0
Week 16 Negative	0	2	0	0
Week 20 Negative	1	2	0	0
Week 24 Negative	0	2	0	0
Week 26 Negative	1	1	0	0
Week 28 Negative	1	1	0	0
Week 32 Negative	1	1	0	0
Week 36 Negative	1	1	0	0
Week 38 Negative	1	1	0	0
Week 40 Negative	1	1	0	0
Week 48 Negative	0	1	0	0
Day 1 Positive	2	0	1	0
Week 2 Positive	1	0	1	1
Week4 Positive	3	0	1	1
Week 8 Positive	7	3	3	3
Week 12 Positive	8	3	3	3
Week 14 Positive	8	3	1	3
Week 16 Positive	8	3	2	3
Week 20 Positive	7	3	2	3
Week 24 Positive	8	3	1	3
Week 26 Positive	6	4	1	1
Week 28 Positive	6	4	1	1
Week 32 Positive	5	1	0	0
Week 36 Positive	4	4	1	1
Week 38 Positive	3	1	0	0
Week 40 Positive	3	0	0	0
Week 48 Positive	1	0	0	0

Notes:

[43] - n=7(weeks 26,28) n=6(week 32) n=5(week 36) n=4(weeks 38,40) n=1(week 48)

[44] - n=2(weeks 32,38) n=1(weeks 40,48)

[45] - n=2(weeks 16,20) n=1(weeks 14,24,26,28,36)
n=0(weeks 32,38,40,48)

[46] - n=1(weeks 26,28,36)
n=0(weeks 32,38,40,48)

End point values	24-weeks CSJ117 0.5mg	24-weeks Placebo	12 weeks wash-out + 12 weeks CSJ117 8mg	12 weeks wash-out + 12 weeks CSJ117 4mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5 ^[47]	6 ^[48]	7 ^[49]	3 ^[50]
Units: Participants				
Day 1 Negative	4	4	7	3
Week 2 Negative	5	3	7	3
Week4 Negative	5	3	5	1
Week 8 Negative	4	5	3	0
Week 12 Negative	3	4	3	0
Week 14 Negative	2	4	2	0
Week 16 Negative	3	4	1	0
Week 20 Negative	3	4	2	0
Week 24 Negative	3	4	2	0
Week 26 Negative	2	3	2	0
Week 28 Negative	1	2	2	0
Week 32 Negative	0	2	2	0
Week 36 Negative	0	3	2	0
Week 38 Negative	0	1	0	0
Week 40 Negative	0	1	1	0
Week 48 Negative	0	0	1	0
Day 1 Positive	1	2	0	0
Week 2 Positive	0	3	0	0
Week4 Positive	0	3	2	2
Week 8 Positive	1	1	4	3
Week 12 Positive	2	1	4	3
Week 14 Positive	3	2	5	3
Week 16 Positive	2	1	6	3
Week 20 Positive	2	1	5	3
Week 24 Positive	2	1	4	3
Week 26 Positive	2	0	4	2
Week 28 Positive	2	1	3	2
Week 32 Positive	1	0	2	2
Week 36 Positive	2	0	2	2
Week 38 Positive	1	0	3	2
Week 40 Positive	1	0	2	2
Week 48 Positive	1	0	0	0

Notes:

[47] - n=4(week 26)

n=3(week 28)

n=2(week 36) n=1(weeks 32,38,40,48)

[48] - n=5(weeks 12,16,20,24) n=3(weeks 26,28,36) n=2(week 32) n=1(weeks 38,40) n=0(week 48)

[49] - n=6(weeks 24,26) n=5(weeks 28) n=4(week 32,36) n=3(weeks 38,40) n=1(week 48)

[50] - n=2(weeks 26,28,32,36,38,40) n=0(week 48)

End point values	12 weeks wash-out + 12 weeks CSJ117 2mg	12 weeks wash-out + 12 weeks CSJ117 1mg	12 weeks wash-out + 12 weeks CSJ117 0.5mg	12 weeks wash-out + 12 weeks Placebo
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Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2 ^[51]	3 ^[52]	1 ^[53]	4 ^[54]
Units: Participants				
Day 1 Negative	2	3	1	4
Week 2 Negative	2	3	1	4
Week4 Negative	2	3	1	4
Week 8 Negative	1	2	1	3
Week 12 Negative	1	2	0	3
Week 14 Negative	1	2	0	4
Week 16 Negative	1	2	0	3
Week 20 Negative	1	2	0	3
Week 24 Negative	1	2	0	3
Week 26 Negative	0	1	0	3
Week 28 Negative	0	1	0	3
Week 32 Negative	0	0	0	3
Week 36 Negative	0	0	0	3
Week 38 Negative	0	0	0	2
Week 40 Negative	0	0	0	2
Week 48 Negative	0	0	0	0
Day 1 Positive	0	0	0	0
Week 2 Positive	0	0	0	0
Week4 Positive	0	0	0	0
Week 8 Positive	1	1	0	1
Week 12 Positive	1	1	1	1
Week 14 Positive	1	1	1	0
Week 16 Positive	1	1	1	0
Week 20 Positive	1	1	1	0
Week 24 Positive	1	1	0	0
Week 26 Positive	1	1	0	0
Week 28 Positive	1	1	0	0
Week 32 Positive	1	1	0	0
Week 36 Positive	0	1	0	0
Week 38 Positive	0	1	0	0
Week 40 Positive	0	1	0	0
Week 48 Positive	0	0	0	1

Notes:

[51] - n=1(weeks 26,28,32) n=0 (weeks 36,38,40,48)

[52] - n=2(weeks 26,28) n=1(weeks 32,36,38,40) n=0 (week 48)

[53] - n=0(weeks 24,26,28,32,36,38,40,48)

[54] - n=3(weeks 16,20,24,26,28,32,36) n=2(weeks 38,40)
n=1(week 48)

End point values	12 weeks drug-free + 12 weeks CSJ117 8mg	12 weeks drug-free + 12 weeks CSJ117 4mg	12 weeks drug-free + 12 weeks CSJ117 2mg	12 weeks drug-free + 12 weeks CSJ117 1mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	18 ^[55]	24 ^[56]	10 ^[57]	7 ^[58]
Units: Participants				
Day 1 Negative	14	22	8	6
Week 2 Negative	14	21	8	5
Week4 Negative	11	16	6	5
Week 8 Negative	6	5	3	4

Week 12 Negative	4	3	2	2
Week 14 Negative	6	3	2	2
Week 16 Negative	5	2	2	3
Week 20 Negative	5	2	4	2
Week 24 Negative	6	3	3	3
Week 26 Negative	6	2	3	2
Week 28 Negative	4	2	3	3
Week 32 Negative	6	2	3	3
Week 36 Negative	5	4	3	1
Week 38 Negative	5	1	2	1
Week 40 Negative	4	2	1	1
Week 48 Negative	3	1	2	2
Day 1 Positive	4	2	2	1
Week 2 Positive	4	3	2	2
Week4 Positive	7	8	4	2
Week 8 Positive	12	19	7	3
Week 12 Positive	14	21	8	5
Week 14 Positive	12	21	8	5
Week 16 Positive	13	22	8	4
Week 20 Positive	13	22	6	5
Week 24 Positive	12	20	7	4
Week 26 Positive	12	21	5	5
Week 28 Positive	14	21	7	4
Week 32 Positive	11	20	6	4
Week 36 Positive	10	18	5	6
Week 38 Positive	10	18	6	5
Week 40 Positive	10	16	7	5
Week 48 Positive	8	14	4	3

Notes:

[55] - n=17(weeks 32) n=15(weeks 36,38) n=14(week 40) n=11(week 48)

[56] - n=23(weeks 24,26,28) n=22(weeks 32,36) n=19(week 38) n=18(week 40)
n=15(week 48)

[57] - n=9(week 32)
n=8(weeks 26,36,38,40)
n=6(week 48)

[58] - n=6(weeks 38,40) n=5(week 48)

End point values	12 weeks drug-free + 12 weeks CSJ117 0.5mg	12 weeks drug-free + 12 weeks Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9 ^[59]	18 ^[60]		
Units: Participants				
Day 1 Negative	7	15		
Week 2 Negative	6	13		
Week4 Negative	6	14		
Week 8 Negative	1	15		
Week 12 Negative	0	14		
Week 14 Negative	0	15		
Week 16 Negative	0	15		
Week 20 Negative	1	14		
Week 24 Negative	3	14		
Week 26 Negative	1	14		

Week 28 Negative	0	17		
Week 32 Negative	0	15		
Week 36 Negative	0	13		
Week 38 Negative	0	12		
Week 40 Negative	0	11		
Week 48 Negative	0	8		
Day 1 Positive	2	3		
Week 2 Positive	3	4		
Week4 Positive	3	4		
Week 8 Positive	8	3		
Week 12 Positive	9	4		
Week 14 Positive	9	3		
Week 16 Positive	9	3		
Week 20 Positive	8	3		
Week 24 Positive	6	4		
Week 26 Positive	8	4		
Week 28 Positive	9	1		
Week 32 Positive	9	2		
Week 36 Positive	9	2		
Week 38 Positive	9	2		
Week 40 Positive	9	2		
Week 48 Positive	7	1		

Notes:

[59] - n=7(week 48)

[60] - n=17(weeks 2,20,32) n=15(week 36) n=14(week 38) n=13(week 40)
n=9(week 48)

Statistical analyses

No statistical analyses for this end point

Secondary: CSJ117 serum concentration

End point title	CSJ117 serum concentration ^[61]
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End point description:

CSJ117 concentration was determined in serum by a validated immunoassay method. Concentrations below the lower limit of quantification (LLOQ) were treated as "zero".

Due to EudraCT system limitations, data fields in the table cannot contain letters (eg. NA indicating 'not applicable'). Therefore, not applicable values are indicated as '999'.

The Number of Subjects Analyzed differs as stated on the comment field for each column, in case of difference from Number of subjects that started the Arm.

End point type	Secondary
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End point timeframe:

Day 1 and Week 12(extension) (Weeks 12 and 24 overall):pre-dose, 2 and 4 hours post-dose; Weeks 2, 4, 8(extension) (Weeks 14, 16 and 20 overall):pre-dose and 4 hours post-dose; Weeks 14, 16, 20 and 24(extension) (Weeks 26, 28, 32 and 36 overall):pre-dose

Notes:

[61] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: No statistical analysis conducted for this endpoint.

End point values	24 weeks CSJ117 8mg	24 weeks CSJ117 4mg	24 weeks CSJ117 2mg	24 weeks CSJ117 1mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8 ^[62]	5 ^[63]	3 ^[64]	3 ^[65]
Units: ng/mL				
arithmetic mean (standard deviation)				
Day 1, pre-dose	0.00 (± 0.00)	0.00 (± 0.00)	0.00 (± 0.00)	0.00 (± 0.00)
Day 1, 2 hours post-dose	0.698 (± 1.97)	0.00 (± 0.00)	0.00 (± 0.00)	0.00 (± 0.00)
Day 1, 4 hours post-dose	1.60 (± 2.98)	0.00 (± 0.00)	0.00 (± 0.00)	0.00 (± 0.00)
Week 2, pre-dose	10.1 (± 7.65)	0.00 (± 0.00)	0.00 (± 0.00)	0.00 (± 0.00)
Week 2, 2 hours post-dose	10.0 (± 7.46)	999 (± 999)	999 (± 999)	999 (± 999)
Week 4, pre-dose	24.0 (± 36.8)	3.67 (± 3.40)	0.00 (± 0.00)	0.00 (± 0.00)
Week 4, 2 hours post-dose	31.4 (± 49.8)	2.43 (± 3.36)	0.00 (± 0.00)	0.00 (± 0.00)
Week 8, pre-dose	67.0 (± 56.3)	9.32 (± 16.4)	5.77 (± 5.96)	3.93 (± 6.81)
Week 8, 2 hours post-dose	64.9 (± 46.5)	9.31 (± 16.9)	3.57 (± 6.18)	4.00 (± 6.93)
Week 12, pre-dose	73.7 (± 62.4)	11.3 (± 19.4)	8.53 (± 9.84)	0.00 (± 0.00)
Week 12, 2 hours post-dose	79.5 (± 68.5)	12.4 (± 24.7)	9.74 (± 12.5)	0.00 (± 0.00)
Week 12, 4 hours post-dose	79.1 (± 69.5)	15.5 (± 24.8)	7.70 (± 9.28)	0.00 (± 0.00)
Week 14, pre-dose	50.8 (± 51.1)	16.8 (± 26.1)	0.00 (± 0.00)	0.00 (± 0.00)
Week 16, pre-dose	49.3 (± 60.7)	17.2 (± 30.2)	0.00 (± 0.00)	0.00 (± 0.00)
Week 20, pre-dose	43.3 (± 61.0)	16.5 (± 26.8)	0.00 (± 0.00)	2.40 (± 4.16)
Week 24, pre-dose	35.2 (± 47.8)	15.3 (± 22.4)	0.00 (± 0.00)	3.40 (± 5.89)
Week 26, pre-dose	13.9 (± 31.0)	0.00 (± 0.00)	999 (± 999)	999 (± 999)
Week 28, pre-dose	12.3 (± 27.5)	0.00 (± 0.00)	999 (± 999)	999 (± 999)
Week 32, pre-dose	9.24 (± 20.7)	0.00 (± 0.00)	999 (± 999)	999 (± 999)
Week 36, pre-dose	55.7 (± 105)	4.86 (± 6.87)	999 (± 999)	999 (± 999)
Week 38, 336 hours post-dose	21.3 (± 42.6)	0.00 (± 0.00)	999 (± 999)	999 (± 999)
Week 40, 672 hours post-dose	12.7 (± 25.3)	0.00 (± 0.00)	999 (± 999)	999 (± 999)
Week 48, 2016 hours post-dose	0.00 (± 0.00)	0.00 (± 0.00)	999 (± 999)	999 (± 999)

