



Clinical trial results:

A multicenter, randomized, double-blind, parallel-group, placebo-controlled study of fevipiprant once daily plus standard-of-care (SoC) for assessment of the efficacy in reduction of nasal polyps size in patients with nasal polyposis and concomitant asthma

Summary

EudraCT number	2018-002073-22
Trial protocol	DE NL CZ BE IT
Global end of trial date	10 June 2020

Results information

Result version number	v1 (current)
This version publication date	25 December 2020
First version publication date	25 December 2020

Trial information

Trial identification

Sponsor protocol code	CQAW039A2322
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03681093
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Novartis Pharma AG
Sponsor organisation address	CH-4002, 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	10 June 2020
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	10 June 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The purpose of this study was to evaluate the efficacy and safety of fevipirant 150 mg and 450 mg compared to placebo in the reduction of nasal polyps size and the effect on symptoms, quality of life and smell via patient-reported outcomes in patients with nasal polyposis and concomitant asthma.

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.

At the start of the Run-in period, all patients were provided with a short-acting bronchodilator (SABA, such as salbutamol 100 mcg or albuterol 90 mcg) which they were instructed to use throughout the study as rescue medication on an 'as needed basis'.

Background therapy:

During the Run-in period and Treatment period patients utilized mometasone furoate spray (200 µg once daily, administered as two 50 µg actuations into each nostril).

Evidence for comparator: -

Actual start date of recruitment	26 March 2019
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Argentina: 38
Country: Number of subjects enrolled	Belgium: 6
Country: Number of subjects enrolled	Canada: 7
Country: Number of subjects enrolled	Czechia: 13
Country: Number of subjects enrolled	Germany: 13
Country: Number of subjects enrolled	Italy: 8
Country: Number of subjects enrolled	Netherlands: 8
Country: Number of subjects enrolled	Poland: 4
Country: Number of subjects enrolled	United States: 1
Worldwide total number of subjects	98
EEA total number of subjects	52

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)	82
From 65 to 84 years	16
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants took part in 25 investigative sites in 9 countries.

Pre-assignment

Screening details:

After the screening, participants went through a Run-in period of 4 weeks where they utilized mometasone furoate spray into each nostril. Afterwards, patients were randomized in 1:1:1 ratio in either of the 3 arms and continued to use the mometasone furoate spray.

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	Investigator, Monitor, Carer, Assessor, Subject

Arms

Are arms mutually exclusive?	Yes
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Arm title	Fevipirant 150 mg
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Arm description:

Fevipirant (QAW039) 150 mg once daily orally

Arm type	Experimental
Investigational medicinal product name	Fevipirant
Investigational medicinal product code	QAW039
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Fevipirant (QAW039) 150 mg once daily administered orally for 16 weeks.

Arm title	Fevipirant 450 mg
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Arm description:

Fevipirant (QAW039) 450 mg once daily orally

Arm type	Experimental
Investigational medicinal product name	Fevipirant
Investigational medicinal product code	QAW039
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Fevipirant (QAW039) 450 mg once daily administered orally for 16 weeks.

Arm title	Placebo
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Arm description:

Placebo once daily orally

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

Dosage and administration details:

Placebo once daily administered orally for 16 weeks.

Number of subjects in period 1	Fevipirant 150 mg	Fevipirant 450 mg	Placebo
Started	32	34	32
Completed	32	32	31
Not completed	0	2	1
Subject decision	-	2	1

Baseline characteristics

Reporting groups	
Reporting group title	Fevipirant 150 mg
Reporting group description: Fevipirant (QAW039) 150 mg once daily orally	
Reporting group title	Fevipirant 450 mg
Reporting group description: Fevipirant (QAW039) 450 mg once daily orally	
Reporting group title	Placebo
Reporting group description: Placebo once daily orally	

Reporting group values	Fevipirant 150 mg	Fevipirant 450 mg	Placebo
Number of subjects	32	34	32
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	27	28	27
From 65-84 years	5	6	5
85 years and over	0	0	0
Age Continuous			
Units: years			
arithmetic mean	50.8	50.9	48.5
standard deviation	± 13.36	± 13.10	± 13.43
Sex: Female, Male			
Units: participants			
Female	16	15	12
Male	16	19	20
Race/Ethnicity, Customized			
Units: Subjects			
White	32	34	31
Black	0	0	1

Reporting group values	Total		
Number of subjects	98		
Age categorical			
Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	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)	82		
From 65-84 years	16		
85 years and over	0		
Age Continuous Units: years arithmetic mean standard deviation	-		
Sex: Female, Male Units: participants			
Female	43		
Male	55		
Race/Ethnicity, Customized Units: Subjects			
White	97		
Black	1		

End points

End points reporting groups

Reporting group title	Fevipirant 150 mg
Reporting group description:	Fevipirant (QAW039) 150 mg once daily orally
Reporting group title	Fevipirant 450 mg
Reporting group description:	Fevipirant (QAW039) 450 mg once daily orally
Reporting group title	Placebo
Reporting group description:	Placebo once daily orally

Primary: Change from baseline in Nasal Polyp Score at Week 16

End point title	Change from baseline in Nasal Polyp Score at Week 16
End point description:	Nasal Polyp Score (NPS) is the sum of the right and left nostril scores, as evaluated by means of nasal endoscopy. Total score ranges from 0 to 8 (scored 0 [no polyp] to 4 [large polyps] for each nostril), with a lower score indicating smaller-sized polyps. Baseline NPS is defined as the last measurement performed on or before the date of randomization. A negative change from baseline in NPS is considered a favorable outcome.
End point type	Primary
End point timeframe:	Baseline, Week 16

End point values	Fevipirant 150 mg	Fevipirant 450 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	31	32	28	
Units: score on scale				
least squares mean (standard error)	0.20 (± 0.224)	-0.10 (± 0.216)	0.14 (± 0.233)	

Statistical analyses

Statistical analysis title	Change NPS score - fevipirant 150 mg vs placebo
Comparison groups	Fevipirant 150 mg v Placebo
Number of subjects included in analysis	59
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.979 ^[1]
Method	Mixed Model for Repeated Measures (MMRM)
Parameter estimate	Least Squares (LS) Mean
Point estimate	0.05

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.59
upper limit	0.7
Variability estimate	Standard error of the mean
Dispersion value	0.323

Notes:

[1] - Adjusted p-value is reported. The adjusted p-value was obtained from the Dunnett Multiplicity Correction applied to control the Type I error for the primary analysis.

Statistical analysis title	Change NPS score - fevipirant 450 mg vs placebo
Comparison groups	Fevipirant 450 mg v Placebo
Number of subjects included in analysis	60
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.656 [2]
Method	MMRM
Parameter estimate	LS Mean
Point estimate	-0.25
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.88
upper limit	0.39
Variability estimate	Standard error of the mean
Dispersion value	0.319

Notes:

[2] - Adjusted p-value is reported. The adjusted p-value was obtained from the Dunnett Multiplicity Correction applied to control the Type I error for the primary analysis.

Secondary: Change from baseline in Nasal Congestion Score at Week 16

End point title	Change from baseline in Nasal Congestion Score at Week 16
End point description:	
The nasal congestion score (NCS) is assessed via a questionnaire where patients are asked "Is your nose blocked?" with responses ranging from 0 = not at all, to 3=severe. Baseline NCS is defined as the last assessment performed on or before the date of randomization. A negative change from baseline in NCS is considered a favorable outcome.	
End point type	Secondary
End point timeframe:	
Baseline, Week 16	

End point values	Fevipirant 150 mg	Fevipirant 450 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	31	32	28	
Units: score on scale				
least squares mean (standard error)	-0.15 (± 0.172)	-0.35 (± 0.171)	-0.80 (± 0.181)	

Statistical analyses

Statistical analysis title	Change NCS score - fevipirant 150 mg vs placebo
Comparison groups	Fevipirant 150 mg v Placebo
Number of subjects included in analysis	59
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.012 [3]
Method	MMRM
Parameter estimate	LS Mean
Point estimate	0.64
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.15
upper limit	1.14
Variability estimate	Standard error of the mean
Dispersion value	0.249

Notes:

[3] - Unadjusted p-value

Statistical analysis title	Change NCS score - fevipirant 450 mg vs placebo
Comparison groups	Fevipirant 450 mg v Placebo
Number of subjects included in analysis	60
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.074 [4]
Method	MMRM
Parameter estimate	LS Mean
Point estimate	0.45
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.04
upper limit	0.94
Variability estimate	Standard error of the mean
Dispersion value	0.248

Notes:

[4] - Unadjusted p-value

Secondary: Change from baseline in Quality of Life as assessed by the SNOT-22 questionnaire at Week 16

End point title	Change from baseline in Quality of Life as assessed by the SNOT-22 questionnaire at Week 16
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End point description:

SNOT-22 (Sino-Nasal Outcome Test) Questionnaire is a disease specific Health-Related Quality of Life (HRQoL) measure that comprises a list of 22 symptoms and social or emotional consequences of the nasal disorder. Every participant is asked to rate how severe each problem had been for them over the past 2 weeks on a scale from 0 (no problem) to 5 (problem as bad as it can be). The total score is the sum of the scores for all 22 items, ranging from 0 to 110, with a lower score indicating better HRQoL. Baseline SNOT-22 is defined as the last assessment performed on or before the date of randomization. A negative change from baseline in SNOT-22 is considered a favorable outcome.

End point type	Secondary
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End point timeframe:

Baseline, Week 16

End point values	Fevipirant 150 mg	Fevipirant 450 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	31	32	28	
Units: score on scale				
least squares mean (standard error)	-3.23 (\pm 3.349)	-10.61 (\pm 3.358)	-8.44 (\pm 3.571)	

Statistical analyses

Statistical analysis title	Change SNOT-22 - fevipirant 150 mg vs placebo
Comparison groups	Fevipirant 150 mg v Placebo
Number of subjects included in analysis	59
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.288 ^[5]
Method	MMRM
Parameter estimate	LS Mean
Point estimate	5.22
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.49
upper limit	14.93
Variability estimate	Standard error of the mean
Dispersion value	4.881

Notes:

[5] - Unadjusted p-value

Statistical analysis title	Change SNOT-22 - fevipirant 450 mg vs placebo
Comparison groups	Fevipirant 450 mg v Placebo

Number of subjects included in analysis	60
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.661 ^[6]
Method	MMRM
Parameter estimate	LS Mean
Point estimate	-2.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.99
upper limit	7.65
Variability estimate	Standard error of the mean
Dispersion value	4.936

Notes:

[6] - Unadjusted p-value

Secondary: Change from baseline in sense of smell as assessed by the University of Pennsylvania Smell Identification Test (UPSIT) at Week 16

End point title	Change from baseline in sense of smell as assessed by the University of Pennsylvania Smell Identification Test (UPSIT) at Week 16
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End point description:

The UPSIT (University of Pennsylvania Smell Identification Test) is a test that measures an individual's ability to detect odors. It consists of 4 workbooks of 10 pages each. On each page there is a different "scratch and sniff" strip which is embedded with a microencapsulated odorant and a question regarding the smell detected with a four-choice option for the response. The total number of questions in UPSIT is 40. The number of correct responses regarding the smells being experienced is summed to provide a total score that ranges from 0 to 40, with a higher score indicating a better sense of smell.

Baseline UPSIT is defined as the last assessment performed on or before the date of randomization. A positive change from baseline in UPSIT is considered a favorable outcome.

End point type	Secondary
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End point timeframe:

Baseline, Week 16

End point values	Fevipirant 150 mg	Fevipirant 450 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	31	32	28	
Units: score on scale				
least squares mean (standard error)	1.05 (± 1.242)	4.95 (± 1.259)	0.44 (± 1.315)	

Statistical analyses

Statistical analysis title	Change UPSIT - fevipirant 150 mg vs placebo
Comparison groups	Fevipirant 150 mg v Placebo

Number of subjects included in analysis	59
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.735 ^[7]
Method	MMRM
Parameter estimate	LS Mean
Point estimate	0.61
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.98
upper limit	4.21
Variability estimate	Standard error of the mean
Dispersion value	1.809

Notes:

[7] - Unadjusted p-value

Statistical analysis title	Change UPSIT - fevipirant 450 mg vs placebo
Comparison groups	Fevipirant 450 mg v Placebo
Number of subjects included in analysis	60
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.015 ^[8]
Method	MMRM
Parameter estimate	LS Mean
Point estimate	4.51
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.89
upper limit	8.13
Variability estimate	Standard error of the mean
Dispersion value	1.821

Notes:

[8] - Unadjusted p-value

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From first dose of study treatment until end of study treatment plus 2 weeks post treatment, up to Week 18.

Adverse event reporting additional description:

Any sign or symptom that occurs during the study treatment plus 2 weeks post treatment.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	23.0
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Reporting groups

Reporting group title	Fevipirant 150 mg
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Reporting group description:

Fevipirant (QAW039) 150 mg once daily orally

Reporting group title	Fevipirant 450 mg
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Reporting group description:

Fevipirant (QAW039) 450 mg once daily orally

Reporting group title	Placebo
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Reporting group description:

Placebo once daily orally

Serious adverse events	Fevipirant 150 mg	Fevipirant 450 mg	Placebo
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 32 (0.00%)	0 / 34 (0.00%)	0 / 32 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Fevipirant 150 mg	Fevipirant 450 mg	Placebo
Total subjects affected by non-serious adverse events			
subjects affected / exposed	17 / 32 (53.13%)	13 / 34 (38.24%)	11 / 32 (34.38%)
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 32 (0.00%)	1 / 34 (2.94%)	0 / 32 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			

Peripheral swelling subjects affected / exposed occurrences (all)	1 / 32 (3.13%) 1	0 / 34 (0.00%) 0	0 / 32 (0.00%) 0
Pyrexia subjects affected / exposed occurrences (all)	2 / 32 (6.25%) 2	0 / 34 (0.00%) 0	0 / 32 (0.00%) 0
Respiratory, thoracic and mediastinal disorders			
Asthma subjects affected / exposed occurrences (all)	2 / 32 (6.25%) 2	3 / 34 (8.82%) 3	1 / 32 (3.13%) 1
Cough subjects affected / exposed occurrences (all)	1 / 32 (3.13%) 1	0 / 34 (0.00%) 0	0 / 32 (0.00%) 0
Epistaxis subjects affected / exposed occurrences (all)	0 / 32 (0.00%) 0	1 / 34 (2.94%) 1	0 / 32 (0.00%) 0
Nasal congestion subjects affected / exposed occurrences (all)	2 / 32 (6.25%) 2	0 / 34 (0.00%) 0	0 / 32 (0.00%) 0
Oropharyngeal pain subjects affected / exposed occurrences (all)	1 / 32 (3.13%) 1	0 / 34 (0.00%) 0	0 / 32 (0.00%) 0
Paranasal sinus inflammation subjects affected / exposed occurrences (all)	0 / 32 (0.00%) 0	0 / 34 (0.00%) 0	2 / 32 (6.25%) 2
Respiratory disorder subjects affected / exposed occurrences (all)	0 / 32 (0.00%) 0	0 / 34 (0.00%) 0	1 / 32 (3.13%) 1
Rhinorrhoea subjects affected / exposed occurrences (all)	0 / 32 (0.00%) 0	1 / 34 (2.94%) 1	0 / 32 (0.00%) 0
Investigations			
Amylase increased subjects affected / exposed occurrences (all)	1 / 32 (3.13%) 1	0 / 34 (0.00%) 0	0 / 32 (0.00%) 0
Blood creatine phosphokinase increased			

subjects affected / exposed occurrences (all)	0 / 32 (0.00%) 0	0 / 34 (0.00%) 0	1 / 32 (3.13%) 1
Blood creatinine increased subjects affected / exposed occurrences (all)	1 / 32 (3.13%) 1	0 / 34 (0.00%) 0	0 / 32 (0.00%) 0
Lipase increased subjects affected / exposed occurrences (all)	2 / 32 (6.25%) 2	0 / 34 (0.00%) 0	0 / 32 (0.00%) 0
Weight increased subjects affected / exposed occurrences (all)	2 / 32 (6.25%) 2	0 / 34 (0.00%) 0	0 / 32 (0.00%) 0
Injury, poisoning and procedural complications Contusion subjects affected / exposed occurrences (all)	0 / 32 (0.00%) 0	1 / 34 (2.94%) 1	0 / 32 (0.00%) 0
Nervous system disorders Dizziness subjects affected / exposed occurrences (all)	1 / 32 (3.13%) 1	0 / 34 (0.00%) 0	0 / 32 (0.00%) 0
Facial paralysis subjects affected / exposed occurrences (all)	0 / 32 (0.00%) 0	1 / 34 (2.94%) 1	0 / 32 (0.00%) 0
Headache subjects affected / exposed occurrences (all)	2 / 32 (6.25%) 4	0 / 34 (0.00%) 0	0 / 32 (0.00%) 0
Blood and lymphatic system disorders Iron deficiency anaemia subjects affected / exposed occurrences (all)	0 / 32 (0.00%) 0	1 / 34 (2.94%) 1	0 / 32 (0.00%) 0
Ear and labyrinth disorders Ear pain subjects affected / exposed occurrences (all)	1 / 32 (3.13%) 1	0 / 34 (0.00%) 0	0 / 32 (0.00%) 0
Tympanic membrane perforation subjects affected / exposed occurrences (all)	0 / 32 (0.00%) 0	1 / 34 (2.94%) 1	0 / 32 (0.00%) 0

Eye disorders			
Conjunctival haemorrhage			
subjects affected / exposed	0 / 32 (0.00%)	1 / 34 (2.94%)	0 / 32 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 32 (0.00%)	0 / 34 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Mouth ulceration			
subjects affected / exposed	1 / 32 (3.13%)	0 / 34 (0.00%)	0 / 32 (0.00%)
occurrences (all)	1	0	0
Tongue discomfort			
subjects affected / exposed	0 / 32 (0.00%)	0 / 34 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Vomiting			
subjects affected / exposed	1 / 32 (3.13%)	0 / 34 (0.00%)	0 / 32 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 32 (0.00%)	1 / 34 (2.94%)	0 / 32 (0.00%)
occurrences (all)	0	1	0
Scab			
subjects affected / exposed	0 / 32 (0.00%)	0 / 34 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Renal and urinary disorders			
Pollakiuria			
subjects affected / exposed	0 / 32 (0.00%)	1 / 34 (2.94%)	0 / 32 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
Arthritis			
subjects affected / exposed	1 / 32 (3.13%)	0 / 34 (0.00%)	0 / 32 (0.00%)
occurrences (all)	1	0	0
Bursitis			
subjects affected / exposed	0 / 32 (0.00%)	1 / 34 (2.94%)	0 / 32 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			

Acute sinusitis			
subjects affected / exposed	0 / 32 (0.00%)	0 / 34 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Bronchitis			
subjects affected / exposed	0 / 32 (0.00%)	1 / 34 (2.94%)	0 / 32 (0.00%)
occurrences (all)	0	1	0
Ear infection			
subjects affected / exposed	0 / 32 (0.00%)	0 / 34 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Gastric infection			
subjects affected / exposed	0 / 32 (0.00%)	0 / 34 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Gastroenteritis viral			
subjects affected / exposed	1 / 32 (3.13%)	0 / 34 (0.00%)	0 / 32 (0.00%)
occurrences (all)	1	0	0
Gingivitis			
subjects affected / exposed	1 / 32 (3.13%)	0 / 34 (0.00%)	0 / 32 (0.00%)
occurrences (all)	1	0	0
Influenza			
subjects affected / exposed	2 / 32 (6.25%)	1 / 34 (2.94%)	2 / 32 (6.25%)
occurrences (all)	2	1	2
Laryngitis			
subjects affected / exposed	0 / 32 (0.00%)	1 / 34 (2.94%)	0 / 32 (0.00%)
occurrences (all)	0	1	0
Nasopharyngitis			
subjects affected / exposed	1 / 32 (3.13%)	0 / 34 (0.00%)	2 / 32 (6.25%)
occurrences (all)	1	0	2
Oral herpes			
subjects affected / exposed	1 / 32 (3.13%)	2 / 34 (5.88%)	0 / 32 (0.00%)
occurrences (all)	1	2	0
Otitis media			
subjects affected / exposed	0 / 32 (0.00%)	1 / 34 (2.94%)	0 / 32 (0.00%)
occurrences (all)	0	1	0
Pharyngitis			
subjects affected / exposed	0 / 32 (0.00%)	1 / 34 (2.94%)	0 / 32 (0.00%)
occurrences (all)	0	1	0

Sinusitis			
subjects affected / exposed	3 / 32 (9.38%)	1 / 34 (2.94%)	2 / 32 (6.25%)
occurrences (all)	3	1	2
Tonsillitis			
subjects affected / exposed	0 / 32 (0.00%)	1 / 34 (2.94%)	0 / 32 (0.00%)
occurrences (all)	0	1	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 32 (3.13%)	0 / 34 (0.00%)	0 / 32 (0.00%)
occurrences (all)	1	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 32 (0.00%)	0 / 34 (0.00%)	1 / 32 (3.13%)
occurrences (all)	0	0	1
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 32 (0.00%)	1 / 34 (2.94%)	0 / 32 (0.00%)
occurrences (all)	0	1	0
Metabolic syndrome			
subjects affected / exposed	1 / 32 (3.13%)	0 / 34 (0.00%)	0 / 32 (0.00%)
occurrences (all)	1	0	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
12 December 2018	The protocol was amended based on health authority feedback. Additional exclusion criteria were added to ensure that patients taking any of the prohibited medications were appropriately excluded.
30 January 2019	To align the safety requirements with other studies in the QAW039 program including addition of exclusion criteria.
24 September 2019	To provide clarification on the process for assessment of nasal endoscopy at baseline and management of protocol deviations in relation to the statistical analysis sets.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported