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Sponsor

Novartis Pharmaceuticals

Generic Drug Name

CSJ117

Trial Indication(s)

Asthma

Protocol Number

CCSJ117A12201E1

Protocol Title

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

Clinical Trial Phase

Phase 2

Phase of Drug Development

Phase 2

Study Start/End Dates

Study Start Date: September 08, 2021 (Actual)
Primary Completion Date: September 08, 2022 (Actual)
Study Completion Date: September 08, 2022 (Actual)

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Reason for Termination (If applicable)

Due to deprioritization of the program, the study was terminated early, and the investigators were notified of early study termination on 14-Jun-2022. There were no safety findings that contributed to this decision.

Study Design/Methodology

This study is a Phase IIb, multicenter, multi-national, double-blind, randomized, parallel-arm, placebo-controlled extension study to evaluate the safety and tolerability, pharmacokinetics and immunogenicity of 5 dose levels of CSJ117 in adult asthma patients treated with medium or high dose inhaled corticosteroid (ICS) plus long-acting Beta agonist (LABA) alone or with additional asthma controllers (allowed: leukotriene receptor antagonist, long-acting muscarinic antagonist, theophylline or its derivatives), who have completed the prior Phase IIb core study CCSJ117A12201C (NCT04410523). The study included patients entering the extension study after their last treatment visit of CCSJ117A12201C; as well as patients who enter study CCSJ117A12201E1 (NCT04946318) after having completed the 12-week follow-up period of CCSJ117A12201C.

The study included:

- A screening period of up to 3 days to assess eligibility.
- A treatment period of 12 or 24 weeks.
- Patients on each of the five treatment arms (CSJ117 0.5 to 8 mg) or placebo of study A12201C, who entered the extension study after the last treatment period visit (Week 12) of study A12201C, were randomized in a 1:1 ratio to continue on their previously assigned CSJ117 dose or placebo from A12201C for 24 weeks, or to first go through a 12-week "washout period" receiving placebo (for the blinding purpose) and then restart on their previously assigned CSJ117 dose or placebo from A12201C for 12 weeks.
- Patients on each of the five treatment arms (CSJ117 0.5 to 8 mg) or placebo of A12201C, who entered the extension study after the last follow-up visit (Week 24) of study A12201C, will restart on their previously assigned CSJ117 dose or placebo from A12201C for 12 weeks.

- A Follow-up period of 12 weeks, study drug free, following the last dose of study drug.

Centers

59 centers in 14 countries: Japan(12), Hungary(3), Poland(3), United States(10), Czech Republic(2), Canada(3), Germany(8), Russia(2), Bulgaria(2), Latvia(3), Argentina(6), Philippines(3), Belgium(1), Slovakia (Slovak Republic)(1)

Objectives:

The primary objective of the trial was to evaluate the safety and tolerability of five doses of CSJ117 inhaled once daily compared to placebo in participants with moderate to severe asthma receiving standard of care asthma therapy.

The secondary objectives of the trial were:

• To characterize the systemic pharmacokinetic (PK) profile of five doses of CSJ117 inhaled once daily.

• To characterize the immunogenicity of five doses of CSJ117 inhaled once daily.

• To evaluate the Fractional exhaled Nitric Oxide (FeNO) levels of five doses of CSJ117 inhaled once daily compared to placebo.

Test Product (s), Dose(s), and Mode(s) of Administration

Participants received CSJ117 (0.5; 1; 2; 4 and 8 mg) and matching placebo in blister packs as powder filled capsules with a Concept1 inhalation device. All CSJ117 doses and placebo were prepared for a single inhalation.

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Statistical Methods

All AEs including asthma exacerbations were summarized by treatment group/regimen and by study period for Safety Analysis set (SAF). AE summaries were provided by MedDRA (version 25.1) primary system organ class and preferred term, including the number and percentages of patients with at least one event.

Efficacy: All secondary efficacy analysis conducted on the Full Analysis set (FAS) unless otherwise specified.

- FeNO: The change from baseline in FeNO (including all scheduled post baseline visits with FeNO data) were summarized by visit and by treatment group on the FAS.

Patient anti-drug antibodies (ADA) status was conducted on the SAF.

Study Population: Key Inclusion/Exclusion Criteria

Inclusion Criteria:
- All participants must have been treated with a fixed dose combination of fluticasone propionate/salmeterol in one of two doses in stable dose alone or with additional controllers at label approved dosage (allowed only: LTRA, LAMA, Theophylline or its derivatives).
- Participants completing the Treatment period and Follow-up period of study CSJ117A12201C and continuing with study CCSJ117A12201E1 must have completed the Treatment period of CSJ117A12201C (i.e. did not discontinue blinded study treatment prematurely) and Follow-up period of study CSJ117A12201C.

Exclusion Criteria:
- Participants who were enrolled into prior study CSJ117A12201C and developed a significant and/or permanent health condition during the prior study.
- Participants who experienced a serious and drug-related AE in the prior study CSJ117A12201C.
- Participants receiving any prohibited medications.
- Participants with a history or current diagnosis of ECG abnormalities.
-Pregnant or nursing (lactating) women.

Participant Flow Table

Overall Study

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	24 weeks CSJ 117 8mg	24 weeks CSJ 117 4mg	24 weeks CSJ 117 2mg	24 weeks CSJ 117 1mg	24-weeks CSJ 117 0.5mg	24-weeks Placebo	12 weeks was h-out + 12 weeks CSJ 117 8mg	12 weeks was h-out + 12 weeks CSJ 117 4mg	12 weeks was h-out + 12 weeks CSJ 117 2mg	12 weeks was h-out + 12 weeks CSJ 117 1mg	12 weeks was h-out + 12 weeks CSJ 117 0.5mg	12 weeks was h-out + 12 weeks Placebo	12 weeks drug-free + 12 weeks CSJ 117 8mg	12 weeks drug-free + 12 weeks CSJ 117 4mg	12 weeks drug-free + 12 weeks CSJ 117 2mg	12 weeks drug-free + 12 weeks CSJ 117 1mg	12 weeks drug-free + 12 weeks CSJ 117 0.5mg	12 weeks drug-free + 12 weeks Placebo	Total
Arm/ Group Description	Participants who entered the extension study after the last treatment visit (Week 12) of the core study and were treated once daily	Participants who entered the extension study after the last treatment visit (Week 12) of the core study and were treated once daily	Participants who entered the extension study after the last treatment visit (Week 12) of the core study and were treated once daily	Participants who entered the extension study after the last treatment visit (Week 12) of the core study and were treated once daily	Participants who entered the extension study after the last treatment visit (Week 12) of the core study and were treated once daily	Participants who entered the extension study after the last treatment visit (Week 12) of the core study and were treated once daily	Participants who entered the extension study after the last treatment visit (Week 12) of the core study and received Placebo inhal	Participants who entered the extension study after the last treatment visit (Week 12) of the core study and received Placebo inhal	Participants who entered the extension study after the last treatment visit (Week 12) of the core study and received Placebo inhal	Participants who entered the extension study after the last treatment visit (Week 12) of the core study and received Placebo inhal	Participants who entered the extension study after the last treatment visit (Week 12) of the core study and received Placebo inhal	Participants who entered the extension study after the last treatment visit (Week 12) of the core study and received Placebo inhal	Participants who entered the extension study after the last follow-up visit (Week 24) of the core study, therefore after a 12-week	Participants who entered the extension study after the last follow-up visit (Week 24) of the core study, therefore after a 12-week	Participants who entered the extension study after the last follow-up visit (Week 24) of the core study, therefore after a 12-week	Participants who entered the extension study after the last follow-up visit (Week 24) of the core study, therefore after a 12-week	Participants who entered the extension study after the last follow-up visit (Week 24) of the core study, therefore after a 12-week	Participants who entered the extension study after the last follow-up visit (Week 24) of the core study, therefore after a 12-week	

for 24 weeks with the same dose of CSJ117 they had received in the core study (CSJ117 8 mg)	for 24 weeks with the same dose of CSJ117 they had received in the core study (CSJ117 4 mg)	for 24 weeks with the same dose of CSJ117 they had received in the core study (CSJ117 2 mg)	for 24 weeks with the same dose of CSJ117 they had received in the core study (CSJ117 1 mg)	for 24 weeks with the same dose of CSJ117 they had received in the core study (CSJ117 0.5 mg)	for 24 weeks with Placebo	ed 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)	ed 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)	ed 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)	ed 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)	ed 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)	ed once daily for 12 weeks "washout period" and then they were treated once daily for 12 weeks with Placebo	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)	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)	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)	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)	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)	drug-free period, and were treated in the extension once daily for 12 weeks with Placebo

Started	8	5	3	3	5	6	7	3	2	3	1	4	18	24	10	7	9	18	136
FAS1	8	5	3	3	5	6	0	0	0	0	0	4	0	0	0	0	0	18	52
FAS2	0	0	0	0	0	6	7	3	2	3	1	4	18	24	10	7	9	18	112
Completed	6	5	2	1	5	2	4	2	0	1	0	3	16	22	8	7	9	15	108
Not Completed	2	0	1	2	0	4	3	1	2	2	1	1	2	2	2	0	0	3	28
Study terminated by sponsor	2	0	1	2	0	3	3	1	2	2	1	1	2	1	2	0	0	2	25
Adverse Event	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	1
Withdrawal by Subject	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	2

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Baseline Characteristics

	24 weeks CSJ 117 8mg	24 weeks CSJ 117 4mg	24 weeks CSJ 117 2mg	24 weeks CSJ 117 1mg	24-weeks CSJ 117 0.5mg	24-weeks Placebo	12 weeks was h-out + 12 weeks CSJ 117 8mg	12 weeks was h-out + 12 weeks CSJ 117 4mg	12 weeks was h-out + 12 weeks CSJ 117 2mg	12 weeks was h-out + 12 weeks CSJ 117 1mg	12 weeks was h-out + 12 weeks CSJ 117 0.5mg	12 weeks was h-out + 12 weeks Placebo	12 weeks drug-free + 12 weeks CSJ 117 8mg	12 weeks drug-free + 12 weeks CSJ 117 4mg	12 weeks drug-free + 12 weeks CSJ 117 2mg	12 weeks drug-free + 12 weeks CSJ 117 1mg	12 weeks drug-free + 12 weeks CSJ 117 0.5mg	12 weeks drug-free + 12 weeks Placebo	Total
Arm/ Group Description	Participants who entered the extension study after the last treatment visit (Week 12) of the core study and were treated	Participants who entered the extension study after the last treatment visit (Week 12) of the core study and were treated	Participants who entered the extension study after the last treatment visit (Week 12) of the core study and were treated	Participants who entered the extension study after the last treatment visit (Week 12) of the core study and were treated	Participants who entered the extension study after the last treatment visit (Week 12) of the core study and were treated	Participants who entered the extension study after the last treatment visit (Week 12) of the core study and were treated	Participants who entered the extension study after the last treatment visit (Week 12) of the core study and received Plac	Participants who entered the extension study after the last treatment visit (Week 12) of the core study and received Plac	Participants who entered the extension study after the last treatment visit (Week 12) of the core study and received Plac	Participants who entered the extension study after the last treatment visit (Week 12) of the core study and received Plac	Participants who entered the extension study after the last treatment visit (Week 12) of the core study and received Plac	Participants who entered the extension study after the last treatment visit (Week 12) of the core study and received Plac	Participants who entered the extension study after the last follow-up visit (Week 24) of the core study, therefore after	Participants who entered the extension study after the last follow-up visit (Week 24) of the core study, therefore after	Participants who entered the extension study after the last follow-up visit (Week 24) of the core study, therefore after	Participants who entered the extension study after the last follow-up visit (Week 24) of the core study, therefore after	Participants who entered the extension study after the last follow-up visit (Week 24) of the core study, therefore after	Participants who entered the extension study after the last follow-up visit (Week 24) of the core study, therefore after	

once daily for 24 weeks with the same dose of CSJ117 they had received in the core study (CSJ117 8 mg)	once daily for 24 weeks with the same dose of CSJ117 they had received in the core study (CSJ117 4 mg)	once daily for 24 weeks with the same dose of CSJ117 they had received in the core study (CSJ117 2 mg)	once daily for 24 weeks with the same dose of CSJ117 they had received in the core study (CSJ117 1 mg)	once daily for 24 weeks with the same dose of CSJ117 they had received in the core study (CSJ117 0.5 mg)	once daily for 24 weeks with Placebo	ebo 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	ebo 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	ebo 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	ebo 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	ebo 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	ebo inhaled once daily for 12 weeks "washout period" and then they were treated once daily for 12 weeks with Placebo	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)	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)	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)	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)	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)	a 12-week drug-free period, and were treated in the extension once daily for 12 weeks with Placebo

							8 mg)	4 mg)	2 mg)	1 mg)	0.5 mg)								
Number of Participants [units: participants]	8	5	3	3	5	6	7	3	2	3	1	4	18	24	10	7	9	18	136
Baseline Analysis Population Description																			
Age, Customized (units: Participants) Analysis Population Type: Participants Count of Participants (Not Applicable)																			
18 - <40 years	0	2	1	0	2	2	1	0	0	0	0	0	2	6	3	1	1	5	26
40 - <65 years	7	3	1	2	3	4	4	3	2	3	1	4	12	13	6	5	5	9	87
≥65 years	1	0	1	1	0	0	2	0	0	0	0	0	4	5	1	1	3	4	23
Sex: Female, Male (units: Participants)																			

Analysis Population Type: Participants Count of Participants (Not Applicable)																			
Female	5	3	0	2	3	3	4	0	1	2	1	3	14	15	7	4	7	11	85
Male	3	2	3	1	2	3	3	3	1	1	0	1	4	9	3	3	2	7	51
Race/Ethnicity, Customized (units: Participants) Analysis Population Type: Participants Count of Participants (Not Applicable)																			
Asian	5	4	1	2	3	3	2	2	1	1	1	3	3	8	4	2	3	5	53
Black or African American	0	0	0	0	0	0	2	0	0	0	0	0	1	1	0	0	0	0	4
White	3	1	2	1	2	3	3	1	1	2	0	1	14	15	6	5	6	13	79

Primary Outcome Result(s)

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

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

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

Analysis Population Description: Participants in the Safety Analysis Set (SAF) with available safety data at the corresponding time point. SAF includes the participants who received at least one dose of study drug in the extension study. Patients in the SAF were analyzed according to the treatment they actually received.

	24 weeks CSJ117 8mg	24 weeks CSJ117 4mg	24 weeks CSJ117 2mg	24 weeks CSJ117 1mg	24-week CSJ117 0.5mg	24-weeks Placebo	12 weeks wash-out + 12 weeks CSJ117 8mg	12 weeks wash-out + 12 weeks CSJ117 4mg	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	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	12 weeks drug-free + 12 weeks CSJ117 0.5mg	12 weeks drug-free + 12 weeks Placebo
Arm/ Group Description	Participants who entered the extension study after the last treatment visit (Week 12) of the	Participants who entered the extension study after the last treatment visit (Week 12) of the	Participants who entered the extension study after the last treatment visit (Week 12) of the	Participants who entered the extension study after the last treatment visit (Week 12) of the	Participants who entered the extension study after the last treatment visit (Week 12) of the	Participants who entered the extension study after the last treatment visit (Week 12) of the	Participants who entered the extension study after the last treatment visit (Week 12) of the	Participants who entered the extension study after the last treatment visit (Week 12) of the	Participants who entered the extension study after the last treatment visit (Week 12) of the	Participants who entered the extension study after the last treatment visit (Week 12) of the	Participants who entered the extension study after the last treatment visit (Week 12) of the	Participants who entered the extension study after the last treatment visit (Week 12) of the	Participants who entered the extension study after the last follow-up visit (Week 24) of the	Participants who entered the extension study after the last follow-up visit (Week 24) of the	Participants who entered the extension study after the last follow-up visit (Week 24) of the	Participants who entered the extension study after the last follow-up visit (Week 24) of the	Participants who entered the extension study after the last follow-up visit (Week 24) of the	Participants who entered the extension study after the last follow-up visit (Week 24) 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)	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)	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)	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)	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)	core study and were treated once daily for 24 weeks with Placebo	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	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	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	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	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	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	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)	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)	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)	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)	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)	core study, therefore after a 12-week drug-free period, and were treated in the extension once daily for 12 weeks with Placebo

							(CSJ 117 8 mg)	(CSJ 117 4 mg)	(CSJ 117 2 mg)	(CSJ 117 1 mg)	(CSJ 117 0.5 mg)							
Number of Participants Analyzed [units: participants]	8	5	3	3	5	6	7	3	2	3	1	4	18	24	10	7	9	18
Number of participants with treatment emergent adverse events (AEs) and serious adverse events (SAEs) (units: Participants)	**Count of Participants**	**Count of Participants**	**Count of Participants**	**Count of Participants**	**Count of Participants**	**Count of Participants**	**Count of Participants**	**Count of Participants**	**Count of Participants**	**Count of Participants**	**Count of Participants**	**Count of Participants**	**Count of Participants**	**Count of Participants**	**Count of Participants**	**Count of Participants**	**Count of Participants**	**Count of Participants**

Number Analyzed	8	5	3	3	5	6	7	3	2	3	1	4	18	24	10	7	9	18
At least one AE (0 to 12 weeks)	2 (25%)	1 (20%)	2 (66.67 %)	1 (33.33 %)	0 (%)	1 (16.67 %)	2 (28.57 %)	1 (33.33 %)	0 (%)	1 (33.33 %)	0 (%)	1 (25%)	6 (33.33 %)	6 (25%)	3 (30%)	2 (28.57 %)	4 (44.44 %)	9 (50%)
Number Analyzed	8	5	3	3	5	6	7	0	2	3	1	4	18	24	10	7	9	18
At least one AE (week 12 to week 24)	2 (25%)	0 (%)	2 (66.67 %)	2 (66.67 %)	1 (20%)	1 (16.67 %)	2 (28.57 %)	0 (NaN %)	1 (50%)	1 (33.33 %)	0 (%)	1 (25%)	1 (5.56 %)	1 (4.17 %)	1 (10%)	2 (28.57 %)	2 (22.22 %)	2 (11.11 %)
Number Analyzed	8	5	2	0	5	5	6	0	0	0	0	3	18	24	10	7	9	18
At least one AE (week 24 to week 36)	2 (25%)	0 (%)	1 (50%)	0 (NaN %)	1 (20%)	1 (20%)	2 (33.33 %)	0 (NaN %)	0 (NaN %)	0 (NaN %)	0 (NaN %)	2 (66.67 %)	6 (33.33 %)	10 (41.67 %)	4 (40%)	4 (57.14 %)	2 (22.22 %)	4 (22.22 %)
Number	8	5	0	0	0	0	0	0	0	0	0	0	18	24	10	0	0	18

Analyzed																		
At least one AE (week 36 to week 48)	1 (12.5 %)	1 (20%)	0 (NaN %)	0 (NaN %)	0 (NaN %)	0 (NaN %)	0 (NaN %)	0 (NaN %)	0 (NaN %)	0 (NaN %)	0 (NaN %)	0 (NaN %)	3 (16.67 %)	2 (8.33 %)	2 (20%)	0 (NaN %)	0 (NaN %)	3 (16.67 %)
Number Analyzed	8	5	3	3	5	6	7	3	2	3	1	4	18	24	10	7	9	18
At least one SAE (0 to 12 weeks)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
Number Analyzed	8	5	3	3	5	6	7	0	2	3	1	4	18	24	10	7	9	18
At least one SAE (week 12 to week 24)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (NaN %)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
Number Analyzed	8	5	2	0	5	5	6	0	0	0	0	3	18	24	10	7	9	18

At least one SAE (week 24 to week 36)	0 (%)	0 (%)	0 (%)	0 (NaN %)	0 (%)	0 (%)	0 (%)	0 (NaN %)	0 (NaN %)	0 (NaN %)	0 (NaN %)	0 (%)	0 (%)	1 (4.17 %)	0 (%)	0 (%)	0 (%)	0 (%)
Number Analyzed	8	5	0	0	0	0	0	0	0	0	0	0	18	24	10	0	0	18
At least one SAE (week 36 to week 48)	0 (%)	0 (%)	0 (NaN %)	0 (NaN %)	0 (NaN %)	0 (NaN %)	0 (NaN %)	0 (NaN %)	0 (NaN %)	0 (NaN %)	0 (NaN %)	0 (NaN %)	0 (%)	0 (%)	0 (%)	0 (NaN %)	0 (NaN %)	0 (%)
Number Analyzed	8	5	3	3	5	6	7	3	2	3	1	4	18	24	10	7	9	18
AE leading to discontinuation (week 0 to week 48)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (16.67 %)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
Number Analyzed	8	5	3	3	5	6	7	3	2	3	1	4	18	24	10	7	9	18

SAE leading to discontinuation (week 0 to week 48)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)

Number of treatment emergent participant deaths and participant hospitalizations

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.
Time Frame	From start of treatment in the core study until 30 days after end of treatment in the extension study. Up to 48 weeks.
Analysis Population Description	Safety Analysis Set (SAF), includes the participants who received at least one dose of study drug in the extension study. Patients in the SAF were analyzed according to the treatment they actually received.

	24 weeks CSJ117 8mg	**24 weeks CSJ117 4mg**	**24 weeks CSJ117 2mg**	**24 weeks CSJ117 1mg**	**24-week CSJ117 0.5mg**	**24-weeks Placebo**	**12 weeks wash-out + 12 weeks CSJ117 8mg**	**12 weeks wash-out + 12 weeks CSJ117 4mg**	**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**	**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**	**12 weeks drug-free + 12 weeks CSJ117 0.5mg**	**12 weeks drug-free + 12 weeks Placebo**

Arm/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	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	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	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	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	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	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	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	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	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	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	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	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	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	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	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	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	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

	in the core study (CSJ 117 8 mg)	in the core study (CSJ 117 4 mg)	in the core study (CSJ 117 2 mg)	in the core study (CSJ 117 1 mg)	in the core study (CSJ 117 0.5 mg)		treated once daily for 12 weeks with the same dose of CSJ117 they had received in the core study (CSJ 117 8 mg)	treated once daily for 12 weeks with the same dose of CSJ117 they had received in the core study (CSJ 117 4 mg)	treated once daily for 12 weeks with the same dose of CSJ117 they had received in the core study (CSJ 117 2 mg)	treated once daily for 12 weeks with the same dose of CSJ117 they had received in the core study (CSJ 117 1 mg)	treated once daily for 12 weeks with the same dose of CSJ117 they had received in the core study (CSJ 117 0.5 mg)	treated once daily for 12 weeks with Placebo	weeks with the same dose of CSJ117 they had received in the core study (CSJ 117 8 mg)	weeks with the same dose of CSJ117 they had received in the core study (CSJ 117 4 mg)	weeks with the same dose of CSJ117 they had received in the core study (CSJ 117 2 mg)	weeks with the same dose of CSJ117 they had received in the core study (CSJ 117 1 mg)	weeks with the same dose of CSJ117 they had received in the core study (CSJ 117 0.5 mg)	weeks with Placebo
Number of Participants Analyzed [units: participants]	8	5	3	3	5	6	7	3	2	3	1	4	18	24	10	7	9	18
Number of treatment emergent	**Count of Participants (Not**	**Count of Participants (Not**	**Count of Participants (Not**	**Count of Participants (Not**	**Count of Participants (Not**	**Count of Participants (Not**	**Count of Participants (Not**	**Count of Participants (Not**	**Count of Participants (Not**	**Count of Participants (Not**	**Count of Participants (Not**	**Count of Participants (Not**	**Count of Participants (Not**	**Count of Participants (Not**	**Count of Participants (Not**	**Count of Participants (Not**	**Count of Participants (Not**	**Count of Participants (Not**

participant deaths and participant hospitalizations (units: Participants)	**Applicable)**	**Applicable)**	**Applicable)**	**Applicable)**	**Applicable)**	**Applicable)**	**Applicable)**	**Applicable)**	**Applicable)**	**Applicable)**	**Applicable)**	**Applicable)**	**Applicable)**	**Applicable)**	**Applicable)**	**Applicable)**	**Applicable)**	**Applicable)**
Deaths	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)
Hospitalizations	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	1 (4.17 %)	0 (%)	0 (%)	0 (%)	0 (%)

Secondary Outcome Result(s)

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

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.
Time Frame	Baseline (from core study), Weeks 2, 4, 8, 12, 14, 16, 20, 24, 26, 28, 32, 36, 38, 40 and 48.
Analysis Population Description	Participants in the Full Analysis Set 1 (FAS1) with a valid measurement for the endpoint at baseline and the corresponding time point. All participants who received placebo (without interruption or with a 12-week gap period drug-free) are pooled together.

	24 weeks CSJ117 8mg	24 weeks CSJ117 4mg	24 weeks CSJ117 2mg	24 weeks CSJ117 1mg	24-week CSJ117 0.5mg	Placebo
Arm/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)	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)	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)	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)	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)	Participants who in the extension study received placebo once daily for either 12 or 24 weeks. In this group, participants either received placebo for 36 weeks without interruption or restarted placebo after a 12-week gap period drug-free.
Number of Participants Analyzed [units: participants]	7	2	2	2	1	28
Change from baseline in fractional exhaled Nitric Oxide (FeNO) levels (CSJ117 continuous treatment and placebo) (units: parts per billion (ppb))	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**
Number Analyzed	7	2	2	1	1	26
Week 2	-5.1 ± 10.76	-16.0 ± 8.49	-22.5 ± 37.48	-52.0	5.0	-2.1 ± 6.4
Number Analyzed	7	2	2	1	1	28
Week 4	-6.9 ± 12.51	-13.5 ± 17.68	-24.0 ± 32.53	-57.0	6.0	0.6 ± 8.65
Number Analyzed	7	2	2	1	1	28
Week 8	-1.6 ± 18.25	-13.0 ± 2.83	-27.0 ± 42.43	-53.0	3.0	0.3 ± 7.72
Number Analyzed	7	2	2	1	1	28
Week 12	-1.3 ± 14.58	-8.5 ± 19.09	-24.5 ± 43.13	-50.0	7.0	-1.3 ± 12.23

Number Analyzed	7	2	2	1	1	28
Week 14	-2.9 ± 14.72	-13.0 ± 7.07	-47.0 ± 60.81	-64.0	8.0	-2.7 ± 13.29
Number Analyzed	7	2	2	0	1	26
Week 16	-3.6 ± 16.25	-20.0 ± 12.73	-33.5 ± 58.69		4.0	0.6 ± 12.34
Number Analyzed	7	2	2	1	1	24
Week 20	-2.3 ± 13.60	-23.5 ± 24.75	-32.0 ± 52.33	-63.0	-1.0	-0.7 ± 9.99
Number Analyzed	6	2	1	1	1	26
Week 24	-4.0 ± 10.58	-27.5 ± 20.51	-89.0	-61.0	-5.0	0.6 ± 14.35
Number Analyzed	6	2	1	0	1	24
Week 26	-4.0 ± 7.51	-34.0 ± 15.56	-76.0		16.0	-1.9 ± 8.73
Number Analyzed	6	2	1	0	1	24
Week 28	1.2 ± 7.55	-28.5 ± 7.78	-69.0		8.0	-2.0 ± 13.05
Number Analyzed	6	2	1	0	1	22
Week 32	-1.3 ± 9.56	-13.5 ± 0.71	-80.0		-1.0	-1.2 ± 10.48
Number Analyzed	5	2	1	0	1	20
Week 36	-5.0 ± 5.96	2.5 ± 20.51	-72.0		4.0	-2.3 ± 23.85
Number Analyzed	4	2	0	0	1	17
Week 38	-1.5 ± 11.56	11.5 ± 26.16			0.0	-2.6 ± 11.41
Number Analyzed	4	1	0	0	1	16
Week 40	-4.3 ± 10.40	-16.0			1.0	-3.5 ± 20.83
Number Analyzed	1	1	0	0	1	10
Week 48	-3.0	-21.0			0.0	2.5 ± 19.59

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

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.
Time Frame	Baseline (from core study), Weeks 2, 4, 8, 12, 14, 16, 20, 24, 26, 28, 32, 36, 38, 40 and 48.
Analysis Population Description	Participants in the Full Analysis Set 2 (FAS2) with a valid measurement for the endpoint at baseline and the corresponding time point. Participants who in the extension study received 12 weeks of treatment with CSJ117 at the same dose level are pooled independently of what they received in the previous 12-week gap period (either placebo or drug-free). Patients who received Placebo are also pooled.

	12 weeks CSJ117 8mg	12 weeks CSJ117 4mg	12 weeks CSJ117 2mg	12 weeks CSJ117 1mg	12 weeks CSJ117 0.5mg	Placebo
Arm/Group Description	Participants who in the extension study were treated once daily for 12 weeks with the same dose of CSJ117 they had received in the core study (CSJ117 8 mg). In this group, participants restarted CSJ117 after a 12-week gap period with placebo or drug-free.	Participants who in the extension study were treated once daily for 12 weeks with the same dose of CSJ117 they had received in the core study (CSJ117 4 mg). In this group, participants restarted CSJ117 after a 12-week gap period with placebo or drug-free.	Participants who in the extension study were treated once daily for 12 weeks with the same dose of CSJ117 they had received in the core study (CSJ117 2 mg). In this group, participants restarted CSJ117 after a 12-week gap period with placebo or drug-free.	Participants who in the extension study were treated once daily for 12 weeks with the same dose of CSJ117 they had received in the core study (CSJ117 1 mg). In this group, participants restarted CSJ117 after a 12-week gap period with placebo or drug-free.	Participants who in the extension study were treated once daily for 12 weeks with the same dose of CSJ117 they had received in the core study (CSJ117 0.5 mg). In this group, participants restarted CSJ117 after a 12-week gap period with placebo or drug-free.	Participants who in the extension study received placebo once daily for either 12 or 24 weeks. In this group, participants either received placebo for 36 weeks without interruption or restarted placebo after a 12-week gap period drug-free.
Number of Participants Analyzed [units: participants]	26	30	13	11	14	28
Change from baseline in fractional exhaled Nitric Oxide (FeNO) levels (CSJ117 interrupted treatment and	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**

placebo)
(units: parts per billion (ppb))

Number Analyzed	23	29	12	10	14	26
Week 2	-2.7 ± 8.99	-4.9 ± 13.85	-10.4 ± 15.59	-4.5 ± 9.83	-4.3 ± 12.59	-2.1 ± 6.4
Number Analyzed	23	29	12	11	14	28
Week 4	-1.5 ± 8.36	-2.5 ± 7.59	-12.2 ± 19.69	-1.5 ± 6.92	-0.1 ± 8.45	0.6 ± 8.65
Number Analyzed	24	28	12	11	12	28
Week 8	3.3 ± 9.46	-2.5 ± 9.39	-8.5 ± 15.76	-3.4 ± 7.47	2.3 ± 9.16	0.3 ± 7.72
Number Analyzed	23	27	11	11	14	28
Week 12	0.5 ± 9.51	1.7 ± 17.12	-3.5 ± 17.25	-2.5 ± 10.02	-5.9 ± 14.86	-1.3 ± 12.23
Number Analyzed	23	28	12	11	14	28
Week 14	-0.7 ± 9.08	0.6 ± 14.80	-9.8 ± 16.43	-5.5 ± 8.58	-3.7 ± 21.54	-2.7 ± 13.29
Number Analyzed	24	27	12	11	12	26
Week 16	-0.3 ± 9.03	0.4 ± 13.49	-11.6 ± 16.48	-2.4 ± 12.30	-5.1 ± 14.17	0.6 ± 12.34
Number Analyzed	23	28	12	11	13	24
Week 20	0.5 ± 12.58	-0.2 ± 19.14	-10.7 ± 16.69	-2.1 ± 8.17	-6.1 ± 14.83	-0.7 ± 9.99
Number Analyzed	23	28	12	11	13	26
Week 24	0.5 ± 8.86	-1.4 ± 12.80	-8.9 ± 17.03	-3.5 ± 14.88	0.3 ± 26.83	0.6 ± 14.35
Number Analyzed	23	26	10	10	11	24
Week 26	3.7 ± 14.48	2.4 ± 9.81	-10.5 ± 18.28	-6.0 ± 9.53	0.8 ± 13.57	-1.9 ± 8.73
Number Analyzed	22	27	10	10	11	24
Week 28	1.1 ± 11.89	0.8 ± 17.41	-14.0 ± 21.80	-7.4 ± 10.38	-2.4 ± 5.12	-2.0 ± 13.05
Number Analyzed	19	23	10	7	8	22
Week 32	-2.2 ± 10.44	-2.6 ± 11.50	-13.3 ± 18.62	-4.0 ± 8.31	-1.8 ± 8.81	-1.2 ± 10.48
Number Analyzed	18	26	8	9	9	20
Week 36	-1.3 ± 11.25	-0.5 ± 14.89	-15.6 ± 23.62	-7.1 ± 9.52	-1.2 ± 5.33	-2.3 ± 23.85

Number Analyzed	18	20	8	7	9	17
Week 38	-0.5 ± 10.17	-3.6 ± 10.18	-10.1 ± 21.01	-7.0 ± 9.73	-4.7 ± 5.02	-2.6 ± 11.41
Number Analyzed	17	18	8	7	9	16
Week 40	1.3 ± 7.69	-1.1 ± 9.28	-9.6 ± 21.23	-8.6 ± 10.60	-3.9 ± 6.60	-3.5 ± 20.83
Number Analyzed	12	14	6	5	7	10
Week 48	5.0 ± 11.82	-4.9 ± 13.66	-17.3 ± 21.04	-6.6 ± 11.76	-4.1 ± 6.52	2.5 ± 19.59

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

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

	24 weeks CSJ117 8mg	**24 weeks CSJ117 4mg**	**24 weeks CSJ117 2mg**	**24 weeks CSJ117 1mg**	**24-week 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**	**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**	**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**
Arm/Group Description	Participants who entered the extension study after	Participants who entered the extension study after	Participants who entered the extension study after	Participants who entered the extension study after	Participants who entered the extension study after	Participants who entered the extension study after	Participants who entered the extension study after	Participants who entered the extension study after	Participants who entered the extension study after	Participants who entered the extension study after	Participants who entered the extension study after	Participants who entered the extension study after	Participants who entered the extension study after	Participants who entered the extension study after	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)	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)	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)	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)	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)	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	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	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	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	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	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)	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)	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)	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)	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)

						core study (CSJ117 8 mg)	core study (CSJ117 4 mg)	core study (CSJ117 2 mg)	core study (CSJ117 1 mg)	core study (CSJ117 0.5 mg)					
Number of Participants Analyzed [units: participants]	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Terminal Elimination half-life (T1/2) at Steady State (units:)	()	()	()	()	()	()	()	()	()	()	()	()	()	()	()

Number of participants with anti-CSJ117 antibodies

Description	Immunogenicity (antibody formation against CSJ117) was evaluated in serum by a validated bridging electrochemiluminescence immunoassay (ECLIA).
Time Frame	Day 1, Week 2, 4, 8, 12, 14, 16, 20, 24, 26, 28, 32, 36, 38, 40 and 48
Analysis Population Description	Participants in the Safety Analysis Set (SAF) with a valid measurement for the endpoint. SAF includes the participants who received at least one dose of study drug in the extension study. The number analyzed per row represents participants with data at the corresponding time point.

	24 weeks CSJ117 8mg	24 weeks CSJ117 4mg	24 weeks CSJ117 2mg	24 weeks CSJ117 1mg	24-week CSJ117 0.5mg	24-weeks Placebo	12 weeks wash-out + 12 weeks CSJ117 8mg	12 weeks wash-out + 12 weeks CSJ117 4mg	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	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	12 weeks drug-free + 12 weeks CSJ117 0.5mg	12 weeks drug-free + 12 weeks Placebo
Arm/ 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 week	Participants who entered the extension study after the last treatment visit (Week 12) of the core study and were treated once daily for 24 week	Participants who entered the extension study after the last treatment visit (Week 12) of the core study and were treated once daily for 24 week	Participants who entered the extension study after the last treatment visit (Week 12) of the core study and were treated once daily for 24 week	Participants who entered the extension study after the last treatment visit (Week 12) of the core study and were treated once daily for 24 week	Participants who entered the extension study after the last treatment visit (Week 12) of the core study and were treated once daily for 24 week	Participants who entered the extension study after the last treatment visit (Week 12) of the core study and received Placebo inhaled once	Participants who entered the extension study after the last treatment visit (Week 12) of the core study and received Placebo inhaled once	Participants who entered the extension study after the last treatment visit (Week 12) of the core study and received Placebo inhaled once	Participants who entered the extension study after the last treatment visit (Week 12) of the core study and received Placebo inhaled once	Participants who entered the extension study after the last treatment visit (Week 12) of the core study and received Placebo inhaled once	Participants who entered the extension study after the last treatment visit (Week 12) of the core study and received Placebo inhaled once	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	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	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	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	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	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

	s with the same dose of CSJ117 they had received in the core study (CSJ117 8 mg)	s with the same dose of CSJ117 they had received in the core study (CSJ117 4 mg)	s with the same dose of CSJ117 they had received in the core study (CSJ117 2 mg)	s with the same dose of CSJ117 they had received in the core study (CSJ117 1 mg)	s with the same dose of CSJ117 they had received in the core study (CSJ117 0.5 mg)	s with Placebo	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)	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)	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)	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)	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)	daily for 12 weeks "washout period" and then they were treated once daily for 12 weeks with Placebo	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)	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)	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)	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)	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)	period, and were treated in the extension once daily for 12 weeks with Placebo
Number of Participan	8	5	3	3	5	6	7	3	2	3	1	4	18	24	10	7	9	18

ts Analyzed [units: participants]																		
Number of participants with anti-CSJ117 antibodies (units: Participants)	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**
Number Analyzed	8	5	3	3	5	6	7	3	2	3	1	4	18	24	10	7	9	18
Day 1: Negative	6 (75%)	5 (100%)	2 (66.67%)	3 (100%)	4 (80%)	4 (66.67%)	7 (100%)	3 (100%)	2 (100%)	3 (100%)	1 (100%)	4 (100%)	14 (77.78%)	22 (91.67%)	8 (80%)	6 (85.71%)	7 (77.78%)	15 (83.33%)
Day 1: Positive	2 (25%)	0 (%)	1 (33.33%)	0 (%)	1 (20%)	2 (33.33%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	4 (22.22%)	2 (8.33%)	2 (20%)	1 (14.29%)	2 (22.22%)	3 (16.67%)
Number	8	5	3	3	5	6	7	3	2	3	1	4	18	24	10	7	9	17

Analyzed																		
Week 2 : Negative	7 (87.5 %)	5 (100 %)	2 (66.67 %)	2 (66.67 %)	5 (100 %)	3 (50%)	7 (100 %)	3 (100 %)	2 (100 %)	3 (100 %)	1 (100 %)	4 (100 %)	14 (77.78 %)	21 (87.5 %)	8 (80%)	5 (71.43 %)	6 (66.67 %)	13 (76.47 %)
Week 2 : Positive	1 (12.5 %)	0 (%)	1 (33.33 %)	1 (33.33 %)	0 (%)	3 (50%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	0 (%)	4 (22.22 %)	3 (12.5 %)	2 (20%)	2 (28.57 %)	3 (33.33 %)	4 (23.53 %)
Number Analyzed	8	5	3	3	5	6	7	3	2	3	1	4	18	24	10	7	9	18
Week 4 : Negative	5 (62.5 %)	5 (100 %)	2 (66.67 %)	2 (66.67 %)	5 (100 %)	3 (50%)	5 (71.43 %)	1 (33.33 %)	2 (100 %)	3 (100 %)	1 (100 %)	4 (100 %)	11 (61.11 %)	16 (66.67 %)	6 (60%)	5 (71.43 %)	6 (66.67 %)	14 (77.78 %)
Week 4 : Positive	3 (37.5 %)	0 (%)	1 (33.33 %)	1 (33.33 %)	0 (%)	3 (50%)	2 (28.57 %)	2 (66.67 %)	0 (%)	0 (%)	0 (%)	0 (%)	7 (38.89 %)	8 (33.33 %)	4 (40%)	2 (28.57 %)	3 (33.33 %)	4 (22.22 %)
Number Analyzed	8	5	3	3	5	6	7	3	2	3	1	4	18	24	10	7	9	18
Week 8 : Negative	1 (12.5 %)	2 (40%)	0 (%)	0 (%)	4 (80%)	5 (83.33 %)	3 (42.86 %)	0 (%)	1 (50%)	2 (66.67 %)	1 (100 %)	3 (75%)	6 (33.33 %)	5 (20.83 %)	3 (30%)	4 (57.14 %)	1 (11.11 %)	15 (83.33 %)
Week 8 : Positive	7 (87.5 %)	3 (60%)	3 (100 %)	3 (100 %)	1 (20%)	1 (16.67 %)	4 (57.14 %)	3 (100 %)	1 (50%)	1 (33.33 %)	0 (%)	1 (25%)	12 (66.67 %)	19 (79.17 %)	7 (70%)	3 (42.86 %)	8 (88.89 %)	3 (16.67 %)
Number	8	5	3	3	5	5	7	3	2	3	1	4	18	24	10	7	9	18

Analyzed																		
Week 12 : Negative	0 (%)	2 (40%)	0 (%)	0 (%)	3 (60%)	4 (80%)	3 (42.86 %)	0 (%)	1 (50%)	2 (66.67 %)	0 (%)	3 (75%)	4 (22.22 %)	3 (12.5 %)	2 (20%)	2 (28.57 %)	0 (%)	14 (77.78 %)
Week 12 : Positive	8 (100%)	3 (60%)	3 (100%)	3 (100%)	2 (40%)	1 (20%)	4 (57.14 %)	3 (100%)	1 (50%)	1 (33.33 %)	1 (100%)	1 (25%)	14 (77.78 %)	21 (87.5 %)	8 (80%)	5 (71.43 %)	9 (100%)	4 (22.22 %)
Number Analyzed	8	5	1	3	5	6	7	3	2	3	1	4	18	24	10	7	9	18
Week 14 : Negative	0 (%)	2 (40%)	0 (%)	0 (%)	2 (40%)	4 (66.67 %)	2 (28.57 %)	0 (%)	1 (50%)	2 (66.67 %)	0 (%)	4 (100%)	6 (33.33 %)	3 (12.5 %)	2 (20%)	2 (28.57 %)	0 (%)	15 (83.33 %)
Week 14 : Positive	8 (100%)	3 (60%)	1 (100%)	3 (100%)	3 (60%)	2 (33.33 %)	5 (71.43 %)	3 (100%)	1 (50%)	1 (33.33 %)	1 (100%)	0 (%)	12 (66.67 %)	21 (87.5 %)	8 (80%)	5 (71.43 %)	9 (100%)	3 (16.67 %)
Number Analyzed	8	5	2	3	5	5	7	3	2	3	1	3	18	24	10	7	9	18
Week 16 : Negative	0 (%)	2 (40%)	0 (%)	0 (%)	3 (60%)	4 (80%)	1 (14.29 %)	0 (%)	1 (50%)	2 (66.67 %)	0 (%)	3 (100%)	5 (27.78 %)	2 (8.33 %)	2 (20%)	3 (42.86 %)	0 (%)	15 (83.33 %)
Week 16 : Positive	8 (100%)	3 (60%)	2 (100%)	3 (100%)	2 (40%)	1 (20%)	6 (85.71 %)	3 (100%)	1 (50%)	1 (33.33 %)	1 (100%)	0 (%)	13 (72.22 %)	22 (91.67 %)	8 (80%)	4 (57.14 %)	9 (100%)	3 (16.67 %)
Number	8	5	2	3	5	5	7	3	2	3	1	3	18	24	10	7	9	17

Analyzed																		
Week 20 : Negative	1 (12.5 %)	2 (40%)	0 (%)	0 (%)	3 (60%)	4 (80%)	2 (28.57 %)	0 (%)	1 (50%)	2 (66.67 %)	0 (%)	3 (100%)	5 (27.78 %)	2 (8.33 %)	4 (40%)	2 (28.57 %)	1 (11.11 %)	14 (82.35 %)
Week 20 : Positive	7 (87.5 %)	3 (60%)	2 (100%)	3 (100%)	2 (40%)	1 (20%)	5 (71.43 %)	3 (100%)	1 (50%)	1 (33.33 %)	1 (100%)	0 (%)	13 (72.22 %)	22 (91.67 %)	6 (60%)	5 (71.43 %)	8 (88.89 %)	3 (17.65 %)
Number Analyzed	8	5	1	3	5	5	6	3	2	3	0	3	18	23	10	7	9	18
Week 24 : Negative	0 (%)	2 (40%)	0 (%)	0 (%)	3 (60%)	4 (80%)	2 (33.33 %)	0 (%)	1 (50%)	2 (66.67 %)	0 (NaN %)	3 (100%)	6 (33.33 %)	3 (13.04 %)	3 (30%)	3 (42.86 %)	3 (33.33 %)	14 (77.78 %)
Week 24 : Positive	8 (100%)	3 (60%)	1 (100%)	3 (100%)	2 (40%)	1 (20%)	4 (66.67 %)	3 (100%)	1 (50%)	1 (33.33 %)	0 (NaN %)	0 (%)	12 (66.67 %)	20 (86.96 %)	7 (70%)	4 (57.14 %)	6 (66.67 %)	4 (22.22 %)
Number Analyzed	7	5	1	1	4	3	6	2	1	2	0	3	18	23	8	7	9	18
Week 26 : Negative	1 (14.29 %)	1 (20%)	0 (%)	0 (%)	2 (50%)	3 (100%)	2 (33.33 %)	0 (%)	0 (%)	1 (50%)	0 (NaN %)	3 (100%)	6 (33.33 %)	2 (8.7%)	3 (37.5 %)	2 (28.57 %)	1 (11.11 %)	14 (77.78 %)
Week 26 : Positive	6 (85.71 %)	4 (80%)	1 (100%)	1 (100%)	2 (50%)	0 (%)	4 (66.67 %)	2 (100%)	1 (100%)	1 (50%)	0 (NaN %)	0 (%)	12 (66.67 %)	21 (91.3 %)	5 (62.5 %)	5 (71.43 %)	8 (88.89 %)	4 (22.22 %)
Number	7	5	1	1	3	3	5	2	1	2	0	3	18	23	10	7	9	18

Analyzed																		
Week 28 : Negative	1 (14.29 %)	1 (20%)	0 (%)	0 (%)	1 (33.33 %)	2 (66.67 %)	2 (40%)	0 (%)	0 (%)	1 (50%)	0 (NaN %)	3 (100%)	4 (22.22 %)	2 (8.7%)	3 (30%)	3 (42.86 %)	0 (%)	17 (94.44 %)
Week 28 : Positive	6 (85.71 %)	4 (80%)	1 (100%)	1 (100%)	2 (66.67 %)	1 (33.33 %)	3 (60%)	2 (100%)	1 (100%)	1 (50%)	0 (NaN %)	0 (%)	14 (77.78 %)	21 (91.3 %)	7 (70%)	4 (57.14 %)	9 (100%)	1 (5.56 %)
Number Analyzed	6	2	0	0	1	2	4	2	1	1	0	3	17	22	9	7	9	17
Week 32 : Negative	1 (16.67 %)	1 (50%)	0 (NaN %)	0 (NaN %)	0 (%)	2 (100%)	2 (50%)	0 (%)	0 (%)	0 (%)	0 (NaN %)	3 (100%)	6 (35.29 %)	2 (9.09 %)	3 (33.33 %)	3 (42.86 %)	0 (%)	15 (88.24 %)
Week 32 : Positive	5 (83.33 %)	1 (50%)	0 (NaN %)	0 (NaN %)	1 (100%)	0 (%)	2 (50%)	2 (100%)	1 (100%)	1 (100%)	0 (NaN %)	0 (%)	11 (64.71 %)	20 (90.91 %)	6 (66.67 %)	4 (57.14 %)	9 (100%)	2 (11.76 %)
Number Analyzed	5	5	1	1	2	3	4	2	0	1	0	3	15	22	8	7	9	15
Week 36 : Negative	1 (20%)	1 (20%)	0 (%)	0 (%)	0 (%)	3 (100%)	2 (50%)	0 (%)	0 (NaN %)	0 (%)	0 (NaN %)	3 (100%)	5 (33.33 %)	4 (18.18 %)	3 (37.5 %)	1 (14.29 %)	0 (%)	13 (86.67 %)
Week 36 : Positive	4 (80%)	4 (80%)	1 (100%)	1 (100%)	2 (100%)	0 (%)	2 (50%)	2 (100%)	0 (NaN %)	1 (100%)	0 (NaN %)	0 (%)	10 (66.67 %)	18 (81.82 %)	5 (62.5 %)	6 (85.71 %)	9 (100%)	2 (13.33 %)
Number	4	2	0	0	1	1	3	2	0	1	0	2	15	19	8	6	9	14

Analyzed																		
Week 38 : Negative	1 (25%)	1 (50%)	0 (NaN %)	0 (NaN %)	0 (%)	1 (100%)	0 (%)	0 (%)	0 (NaN %)	0 (%)	0 (NaN %)	2 (100%)	5 (33.33 %)	1 (5.26 %)	2 (25%)	1 (16.67 %)	0 (%)	12 (85.71 %)
Week 38 : Positive	3 (75%)	1 (50%)	0 (NaN %)	0 (NaN %)	1 (100%)	0 (%)	3 (100%)	2 (100%)	0 (NaN %)	1 (100%)	0 (NaN %)	0 (%)	10 (66.67 %)	18 (94.74 %)	6 (75%)	5 (83.33 %)	9 (100%)	2 (14.29 %)
Number Analyzed	4	1	0	0	1	1	3	2	0	1	0	2	14	18	8	6	9	13
Week 40 : Negative	1 (25%)	1 (100%)	0 (NaN %)	0 (NaN %)	0 (%)	1 (100%)	1 (33.33 %)	0 (%)	0 (NaN %)	0 (%)	0 (NaN %)	2 (100%)	4 (28.57 %)	2 (11.11 %)	1 (12.5 %)	1 (16.67 %)	0 (%)	11 (84.62 %)
Week 40 : Positive	3 (75%)	0 (%)	0 (NaN %)	0 (NaN %)	1 (100%)	0 (%)	2 (66.67 %)	2 (100%)	0 (NaN %)	1 (100%)	0 (NaN %)	0 (%)	10 (71.43 %)	16 (88.89 %)	7 (87.5 %)	5 (83.33 %)	9 (100%)	2 (15.38 %)
Number Analyzed	1	1	0	0	1	0	1	0	0	0	0	1	11	15	6	5	7	9
Week 48 : Negative	0 (%)	1 (100%)	0 (NaN %)	0 (NaN %)	0 (%)	0 (NaN %)	1 (100%)	0 (NaN %)	0 (NaN %)	0 (NaN %)	0 (NaN %)	0 (%)	3 (27.27 %)	1 (6.67 %)	2 (33.33 %)	2 (40%)	0 (%)	8 (88.89 %)
Week 48 : Positive	1 (100%)	0 (%)	0 (NaN %)	0 (NaN %)	1 (100%)	0 (NaN %)	0 (%)	0 (NaN %)	0 (NaN %)	0 (NaN %)	0 (NaN %)	1 (100%)	8 (72.73 %)	14 (93.33 %)	4 (66.67 %)	3 (60%)	7 (100%)	1 (11.11 %)

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CSJ117 serum concentration

Description	CSJ117 concentration was determined in serum by a validated immunoassay method. Concentrations below the lower limit of quantification (LLOQ) were treated as “zero”.
Time Frame	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
Analysis Population Description	Participants in the PK set with a valid measurement for the outcome measure. The number analyzed per row represents participants with data at the corresponding time point.

	24 weeks CSJ117 8mg	24 weeks CSJ117 4mg	24 weeks CSJ117 2mg	24 weeks CSJ117 1mg	24-week 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	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	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
Arm/Group Description	Participants who entered the extension study after the last treatment visit (Week 12) of the core study and	Participants who entered the extension study after the last treatment visit (Week 12) of the core study and	Participants who entered the extension study after the last treatment visit (Week 12) of the core study and	Participants who entered the extension study after the last treatment visit (Week 12) of the core study and	Participants who entered the extension study after the last treatment visit (Week 12) of the core study and	Participants who entered the extension study after the last treatment visit (Week 12) of the core study and	Participants who entered the extension study after the last treatment visit (Week 12) of the core study and	Participants who entered the extension study after the last treatment visit (Week 12) of the core study and	Participants who entered the extension study after the last treatment visit (Week 12) of the core study and	Participants who entered the extension study after the last treatment visit (Week 12) of the core study and	Participants who entered the extension study after the last follow-up visit (Week 24) of the core study, therefore after	Participants who entered the extension study after the last follow-up visit (Week 24) of the core study, therefore after	Participants who entered the extension study after the last follow-up visit (Week 24) of the core study, therefore after	Participants who entered the extension study after the last follow-up visit (Week 24) of the core study, therefore after	Participants who entered the extension study after the last follow-up visit (Week 24) of the core study, therefore after

	were treated once daily for 24 weeks with the same dose of CSJ117 they had received in the core study (CSJ117 8 mg)	were treated once daily for 24 weeks with the same dose of CSJ117 they had received in the core study (CSJ117 4 mg)	were treated once daily for 24 weeks with the same dose of CSJ117 they had received in the core study (CSJ117 2 mg)	were treated once daily for 24 weeks with the same dose of CSJ117 they had received in the core study (CSJ117 1 mg)	were treated once daily for 24 weeks with the same dose of CSJ117 they had received in the core study (CSJ117 0.5 mg)	received Placebo inhaled once daily for 12 weeks "wash out 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)	received Placebo inhaled once daily for 12 weeks "wash out 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)	received Placebo inhaled once daily for 12 weeks "wash out 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)	received Placebo inhaled once daily for 12 weeks "wash out 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)	received Placebo inhaled once daily for 12 weeks "wash out 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)	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)	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)	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)	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)	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)
Number of Participants	8	5	3	3	5	7	3	2	3	1	18	24	10	7	9

Analyzed [units: participants]															
CSJ117 serum concentration (units: ng/mL)	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**
	8	5	3	3	5	7	3	2	3	1	18	24	10	7	9
Day 1, pre-dose	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	4.81 ± 15.2	0.00 ± 0.00	0.00 ± 0.00
	8	5	3	3	5	7	3	2	3	1	18	23	10	7	9
Day 1, 2 hours post-dose	0.698 ± 1.97	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	5.50 ± 13.7	0.00 ± 0.00	0.00 ± 0.00
	8	4	3	3	5	7	3	2	3	1	18	24	10	7	9
Day 1, 4 hours post-dose	1.60 ± 2.98	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	1.40 ± 3.70	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	0.678 ± 2.88	0.414 ± 2.03	5.79 ± 14.7	0.00 ± 0.00	0.00 ± 0.00
	8	5	3	3	5	7	3	2	3	1	18	24	10	7	9
Week 2, pre-dose	10.1 ± 7.65	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	8.49 ± 9.99	1.93 ± 3.34	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	3.68 ± 4.54	1.60 ± 3.31	6.28 ± 15.8	0.00 ± 0.00	0.00 ± 0.00
	8	5	3	3	5	7	3	2	3	1	18	24	10	7	9
Week 2, 2 hours post-dose	10.0 ± 7.46	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	9.40 ± 6.68	1.73 ± 3.00	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	4.53 ± 4.91	1.87 ± 3.95	5.93 ± 14.9	0.00 ± 0.00	0.00 ± 0.00
	8	5	3	3	5	7	3	2	3	1	17	24	9	7	9
Week 4, pre-dose	24.0 ± 36.8	3.67 ± 3.40	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	9.15 ± 6.76	2.14 ± 3.70	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	9.30 ± 15.2	2.33 ± 3.89	6.40 ± 17.1	0.00 ± 0.00	0.00 ± 0.00

	7	5	3	3	5	7	3	2	3	1	17	24	10	7	9
Week 4, 2 hours post-dose	31.4 ± 49.8	2.43 ± 3.36	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	9.55 ± 9.53	1.86 ± 3.23	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	12.1 ± 16.7	4.56 ± 6.07	7.00 ± 16.1	0.00 ± 0.00	0.00 ± 0.00
	8	5	3	3	5	7	3	2	3	1	17	24	10	7	9
Week 8, pre-dose	67.0 ± 56.3	9.32 ± 16.4	5.77 ± 5.96	3.93 ± 6.81	1.21 ± 2.70	53.5 ± 90.8	16.9 ± 12.5	0.00 ± 0.00	8.03 ± 13.9	0.00 ± 0.00	33.6 ± 40.1	15.9 ± 16.6	13.3 ± 19.0	0.994 ± 2.63	2.23 ± 4.43
	8	5	3	3	5	7	3	2	3	1	16	23	10	7	9
Week 8, 2 hours post-dose	64.9 ± 46.5	9.31 ± 16.9	3.57 ± 6.18	4.00 ± 6.93	1.33 ± 2.98	50.9 ± 88.6	15.4 ± 9.84	0.00 ± 0.00	8.67 ± 15.0	0.00 ± 0.00	34.0 ± 44.0	15.1 ± 15.0	12.7 ± 18.8	1.30 ± 3.44	2.62 ± 5.23
	8	5	3	3	5	7	3	2	3	1	17	23	9	7	9
Week 12, pre-dose	73.7 ± 62.4	11.3 ± 19.4	8.53 ± 9.84	0.00 ± 0.00	2.22 ± 4.96	63.2 ± 104	27.8 ± 24.6	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	31.6 ± 34.8	18.8 ± 24.2	13.0 ± 18.5	3.73 ± 5.40	3.23 ± 5.25
	8	4	3	3	5	6	3	2	3	1	17	24	9	7	9
Week 12, 2 hours post-dose	79.5 ± 68.5	12.4 ± 24.7	9.74 ± 12.5	0.00 ± 0.00	1.83 ± 4.10	27.4 ± 45.8	29.7 ± 25.8	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	38.8 ± 39.7	18.9 ± 24.0	13.0 ± 18.2	3.85 ± 5.61	3.49 ± 5.54
	8	5	3	3	5	6	3	2	3	1	17	24	9	7	9
Week 12, 4 hours post-dose	79.1 ± 69.5	15.5 ± 24.8	7.70 ± 9.28	0.00 ± 0.00	2.20 ± 4.92	32.7 ± 58.8	30.2 ± 27.2	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	40.7 ± 40.9	18.8 ± 23.6	13.7 ± 18.6	3.78 ± 5.31	3.74 ± 6.07
	7	5	1	3	5	7	3	2	3	1	18	24	9	7	9
Week 14, pre-dose	50.8 ± 51.1	16.8 ± 26.1	0.00 ± 0.00	0.00 ± 0.00	2.12 ± 4.74	13.4 ± 25.8	3.07 ± 5.32	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	8.14 ± 16.6	2.07 ± 5.28	7.54 ± 17.0	0.00 ± 0.00	0.663 ± 1.99

	7	5	2	3	5	7	3	2	3	1	18	24	9	7	9
Week 16, pre-dose	49.3 ± 60.7	17.2 ± 30.2	0.00 ± 0.00	0.00 ± 0.00	2.04 ± 4.56	6.59 ± 13.5	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	2.66 ± 6.44	0.773 ± 2.72	6.47 ± 17.2	0.00 ± 0.00	0.00 ± 0.00
	7	5	1	3	5	7	3	2	3	1	18	24	9	7	9
Week 20, pre-dose	43.3 ± 61.0	16.5 ± 26.8	0.00 ± 0.00	2.40 ± 4.16	1.19 ± 2.66	1.17 ± 3.10	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	5.81 ± 15.4	0.00 ± 0.00	0.00 ± 0.00
	7	5	1	3	5	6	2	2	3	0	18	22	9	7	9
Week 24, pre-dose	35.2 ± 47.8	15.3 ± 22.4	0.00 ± 0.00	3.40 ± 5.89	1.17 ± 2.62	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00		0.00 ± 0.00	0.00 ± 0.00	4.54 ± 11.2	0.00 ± 0.00	0.00 ± 0.00
	5	2	0	0	1	5	2	1	2	0	17	21	8	7	9
Week 26, pre-dose	13.9 ± 31.0	0.00 ± 0.00			0.00 ± 0.00	62.7 ± 81.0	26.1 ± 23.9	22.1	0.00 ± 0.00		21.5 ± 31.3	12.9 ± 26.0	6.31 ± 15.6	3.38 ± 6.64	1.10 ± 3.29
	5	2	0	0	1	5	2	1	2	0	18	22	10	7	9
Week 28, pre-dose	12.3 ± 27.5	0.00 ± 0.00			0.00 ± 0.00	67.9 ± 89.0	5.15 ± 7.28	21.2	0.00 ± 0.00		23.8 ± 52.5	13.2 ± 25.0	5.38 ± 17.0	3.21 ± 8.50	5.35 ± 13.9
	5	2	0	0	1	4	2	1	1	0	15	22	8	7	9
Week 32, pre-dose	9.24 ± 20.7	0.00 ± 0.00			0.00 ± 0.00	79.0 ± 120	0.00 ± 0.00	9.18	0.00		6.32 ± 11.1	7.57 ± 14.0	0.916 ± 2.59	1.38 ± 3.65	5.40 ± 12.1
	5	2	0	0	1	4	2	0	1	0	13	21	8	6	9
Week 36, pre-dose	55.7 ± 105	4.86 ± 6.87			0.00 ± 0.00	68.6 ± 105	0.00 ± 0.00		0.00		24.2 ± 45.0	10.5 ± 18.9	1.24 ± 3.51	2.99 ± 4.70	6.18 ± 14.8
	4	2	0	0	1	3	2	0	1	0	14	19	8	6	9
Week 38, 336 hours	21.3 ± 42.6	0.00 ± 0.00			0.00 ± 0.00	20.8 ± 36.0	0.00 ± 0.00		0.00		3.46 ± 5.81	2.14 ± 5.44	0.689 ± 1.95	0.00 ± 0.00	2.89 ± 8.67

post-dose															
	4	1	0	0	1	3	2	0	1	0	14	18	8	6	9
Week 40, 672 hours post-dose	12.7 ± 25.3	0.00 ± 0.00			0.00 ± 0.00	12.2 ± 21.1	0.00 ± 0.00		0.00		1.53 ± 3.16	1.46 ± 3.66	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00
	1	1	0	0	1	1	0	0	0	0	11	14	6	5	6
Week 48, 2016 hours post-dose	0.00 ± 0.00	0.00 ± 0.00			0.00 ± 0.00	0.00					0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00

Safety Results

Time Frame	From first dose of double-blind treatment up to 12 weeks after last dose (Week 48).
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.
Source Vocabulary for Table Default	MedDRA (25.0)
Collection Approach for Table Default	Systematic Assessment

NOVARTIS

All-Cause Mortality

	CSJ117 8mg N = 33	CSJ117 4mg N = 32	CSJ117 2mg N = 15	CSJ117 1mg N = 13	CSJ117 0.5mg N = 15	Placebo N = 28
Arm/Group Description	CSJ117 8mg	CSJ117 4mg	CSJ117 2mg	CSJ117 1mg	CSJ117 0.5mg	Placebo
Total Number Affected	0	0	0	0	0	0
Total Number At Risk	33	32	15	13	15	28

Serious Adverse Events

	CSJ117 8mg N = 33	CSJ117 4mg N = 32	CSJ117 2mg N = 15	CSJ117 1mg N = 13	CSJ117 0.5mg N = 15	Placebo N = 28
Arm/Group Description	CSJ117 8mg	CSJ117 4mg	CSJ117 2mg	CSJ117 1mg	CSJ117 0.5mg	Placebo
Total # Affected by any Serious Adverse Event	0	1	0	0	0	0
Total # at Risk by any Serious Adverse Event	33	32	15	13	15	28
Infections and infestations						
Pneumonia	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Other (Not Including Serious) Adverse Events

Frequent Event Reporting Threshold 2%

	CSJ117 8mg N = 33	CSJ117 4mg N = 32	CSJ117 2mg N = 15	CSJ117 1mg N = 13	CSJ117 0.5mg N = 15	Placebo N = 28
Arm/Group Description	CSJ117 8mg	CSJ117 4mg	CSJ117 2mg	CSJ117 1mg	CSJ117 0.5mg	Placebo
Total # Affected by any Other Adverse Event	17	17	11	8	6	16
Total # at Risk by any Other Adverse Event	33	32	15	13	15	28
Blood and lymphatic system disorders						
Anaemia	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Leukocytosis	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Leukopenia	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cardiac disorders						
Palpitations	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tachycardia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.57%)
Endocrine disorders						
Hypothyroidism	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.57%)
Eye disorders						
Conjunctivitis allergic	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gastrointestinal disorders						
Abdominal pain	1 (3.03%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Abdominal pain upper	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dental caries	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Diarrhoea	0 (0.00%)	0 (0.00%)	1 (6.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Dry mouth	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Gastrointestinal disorder	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Nausea	1 (3.03%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Pancreatitis acute	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.57%)
General disorders and administration site conditions						
Chest discomfort	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Fatigue	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.57%)
Inflammation	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Non-cardiac chest pain	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.57%)
Pain	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.57%)
Pyrexia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.57%)
Vaccination site swelling	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Infections and infestations						
Acute sinusitis	0 (0.00%)	0 (0.00%)	1 (6.67%)	0 (0.00%)	1 (6.67%)	1 (3.57%)
Body tinea	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Bronchitis	0 (0.00%)	1 (3.13%)	1 (6.67%)	0 (0.00%)	1 (6.67%)	0 (0.00%)
COVID-19	2 (6.06%)	2 (6.25%)	0 (0.00%)	1 (7.69%)	2 (13.33%)	2 (7.14%)
Cystitis	0 (0.00%)	1 (3.13%)	2 (13.33%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Herpes zoster	0 (0.00%)	0 (0.00%)	1 (6.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Laryngitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.57%)
Nasopharyngitis	2 (6.06%)	0 (0.00%)	1 (6.67%)	1 (7.69%)	0 (0.00%)	3 (10.71%)
Oral candidiasis	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Oral herpes	1 (3.03%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Oropharyngeal candidiasis	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Otitis media	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Papilloma viral infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.67%)	0 (0.00%)

Pharyngitis	0 (0.00%)	2 (6.25%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	1 (3.57%)
Pyelitis	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Rhinitis	1 (3.03%)	0 (0.00%)	1 (6.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Sinusitis	2 (6.06%)	1 (3.13%)	1 (6.67%)	1 (7.69%)	1 (6.67%)	1 (3.57%)
Tonsillitis	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tooth abscess	0 (0.00%)	0 (0.00%)	1 (6.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tooth infection	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Upper respiratory tract infection	1 (3.03%)	3 (9.38%)	0 (0.00%)	0 (0.00%)	1 (6.67%)	1 (3.57%)
Urinary tract infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Vaginal infection	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Varicella zoster virus infection	0 (0.00%)	0 (0.00%)	1 (6.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Viral infection	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Viral upper respiratory tract infection	2 (6.06%)	0 (0.00%)	1 (6.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Injury, poisoning and procedural complications						
Arthropod bite	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Chest injury	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.57%)
Corneal abrasion	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.57%)
Ligament sprain	0 (0.00%)	0 (0.00%)	1 (6.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Skin abrasion	0 (0.00%)	0 (0.00%)	1 (6.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Vaccination complication	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	1 (3.57%)
Investigations						
Alanine aminotransferase increased	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Aspartate aminotransferase increased	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blood cholesterol increased	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Blood glucose increased	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	1 (6.67%)	0 (0.00%)
Blood triglycerides increased	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Lipase increased	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.57%)
Metabolism and nutrition disorders						
Dyslipidaemia	1 (3.03%)	0 (0.00%)	1 (6.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Hypercholesterolaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.57%)
Type 2 diabetes mellitus	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (7.14%)
Musculoskeletal and connective tissue disorders						
Back pain	1 (3.03%)	2 (6.25%)	1 (6.67%)	0 (0.00%)	1 (6.67%)	0 (0.00%)
Rheumatic disorder	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Spinal osteoarthritis	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Synovial cyst	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Nervous system disorders						
Dizziness	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Headache	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (3.57%)
Monoparesis	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Sciatica	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Spinal cord herniation	0 (0.00%)	0 (0.00%)	1 (6.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Psychiatric disorders						
Insomnia	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Persistent depressive disorder	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Renal and urinary disorders						
Chronic kidney disease	0 (0.00%)	0 (0.00%)	1 (6.67%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Renal cyst	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Reproductive system and breast disorders						
Erectile dysfunction	0 (0.00%)	0 (0.00%)	1 (6.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Respiratory, thoracic and mediastinal disorders						
Asthma	3 (9.09%)	4 (12.50%)	5 (33.33%)	2 (15.38%)	1 (6.67%)	5 (17.86%)
Chronic rhinosinusitis with nasal polyps	0 (0.00%)	0 (0.00%)	1 (6.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Cough	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)
Dysphonia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (7.14%)
Dyspnoea	0 (0.00%)	0 (0.00%)	2 (13.33%)	0 (0.00%)	1 (6.67%)	0 (0.00%)
Epistaxis	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Productive cough	0 (0.00%)	0 (0.00%)	1 (6.67%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Rhinorrhoea	1 (3.03%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	1 (3.57%)
Throat irritation	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Skin and subcutaneous tissue disorders						
Eczema	1 (3.03%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Ingrowing nail	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pruritus	1 (3.03%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Urticaria	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (6.67%)	0 (0.00%)
Vascular disorders						
Arteriosclerosis	0 (0.00%)	1 (3.13%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Hypertension	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (7.69%)	0 (0.00%)	0 (0.00%)

Conclusion:

CSJ117 at doses up to 8 mg was generally safe and well tolerated in uncontrolled asthma patients previously treated with a medium or high dose of an inhaled corticosteroid in combination with a long-acting beta agonist (LABA).

Date of Clinical Trial Report

20-March-2023