Notes:

[62] - n=7(week 4, 2 hours post-dose; weeks 14,16,20,24) n=5(weeks 26,28,32,36) n=4(weeks38,40) n=1(week48)

[63] - n=4(day 1, 4hrs post-dose, week 12, 2 hrs post-dose) n=2(weeks26,28,32,36,38) n=1(weeks 40,48)

[64] - n=2(week 16) n=1(weeks 14,20,24) n=0(weeks 26,28,32,36,38,40,48)

[65] - n=0(weeks 26,28,32,36,38,40,48)

End point values	24-weeks CSJ117 0.5mg	12 weeks wash-out + 12 weeks CSJ117 8mg	12 weeks wash-out + 12 weeks CSJ117 4mg	12 weeks wash-out + 12 weeks CSJ117 2mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5 ^[66]	7 ^[67]	3 ^[68]	2 ^[69]
Units: ng/mL				
arithmetic mean (standard deviation)				
Day 1, pre-dose	0.00 (± 0.00)	0.00 (± 0.00)	0.00 (± 0.00)	0.00 (± 0.00)
Day 1, 2 hours post-dose	0.00 (± 0.00)	0.00 (± 0.00)	0.00 (± 0.00)	0.00 (± 0.00)
Day 1, 4 hours post-dose	0.00 (± 0.00)	1.40 (± 3.70)	0.00 (± 0.00)	0.00 (± 0.00)
Week 2, pre-dose	0.00 (± 0.00)	8.49 (± 9.99)	1.93 (± 3.34)	0.00 (± 0.00)
Week 2, 2 hours post-dose	0.00 (± 0.00)	9.40 (± 6.68)	1.73 (± 3.00)	999 (± 999)
Week 4, pre-dose	0.00 (± 0.00)	9.15 (± 6.76)	2.14 (± 3.70)	0.00 (± 0.00)
Week 4, 2 hours post-dose	0.00 (± 0.00)	9.55 (± 9.53)	1.86 (± 3.23)	0.00 (± 0.00)
Week 8, pre-dose	1.21 (± 2.70)	53.5 (± 90.8)	16.9 (± 12.5)	0.00 (± 0.00)
Week 8, 2 hours post-dose	1.33 (± 2.98)	50.9 (± 88.6)	15.4 (± 9.84)	0.00 (± 0.00)

Week 12, pre-dose	2.22 (± 4.96)	63.2 (± 104)	27.8 (± 24.6)	0.00 (± 0.00)
Week 12, 2 hours post-dose	1.83 (± 4.10)	27.4 (± 45.8)	29.7 (± 25.8)	0.00 (± 0.00)
Week 12, 4 hours post-dose	2.20 (± 4.92)	32.7 (± 58.8)	30.2 (± 27.2)	0.00 (± 0.00)
Week 14, pre-dose	2.12 (± 4.74)	13.4 (± 25.8)	3.07 (± 5.32)	0.00 (± 0.00)
Week 16, pre-dose	2.04 (± 4.56)	6.59 (± 13.5)	0.00 (± 0.00)	0.00 (± 0.00)
Week 20, pre-dose	1.19 (± 2.66)	1.17 (± 3.10)	0.00 (± 0.00)	0.00 (± 0.00)
Week 24, pre-dose	1.17 (± 2.62)	0.00 (± 0.00)	0.00 (± 0.00)	0.00 (± 0.00)
Week 26, pre-dose	0.00 (± 0.00)	62.7 (± 81.0)	26.1 (± 23.9)	22.1 (± 999)
Week 28, pre-dose	0.00 (± 0.00)	67.9 (± 89.0)	5.15 (± 7.28)	21.2 (± 999)
Week 32, pre-dose	0.00 (± 0.00)	79.0 (± 120)	0.00 (± 0.00)	9.18 (± 999)
Week 36, pre-dose	0.00 (± 0.00)	68.6 (± 105)	0.00 (± 0.00)	999 (± 999)
Week 38, 336 hours post-dose	0.00 (± 0.00)	20.8 (± 36.0)	0.00 (± 0.00)	999 (± 999)
Week 40, 672 hours post-dose	0.00 (± 0.00)	12.2 (± 21.1)	0.00 (± 0.00)	999 (± 999)
Week 48, 2016 hours post-dose	0.00 (± 0.00)	0.00 (± 999)	999 (± 999)	999 (± 999)

Notes:

[66] - n=1 (weeks 26, 28, 32, 36, 38, 40, 48)

[67] - n=6(week12, 2and 4hrs post-dose, week24) n=5(weeks26,28) n=4(weeks32,36) n=3(weeks38, 40) n=1(week48)

[68] - n=2(weeks24,26,28,32,36,38,40)
n=0(week48)

[69] - n=1(weeks26,28,32) n=0(weeks36,38,40,48)

End point values	12 weeks wash-out + 12 weeks CSJ117 1mg	12 weeks wash-out + 12 weeks CSJ117 0.5mg	12 weeks drug-free + 12 weeks CSJ117 8mg	12 weeks drug-free + 12 weeks CSJ117 4mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3 ^[70]	1 ^[71]	18 ^[72]	24 ^[73]
Units: ng/mL				
arithmetic mean (standard deviation)				
Day 1, pre-dose	0.00 (± 0.00)	0.00 (± 0.00)	0.00 (± 0.00)	0.00 (± 0.00)
Day 1, 2 hours post-dose	0.00 (± 0.00)	0.00 (± 0.00)	0.00 (± 0.00)	0.00 (± 0.00)
Day 1, 4 hours post-dose	0.00 (± 0.00)	0.00 (± 0.00)	0.678 (± 2.88)	0.414 (± 2.03)
Week 2, pre-dose	0.00 (± 0.00)	0.00 (± 0.00)	3.68 (± 4.54)	1.60 (± 3.31)
Week 2, 2 hours post-dose	999 (± 999)	999 (± 999)	4.53 (± 4.91)	1.87 (± 3.95)
Week 4, pre-dose	0.00 (± 0.00)	0.00 (± 0.00)	9.30 (± 15.2)	2.33 (± 3.89)
Week 4, 2 hours post-dose	0.00 (± 0.00)	0.00 (± 0.00)	12.1 (± 16.7)	4.56 (± 6.07)
Week 8, pre-dose	8.03 (± 13.9)	0.00 (± 0.00)	33.6 (± 40.1)	15.9 (± 16.6)
Week 8, 2 hours post-dose	8.67 (± 15.0)	0.00 (± 0.00)	34.0 (± 44.0)	15.1 (± 15.0)
Week 12, pre-dose	0.00 (± 0.00)	0.00 (± 0.00)	31.6 (± 34.8)	18.8 (± 24.2)
Week 12, 2 hours post-dose	0.00 (± 0.00)	0.00 (± 0.00)	38.8 (± 39.7)	18.9 (± 24.0)
Week 12, 4 hours post-dose	0.00 (± 0.00)	0.00 (± 0.00)	40.7 (± 40.9)	18.8 (± 23.6)
Week 14, pre-dose	0.00 (± 0.00)	0.00 (± 0.00)	8.14 (± 16.6)	2.07 (± 5.28)
Week 16, pre-dose	0.00 (± 0.00)	0.00 (± 0.00)	2.66 (± 6.44)	0.773 (± 2.72)
Week 20, pre-dose	0.00 (± 0.00)	0.00 (± 0.00)	0.00 (± 0.00)	0.00 (± 0.00)
Week 24, pre-dose	0.00 (± 0.00)	999 (± 999)	0.00 (± 0.00)	0.00 (± 0.00)
Week 26, pre-dose	0.00 (± 0.00)	999 (± 999)	21.5 (± 31.3)	12.9 (± 26.0)
Week 28, pre-dose	0.00 (± 0.00)	999 (± 999)	23.8 (± 52.5)	13.2 (± 25.0)
Week 32, pre-dose	0.00 (± 0.00)	999 (± 999)	6.32 (± 11.1)	7.57 (± 14.0)
Week 36, pre-dose	0.00 (± 999)	999 (± 999)	24.2 (± 45.0)	10.5 (± 18.9)
Week 38, 336 hours post-dose	0.00 (± 999)	999 (± 999)	3.46 (± 5.81)	2.14 (± 5.44)
Week 40, 672 hours post-dose	0.00 (± 999)	999 (± 999)	1.53 (± 3.16)	1.46 (± 3.66)
Week 48, 2016 hours post-dose	999 (± 999)	999 (± 999)	0.00 (± 0.00)	0.00 (± 0.00)

Notes:

[70] - n=2(weeks26,28) n=0(weeks32,36,38,40) n=0(week48)

[71] - n=0(weeks24,26,28,32,36,38,40,48)

[72] - n=17(wk 4; 8 pre-ds; 12; 26) n=16(wk 8, 2hrs post-ds)n=15(wk32)n=14(wk 38,40) n=13(wk36) n=11(wk48)

[73] - n=23(Day1,2hrs pst-ds;wk8,2hrs pst-d;12,pre-d)n=22(wk24,28,32) n=21(wk26,36)n=19/18/14(wk38/40/48)

End point values	12 weeks drug-free + 12 weeks CSJ117 2mg	12 weeks drug-free + 12 weeks CSJ117 1mg	12 weeks drug-free + 12 weeks CSJ117 0.5mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10 ^[74]	7 ^[75]	9 ^[76]	
Units: ng/mL				
arithmetic mean (standard deviation)				
Day 1, pre-dose	4.81 (± 15.2)	0.00 (± 0.00)	0.00 (± 0.00)	
Day 1, 2 hours post-dose	5.50 (± 13.7)	0.00 (± 0.00)	0.00 (± 0.00)	
Day 1, 4 hours post-dose	5.79 (± 14.7)	0.00 (± 0.00)	0.00 (± 0.00)	
Week 2, pre-dose	6.28 (± 15.8)	0.00 (± 0.00)	0.00 (± 0.00)	
Week 2, 2 hours post-dose	5.93 (± 14.9)	0.00 (± 0.00)	0.00 (± 0.00)	
Week 4, pre-dose	6.40 (± 17.1)	0.00 (± 0.00)	0.00 (± 0.00)	
Week 4, 2 hours post-dose	7.00 (± 16.1)	0.00 (± 0.00)	0.00 (± 0.00)	
Week 8, pre-dose	13.3 (± 19.0)	0.994 (± 2.63)	2.23 (± 4.43)	
Week 8, 2 hours post-dose	12.7 (± 18.8)	1.30 (± 3.44)	2.62 (± 5.23)	
Week 12, pre-dose	13.0 (± 18.5)	3.73 (± 5.40)	3.23 (± 5.25)	
Week 12, 2 hours post-dose	13.0 (± 18.2)	3.85 (± 5.61)	3.49 (± 5.54)	
Week 12, 4 hours post-dose	13.7 (± 18.6)	3.78 (± 5.31)	3.74 (± 6.07)	
Week 14, pre-dose	7.54 (± 17.0)	0.00 (± 0.00)	0.663 (± 1.99)	
Week 16, pre-dose	6.47 (± 17.2)	0.00 (± 0.00)	0.00 (± 0.00)	
Week 20, pre-dose	5.81 (± 15.4)	0.00 (± 0.00)	0.00 (± 0.00)	
Week 24, pre-dose	4.54 (± 11.2)	0.00 (± 0.00)	0.00 (± 0.00)	
Week 26, pre-dose	6.31 (± 15.6)	3.38 (± 6.64)	1.10 (± 3.29)	
Week 28, pre-dose	5.38 (± 17.0)	3.21 (± 8.50)	5.35 (± 13.9)	
Week 32, pre-dose	0.916 (± 2.59)	1.38 (± 3.65)	5.40 (± 12.1)	
Week 36, pre-dose	1.24 (± 3.51)	2.99 (± 4.70)	6.18 (± 14.8)	
Week 38, 336 hours post-dose	0.689 (± 1.95)	0.00 (± 0.00)	2.89 (± 8.67)	
Week 40, 672 hours post-dose	0.00 (± 0.00)	0.00 (± 0.00)	0.00 (± 0.00)	
Week 48, 2016 hours post-dose	0.00 (± 0.00)	0.00 (± 0.00)	0.00 (± 0.00)	

Notes:

[74] - n=9(weeks 4 pre-dose;12 pre-dose, 2, 4 hrs post-dose;14,16,20,24)n=8(weeks26,32,36,38,40) n=6(week48)

[75] - n=6 (weeks 36, 38, 40) n=5 (week 48)

[76] - n=6 (week 48)

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From first dose of double-blind treatment up to 12 weeks after last dose (Week 48).

Adverse event reporting additional description:

For AE reporting, the "24 weeks", the "12 weeks wash-out + 12 weeks" and the "12 weeks drug-free + 12 weeks" arms for a dose were pooled. AEs occurring during the 12 week wash-out or drug-free period were accounted for in the dose received prior to the wash-out or drug-free period.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	25.0
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Reporting groups

Reporting group title	CSJ117 8mg
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Reporting group description:

CSJ117 8mg

Reporting group title	CSJ117 4mg
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Reporting group description:

CSJ117 4mg

Reporting group title	CSJ117 2mg
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Reporting group description:

CSJ117 2mg

Reporting group title	CSJ117 1mg
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Reporting group description:

CSJ117 1mg

Reporting group title	CSJ117 0.5mg
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Reporting group description:

CSJ117 0.5mg

Reporting group title	Placebo
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Reporting group description:

Placebo

Serious adverse events	CSJ117 8mg	CSJ117 4mg	CSJ117 2mg
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 33 (0.00%)	1 / 32 (3.13%)	0 / 15 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Infections and infestations			
Pneumonia			
subjects affected / exposed	0 / 33 (0.00%)	1 / 32 (3.13%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	CSJ117 1mg	CSJ117 0.5mg	Placebo
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	0 / 28 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Infections and infestations			
Pneumonia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	0 / 28 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Frequency threshold for reporting non-serious adverse events: 2 %

Non-serious adverse events	CSJ117 8mg	CSJ117 4mg	CSJ117 2mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	17 / 33 (51.52%)	17 / 32 (53.13%)	11 / 15 (73.33%)
Vascular disorders			
Arteriosclerosis			
subjects affected / exposed	0 / 33 (0.00%)	1 / 32 (3.13%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Hypertension			
subjects affected / exposed	0 / 33 (0.00%)	0 / 32 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Chest discomfort			
subjects affected / exposed	1 / 33 (3.03%)	0 / 32 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Pain			
subjects affected / exposed	1 / 33 (3.03%)	0 / 32 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 33 (0.00%)	0 / 32 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Inflammation			
subjects affected / exposed	1 / 33 (3.03%)	0 / 32 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Fatigue			

subjects affected / exposed	1 / 33 (3.03%)	0 / 32 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Pyrexia			
subjects affected / exposed	0 / 33 (0.00%)	0 / 32 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Vaccination site swelling			
subjects affected / exposed	0 / 33 (0.00%)	0 / 32 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Erectile dysfunction			
subjects affected / exposed	0 / 33 (0.00%)	0 / 32 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 33 (0.00%)	0 / 32 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Chronic rhinosinusitis with nasal polyps			
subjects affected / exposed	0 / 33 (0.00%)	0 / 32 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Asthma			
subjects affected / exposed	3 / 33 (9.09%)	4 / 32 (12.50%)	5 / 15 (33.33%)
occurrences (all)	3	7	6
Dysphonia			
subjects affected / exposed	0 / 33 (0.00%)	0 / 32 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	0 / 33 (0.00%)	0 / 32 (0.00%)	2 / 15 (13.33%)
occurrences (all)	0	0	2
Epistaxis			
subjects affected / exposed	1 / 33 (3.03%)	0 / 32 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Productive cough			
subjects affected / exposed	0 / 33 (0.00%)	0 / 32 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Throat irritation			

subjects affected / exposed occurrences (all)	0 / 33 (0.00%) 0	1 / 32 (3.13%) 1	0 / 15 (0.00%) 0
Rhinorrhoea subjects affected / exposed occurrences (all)	1 / 33 (3.03%) 1	0 / 32 (0.00%) 0	0 / 15 (0.00%) 0
Psychiatric disorders Insomnia subjects affected / exposed occurrences (all)	0 / 33 (0.00%) 0	1 / 32 (3.13%) 1	0 / 15 (0.00%) 0
Persistent depressive disorder subjects affected / exposed occurrences (all)	0 / 33 (0.00%) 0	1 / 32 (3.13%) 1	0 / 15 (0.00%) 0
Investigations Blood triglycerides increased subjects affected / exposed occurrences (all)	0 / 33 (0.00%) 0	1 / 32 (3.13%) 1	0 / 15 (0.00%) 0
Blood glucose increased subjects affected / exposed occurrences (all)	0 / 33 (0.00%) 0	1 / 32 (3.13%) 1	0 / 15 (0.00%) 0
Blood cholesterol increased subjects affected / exposed occurrences (all)	0 / 33 (0.00%) 0	1 / 32 (3.13%) 1	0 / 15 (0.00%) 0
Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	1 / 33 (3.03%) 1	0 / 32 (0.00%) 0	0 / 15 (0.00%) 0
Alanine aminotransferase increased subjects affected / exposed occurrences (all)	1 / 33 (3.03%) 1	0 / 32 (0.00%) 0	0 / 15 (0.00%) 0
Lipase increased subjects affected / exposed occurrences (all)	0 / 33 (0.00%) 0	0 / 32 (0.00%) 0	0 / 15 (0.00%) 0
Injury, poisoning and procedural complications Arthropod bite subjects affected / exposed occurrences (all)	1 / 33 (3.03%) 1	0 / 32 (0.00%) 0	0 / 15 (0.00%) 0
Chest injury			

subjects affected / exposed	0 / 33 (0.00%)	0 / 32 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Corneal abrasion			
subjects affected / exposed	0 / 33 (0.00%)	0 / 32 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			
subjects affected / exposed	0 / 33 (0.00%)	0 / 32 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Skin abrasion			
subjects affected / exposed	0 / 33 (0.00%)	0 / 32 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Vaccination complication			
subjects affected / exposed	0 / 33 (0.00%)	0 / 32 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Palpitations			
subjects affected / exposed	0 / 33 (0.00%)	1 / 32 (3.13%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Tachycardia			
subjects affected / exposed	0 / 33 (0.00%)	0 / 32 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Spinal cord herniation			
subjects affected / exposed	0 / 33 (0.00%)	0 / 32 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Sciatica			
subjects affected / exposed	1 / 33 (3.03%)	0 / 32 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Monoparesis			
subjects affected / exposed	0 / 33 (0.00%)	1 / 32 (3.13%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Headache			
subjects affected / exposed	0 / 33 (0.00%)	0 / 32 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Dizziness			

subjects affected / exposed occurrences (all)	1 / 33 (3.03%) 1	0 / 32 (0.00%) 0	0 / 15 (0.00%) 0
Blood and lymphatic system disorders			
Leukopenia			
subjects affected / exposed	1 / 33 (3.03%)	0 / 32 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Anaemia			
subjects affected / exposed	0 / 33 (0.00%)	1 / 32 (3.13%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Leukocytosis			
subjects affected / exposed	1 / 33 (3.03%)	0 / 32 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Eye disorders			
Conjunctivitis allergic			
subjects affected / exposed	1 / 33 (3.03%)	0 / 32 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 33 (3.03%)	1 / 32 (3.13%)	0 / 15 (0.00%)
occurrences (all)	1	1	0
Abdominal pain upper			
subjects affected / exposed	0 / 33 (0.00%)	1 / 32 (3.13%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Pancreatitis acute			
subjects affected / exposed	0 / 33 (0.00%)	0 / 32 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	1 / 33 (3.03%)	0 / 32 (0.00%)	0 / 15 (0.00%)
occurrences (all)	2	0	0
Gastrointestinal disorder			
subjects affected / exposed	0 / 33 (0.00%)	0 / 32 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	1 / 33 (3.03%)	0 / 32 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Diarrhoea			

subjects affected / exposed occurrences (all)	0 / 33 (0.00%) 0	0 / 32 (0.00%) 0	1 / 15 (6.67%) 1
Dental caries subjects affected / exposed occurrences (all)	1 / 33 (3.03%) 1	0 / 32 (0.00%) 0	0 / 15 (0.00%) 0
Skin and subcutaneous tissue disorders Pruritus subjects affected / exposed occurrences (all)	1 / 33 (3.03%) 1	0 / 32 (0.00%) 0	0 / 15 (0.00%) 0
Ingrowing nail subjects affected / exposed occurrences (all)	1 / 33 (3.03%) 1	0 / 32 (0.00%) 0	0 / 15 (0.00%) 0
Eczema subjects affected / exposed occurrences (all)	1 / 33 (3.03%) 1	1 / 32 (3.13%) 1	0 / 15 (0.00%) 0
Urticaria subjects affected / exposed occurrences (all)	0 / 33 (0.00%) 0	0 / 32 (0.00%) 0	0 / 15 (0.00%) 0
Renal and urinary disorders Renal cyst subjects affected / exposed occurrences (all)	0 / 33 (0.00%) 0	1 / 32 (3.13%) 1	0 / 15 (0.00%) 0
Chronic kidney disease subjects affected / exposed occurrences (all)	0 / 33 (0.00%) 0	0 / 32 (0.00%) 0	1 / 15 (6.67%) 1
Endocrine disorders Hypothyroidism subjects affected / exposed occurrences (all)	0 / 33 (0.00%) 0	0 / 32 (0.00%) 0	0 / 15 (0.00%) 0
Musculoskeletal and connective tissue disorders Synovial cyst subjects affected / exposed occurrences (all)	1 / 33 (3.03%) 1	0 / 32 (0.00%) 0	0 / 15 (0.00%) 0
Back pain subjects affected / exposed occurrences (all)	1 / 33 (3.03%) 1	2 / 32 (6.25%) 2	1 / 15 (6.67%) 1

Rheumatic disorder subjects affected / exposed occurrences (all)	0 / 33 (0.00%) 0	0 / 32 (0.00%) 0	0 / 15 (0.00%) 0
Spinal osteoarthritis subjects affected / exposed occurrences (all)	0 / 33 (0.00%) 0	0 / 32 (0.00%) 0	0 / 15 (0.00%) 0
Infections and infestations			
Herpes zoster subjects affected / exposed occurrences (all)	0 / 33 (0.00%) 0	0 / 32 (0.00%) 0	1 / 15 (6.67%) 1
Cystitis subjects affected / exposed occurrences (all)	0 / 33 (0.00%) 0	1 / 32 (3.13%) 1	2 / 15 (13.33%) 2
COVID-19 subjects affected / exposed occurrences (all)	2 / 33 (6.06%) 2	2 / 32 (6.25%) 2	0 / 15 (0.00%) 0
Bronchitis subjects affected / exposed occurrences (all)	0 / 33 (0.00%) 0	1 / 32 (3.13%) 1	1 / 15 (6.67%) 1
Body tinea subjects affected / exposed occurrences (all)	1 / 33 (3.03%) 1	0 / 32 (0.00%) 0	0 / 15 (0.00%) 0
Acute sinusitis subjects affected / exposed occurrences (all)	0 / 33 (0.00%) 0	0 / 32 (0.00%) 0	1 / 15 (6.67%) 1
Laryngitis subjects affected / exposed occurrences (all)	0 / 33 (0.00%) 0	0 / 32 (0.00%) 0	0 / 15 (0.00%) 0
Nasopharyngitis subjects affected / exposed occurrences (all)	2 / 33 (6.06%) 3	0 / 32 (0.00%) 0	1 / 15 (6.67%) 1
Oral candidiasis subjects affected / exposed occurrences (all)	1 / 33 (3.03%) 1	0 / 32 (0.00%) 0	0 / 15 (0.00%) 0
Oral herpes			

subjects affected / exposed	1 / 33 (3.03%)	0 / 32 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Oropharyngeal candidiasis			
subjects affected / exposed	1 / 33 (3.03%)	0 / 32 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Tonsillitis			
subjects affected / exposed	1 / 33 (3.03%)	0 / 32 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Tooth abscess			
subjects affected / exposed	0 / 33 (0.00%)	0 / 32 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Rhinitis			
subjects affected / exposed	1 / 33 (3.03%)	0 / 32 (0.00%)	1 / 15 (6.67%)
occurrences (all)	2	0	1
Pyelitis			
subjects affected / exposed	0 / 33 (0.00%)	1 / 32 (3.13%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Pharyngitis			
subjects affected / exposed	0 / 33 (0.00%)	2 / 32 (6.25%)	0 / 15 (0.00%)
occurrences (all)	0	2	0
Papilloma viral infection			
subjects affected / exposed	0 / 33 (0.00%)	0 / 32 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	1 / 33 (3.03%)	0 / 32 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Sinusitis			
subjects affected / exposed	2 / 33 (6.06%)	1 / 32 (3.13%)	1 / 15 (6.67%)
occurrences (all)	2	1	1
Tooth infection			
subjects affected / exposed	0 / 33 (0.00%)	1 / 32 (3.13%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 33 (3.03%)	3 / 32 (9.38%)	0 / 15 (0.00%)
occurrences (all)	1	4	0
Urinary tract infection			

subjects affected / exposed occurrences (all)	0 / 33 (0.00%) 0	0 / 32 (0.00%) 0	0 / 15 (0.00%) 0
Vaginal infection subjects affected / exposed occurrences (all)	1 / 33 (3.03%) 1	0 / 32 (0.00%) 0	0 / 15 (0.00%) 0
Varicella zoster virus infection subjects affected / exposed occurrences (all)	0 / 33 (0.00%) 0	0 / 32 (0.00%) 0	1 / 15 (6.67%) 1
Viral infection subjects affected / exposed occurrences (all)	0 / 33 (0.00%) 0	1 / 32 (3.13%) 1	0 / 15 (0.00%) 0
Viral upper respiratory tract infection subjects affected / exposed occurrences (all)	2 / 33 (6.06%) 3	0 / 32 (0.00%) 0	1 / 15 (6.67%) 1
Metabolism and nutrition disorders			
Hypercholesterolaemia subjects affected / exposed occurrences (all)	0 / 33 (0.00%) 0	0 / 32 (0.00%) 0	0 / 15 (0.00%) 0
Type 2 diabetes mellitus subjects affected / exposed occurrences (all)	1 / 33 (3.03%) 1	0 / 32 (0.00%) 0	0 / 15 (0.00%) 0
Dyslipidaemia subjects affected / exposed occurrences (all)	1 / 33 (3.03%) 1	0 / 32 (0.00%) 0	1 / 15 (6.67%) 1

Non-serious adverse events	CSJ117 1mg	CSJ117 0.5mg	Placebo
Total subjects affected by non-serious adverse events subjects affected / exposed	8 / 13 (61.54%)	6 / 15 (40.00%)	16 / 28 (57.14%)
Vascular disorders			
Arteriosclerosis subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 15 (0.00%) 0	0 / 28 (0.00%) 0
Hypertension subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	0 / 15 (0.00%) 0	0 / 28 (0.00%) 0
General disorders and administration site conditions			

Chest discomfort			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	1 / 28 (3.57%)
occurrences (all)	0	0	1
Non-cardiac chest pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	1 / 28 (3.57%)
occurrences (all)	0	0	1
Inflammation			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	1 / 28 (3.57%)
occurrences (all)	0	0	1
Pyrexia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	1 / 28 (3.57%)
occurrences (all)	0	0	1
Vaccination site swelling			
subjects affected / exposed	1 / 13 (7.69%)	0 / 15 (0.00%)	0 / 28 (0.00%)
occurrences (all)	1	0	0
Reproductive system and breast disorders			
Erectile dysfunction			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 13 (7.69%)	0 / 15 (0.00%)	0 / 28 (0.00%)
occurrences (all)	2	0	0
Chronic rhinosinusitis with nasal polyps			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Asthma			
subjects affected / exposed	2 / 13 (15.38%)	1 / 15 (6.67%)	5 / 28 (17.86%)
occurrences (all)	2	2	5

Dysphonia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	2 / 28 (7.14%)
occurrences (all)	0	0	2
Dyspnoea			
subjects affected / exposed	0 / 13 (0.00%)	1 / 15 (6.67%)	0 / 28 (0.00%)
occurrences (all)	0	1	0
Epistaxis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Throat irritation			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	1 / 13 (7.69%)	0 / 15 (0.00%)	1 / 28 (3.57%)
occurrences (all)	1	0	1
Psychiatric disorders			
Insomnia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Persistent depressive disorder			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Investigations			
Blood triglycerides increased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Blood glucose increased			
subjects affected / exposed	0 / 13 (0.00%)	1 / 15 (6.67%)	0 / 28 (0.00%)
occurrences (all)	0	2	0
Blood cholesterol increased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			

subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 15 (0.00%) 0	0 / 28 (0.00%) 0
Alanine aminotransferase increased subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 15 (0.00%) 0	0 / 28 (0.00%) 0
Lipase increased subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 15 (0.00%) 0	1 / 28 (3.57%) 1
Injury, poisoning and procedural complications			
Arthropod bite subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 15 (0.00%) 0	0 / 28 (0.00%) 0
Chest injury subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 15 (0.00%) 0	1 / 28 (3.57%) 1
Corneal abrasion subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 15 (0.00%) 0	1 / 28 (3.57%) 1
Ligament sprain subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 15 (0.00%) 0	0 / 28 (0.00%) 0
Skin abrasion subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 15 (0.00%) 0	0 / 28 (0.00%) 0
Vaccination complication subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	0 / 15 (0.00%) 0	1 / 28 (3.57%) 1
Cardiac disorders			
Palpitations subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 15 (0.00%) 0	0 / 28 (0.00%) 0
Tachycardia subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 15 (0.00%) 0	1 / 28 (3.57%) 1
Nervous system disorders			

Spinal cord herniation subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 15 (0.00%) 0	0 / 28 (0.00%) 0
Sciatica subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 15 (0.00%) 0	0 / 28 (0.00%) 0
Monoparesis subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 15 (0.00%) 0	0 / 28 (0.00%) 0
Headache subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 15 (0.00%) 0	1 / 28 (3.57%) 1
Dizziness subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 15 (0.00%) 0	0 / 28 (0.00%) 0
Blood and lymphatic system disorders Leukopenia subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 15 (0.00%) 0	0 / 28 (0.00%) 0
Anaemia subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 15 (0.00%) 0	0 / 28 (0.00%) 0
Leukocytosis subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 15 (0.00%) 0	0 / 28 (0.00%) 0
Eye disorders Conjunctivitis allergic subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 15 (0.00%) 0	0 / 28 (0.00%) 0
Gastrointestinal disorders Abdominal pain subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 15 (0.00%) 0	0 / 28 (0.00%) 0
Abdominal pain upper subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 15 (0.00%) 0	0 / 28 (0.00%) 0
Pancreatitis acute			

subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	1 / 28 (3.57%)
occurrences (all)	0	0	2
Nausea			
subjects affected / exposed	1 / 13 (7.69%)	0 / 15 (0.00%)	0 / 28 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorder			
subjects affected / exposed	1 / 13 (7.69%)	0 / 15 (0.00%)	0 / 28 (0.00%)
occurrences (all)	1	0	0
Dry mouth			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Dental caries			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Ingrowing nail			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 13 (0.00%)	1 / 15 (6.67%)	0 / 28 (0.00%)
occurrences (all)	0	1	0
Renal and urinary disorders			
Renal cyst			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Chronic kidney disease			

subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	0 / 15 (0.00%) 0	0 / 28 (0.00%) 0
Endocrine disorders Hypothyroidism subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 15 (0.00%) 0	1 / 28 (3.57%) 1
Musculoskeletal and connective tissue disorders Synovial cyst subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 15 (0.00%) 0	0 / 28 (0.00%) 0
Back pain subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	1 / 15 (6.67%) 1	0 / 28 (0.00%) 0
Rheumatic disorder subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	0 / 15 (0.00%) 0	0 / 28 (0.00%) 0
Spinal osteoarthritis subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	0 / 15 (0.00%) 0	0 / 28 (0.00%) 0
Infections and infestations Herpes zoster subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 15 (0.00%) 0	0 / 28 (0.00%) 0
Cystitis subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 15 (0.00%) 0	0 / 28 (0.00%) 0
COVID-19 subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	2 / 15 (13.33%) 2	2 / 28 (7.14%) 2
Bronchitis subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	1 / 15 (6.67%) 1	0 / 28 (0.00%) 0
Body tinea subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 15 (0.00%) 0	0 / 28 (0.00%) 0
Acute sinusitis			

subjects affected / exposed	0 / 13 (0.00%)	1 / 15 (6.67%)	1 / 28 (3.57%)
occurrences (all)	0	1	1
Laryngitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	1 / 28 (3.57%)
occurrences (all)	0	0	1
Nasopharyngitis			
subjects affected / exposed	1 / 13 (7.69%)	0 / 15 (0.00%)	3 / 28 (10.71%)
occurrences (all)	1	0	5
Oral candidiasis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	1 / 13 (7.69%)	0 / 15 (0.00%)	0 / 28 (0.00%)
occurrences (all)	2	0	0
Oropharyngeal candidiasis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Tooth abscess			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Pyelitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	0 / 28 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	1 / 13 (7.69%)	0 / 15 (0.00%)	1 / 28 (3.57%)
occurrences (all)	1	0	1
Papilloma viral infection			
subjects affected / exposed	0 / 13 (0.00%)	1 / 15 (6.67%)	0 / 28 (0.00%)
occurrences (all)	0	1	0
Otitis media			

subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 15 (0.00%) 0	0 / 28 (0.00%) 0
Sinusitis			
subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	1 / 15 (6.67%) 1	1 / 28 (3.57%) 1
Tooth infection			
subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 15 (0.00%) 0	0 / 28 (0.00%) 0
Upper respiratory tract infection			
subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	1 / 15 (6.67%) 1	1 / 28 (3.57%) 1
Urinary tract infection			
subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	0 / 15 (0.00%) 0	0 / 28 (0.00%) 0
Vaginal infection			
subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 15 (0.00%) 0	0 / 28 (0.00%) 0
Varicella zoster virus infection			
subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 15 (0.00%) 0	0 / 28 (0.00%) 0
Viral infection			
subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 15 (0.00%) 0	0 / 28 (0.00%) 0
Viral upper respiratory tract infection			
subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 15 (0.00%) 0	0 / 28 (0.00%) 0
Metabolism and nutrition disorders			
Hypercholesterolaemia			
subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 15 (0.00%) 0	1 / 28 (3.57%) 1
Type 2 diabetes mellitus			
subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 15 (0.00%) 0	2 / 28 (7.14%) 2
Dyslipidaemia			
subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 15 (0.00%) 0	0 / 28 (0.00%) 0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Due to EudraCT system limitations, which EMA is aware of, data using 999 as data points in this record are not an accurate representation of the clinical trial results. Please use https://www.novctrd.com/#/

Notes: