Clinical trial results:
Open-Label Extension Study of Omalizumab in Patients with Chronic Rhinosinusitis with Nasal Polyps

Summary

EudraCT number	2017-003450-16
Trial protocol	GB PT FI CZ BE DE HU ES PL
Global end of trial date	16 March 2020

Results information

Result version number	v1
This version publication date	25 March 2021
First version publication date	25 March 2021

Trial information

Trial identification

Sponsor protocol code	WA40169

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03478930
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	F. Hoffmann-La Roche, Ltd.
Sponsor organisation address	Grenzacherstrasse 124., Basel, Switzerland, CH-4070
Public contact	F. Hoffmann-La Roche, Ltd., F. Hoffmann-La Roche, Ltd., 41 616878333, global.trial_information@roche.com
Scientific contact	F. Hoffmann-La Roche, Ltd., F. Hoffmann-La Roche, Ltd., 41 616878333, global.trial_information@roche.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	16 March 2020
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	16 March 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

- To evaluate adverse events associated with usage of omalizumab in subjects with CRSwNP
- To evaluate efficacy of continued treatment with omalizumab after an initial 24 week treatment period
- To evaluate the durability of response following treatment discontinuation

Protection of trial subjects:

This study was conducted in full conformance with the ICH E6 guideline for Good Clinical Practice and the principles of the Declaration of Helsinki, or the laws and regulations of the country in which the research was conducted, whichever afforded the greater protection to the individual. All study subjects were required to read and sign and informed consent form.

Background therapy:

Mometasone furoate monohydrate nasal spray was used as background therapy.

Evidence for comparator: -

Actual start date of recruitment	09 May 2018
Long term follow-up planned	Yes
Long term follow-up rationale	Safety, Efficacy
Long term follow-up duration	6 Months
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Belgium: 5
Country: Number of subjects enrolled	Canada: 6
Country: Number of subjects enrolled	Czechia: 4
Country: Number of subjects enrolled	Germany: 3
Country: Number of subjects enrolled	Spain: 23
Country: Number of subjects enrolled	France: 3
Country: Number of subjects enrolled	Hungary: 7
Country: Number of subjects enrolled	Mexico: 5
Country: Number of subjects enrolled	Poland: 54
Country: Number of subjects enrolled	Portugal: 21
Country: Number of subjects enrolled	Russian Federation: 7
Country: Number of subjects enrolled	Ukraine: 61
Country: Number of subjects enrolled	United Kingdom: 1
Country: Number of subjects enrolled	United States: 49
Worldwide total number of subjects	249
EEA total number of subjects	120

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)	211
From 65 to 84 years	38
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Subjects who completed the treatment period of Study GA39688/GA39855 and fulfilled the eligibility criteria for the open-label extension (OLE) study were enrolled.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Received placebo in GA39688 or GA39855

Arm description:

After completion of the randomized double-blind placebo controlled studies GA39688 or GA39855, eligible subjects were enrolled into WA60169. All subjects in WA60169 received 28 weeks of open-label omalizumab as a subcutaneous injection once every 2 weeks (Q2W) or once every 4 weeks (Q4W) before entering a 24-week off-treatment observation phase of the study. Omalizumab dose during the 28 weeks open-label treatment was determined based on serum total IgE levels and body weight from the screening data from the parent studies.

Arm type	Experimental
Investigational medicinal product name	omalizumab
Investigational medicinal product code	
Other name	Xolair IGE025 RO5489789
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Subjects received omalizumab as a subcutaneous injection once every 2 weeks (Q2W) or once every 4 weeks (Q4W). Omalizumab dose was determined based on serum total IgE levels and body weight from the screening data from the parent studies.

Arm title	Received omalizumab in GA39688 or GA39855

Arm description:

After completion of the randomized double-blind placebo controlled studies GA39688 or GA39855, eligible subjects were enrolled into WA60169. All subjects in WA60169 received 28 weeks of open-label omalizumab as a subcutaneous injection once every 2 weeks (Q2W) or once every 4 weeks (Q4W) before entering a 24-week off-treatment observation phase of the study. Omalizumab dose during the 28 weeks open-label treatment was determined based on serum total IgE levels and body weight from the screening data from the parent studies.

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Subjects received omalizumab as a subcutaneous injection once every 2 weeks (Q2W) or once every 4 weeks (Q4W). Omalizumab dose was determined based on serum total IgE levels and body weight from the screening data from the parent studies.

Number of subjects in period 1	Received placebo in GA39688 or GA39855	Received omalizumab in GA39688 or GA39855
Started	126	123
Completed	117	114
Not completed	9	9
Consent withdrawn by subject	6	5
Adverse event, non-fatal	-	1
Lack of efficacy	3	3

Baseline characteristics

Reporting groups	
Reporting group title	Received placebo in GA39688 or GA39855
Reporting group description:	
After completion of the randomized double-blind placebo controlled studies GA39688 or GA39855, eligible subjects were enrolled into WA60169. All subjects in WA60169 received 28 weeks of open-label omalizumab as a subcutaneous injection once every 2 weeks (Q2W) or once every 4 weeks (Q4W) before entering a 24-week off-treatment observation phase of the study. Omalizumab dose during the 28 weeks open-label treatment was determined based on serum total IgE levels and body weight from the screening data from the parent studies.	
Reporting group title	Received omalizumab in GA39688 or GA39855
Reporting group description:	
After completion of the randomized double-blind placebo controlled studies GA39688 or GA39855, eligible subjects were enrolled into WA60169. All subjects in WA60169 received 28 weeks of open-label omalizumab as a subcutaneous injection once every 2 weeks (Q2W) or once every 4 weeks (Q4W) before entering a 24-week off-treatment observation phase of the study. Omalizumab dose during the 28 weeks open-label treatment was determined based on serum total IgE levels and body weight from the screening data from the parent studies.	

Reporting group values	Received placebo in GA39688 or GA39855	Received omalizumab in GA39688 or GA39855	Total
Number of subjects	126	123	249
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)	105	106	211
From 65-84 years	21	17	38
85 years and over	0	0	0
Age Continuous Units: years			
arithmetic mean	51.6	49.9	
standard deviation	± 11.9	± 13.1	-
Sex: Female, Male Units: participants			
Female	44	45	89
Male	82	78	160
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	2	2
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	2	2
White	126	117	243

More than one race	0	0	0
Unknown or Not Reported	0	2	2
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	8	11	19
Not Hispanic or Latino	117	110	227
Unknown or Not Reported	1	2	3

End points

End points reporting groups

Reporting group title	Received placebo in GA39688 or GA39855

Reporting group description:

After completion of the randomized double-blind placebo controlled studies GA39688 or GA39855, eligible subjects were enrolled into WA60169. All subjects in WA60169 received 28 weeks of open-label omalizumab as a subcutaneous injection once every 2 weeks (Q2W) or once every 4 weeks (Q4W) before entering a 24-week off-treatment observation phase of the study. Omalizumab dose during the 28 weeks open-label treatment was determined based on serum total IgE levels and body weight from the screening data from the parent studies.

Reporting group title	Received omalizumab in GA39688 or GA39855

Reporting group description:

After completion of the randomized double-blind placebo controlled studies GA39688 or GA39855, eligible subjects were enrolled into WA60169. All subjects in WA60169 received 28 weeks of open-label omalizumab as a subcutaneous injection once every 2 weeks (Q2W) or once every 4 weeks (Q4W) before entering a 24-week off-treatment observation phase of the study. Omalizumab dose during the 28 weeks open-label treatment was determined based on serum total IgE levels and body weight from the screening data from the parent studies.

Subject analysis set title	Full Analysis Set of the open label extension (FAS-OLE)
Subject analysis set type	Full analysis

Subject analysis set description:

All subjects enrolled into the OLE, grouped according to the treatment assigned (omalizumab or placebo) at randomization of the previous studies. Subjects who were not enrolled in the OLE study, their parent study data were not included in the analyses. All subjects in the FAS received at least one dose of study drug.

Subject analysis set title	Safety Analysis Population
Subject analysis set type	Safety analysis

Subject analysis set description:

All safety analyses were based on the subset of the FAS-OLE, who received at least one dose of omalizumab in the OLE study (Safety-OLE), grouped according to the treatment received (omalizumab or placebo) in the parent studies. One subject randomized to the placebo arm in a parent study accidently received omalizumab.

Subject analysis set title	Pharmacokinetic Evaluable Analysis Set (PKAS)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

The PKAS consisted of subjects who received study drug in the form of their per-protocol dose according to baseline total IgE and body weight in the dosing table. Subjects receiving the wrong dose or frequency of the treatment assigned (placebo or omalizumab) or the wrong treatment assigned were excluded from this population.

Primary: Change From Baseline in Nasal Polyp Score (NPS)

End point title	Change From Baseline in Nasal Polyp Score (NPS)[1]

End point description:

Total NPS ranges from 0 to 8 (sum of 0-4 for left and right nasal passage scores per the following criteria), with a lower score indicating smaller-sized nasal polyps: 0 = No polyps; 1 = Small polyps in the middle meatus not reaching below the inferior border of the middle turbinate; 2 = Polyps reaching below the lower border of the middle turbinate (modified to accommodate those with a middle turbinectomy, such that polyp must have reached the top of the inferior turbinate.); 3 = Large polyps reaching the lower border of the inferior turbinate or polyps medial to the middle turbinate; and 4 = Large polyps causing complete obstruction of the inferior nasal cavity. Two blinded primary independent expert readers reviewed every post-screening recorded video endoscopy for a given subject to determine total NPS. A third reader chose one of the two scores to be used for analysis in cases where there was any discrepancy in total NPS assigned between the two primary readers.

End point type	Primary

End point timeframe:

Baseline, Weeks 4, 8, 16, 24, 36, 52, 64, and 76

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive statistics was planned to be reported in the endpoint.

End point values	Received placebo in GA39688 or GA39855	Received omalizumab in GA39688 or GA39855		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	126	123		
Units: Sore on a scale				
arithmetic mean (confidence interval 95%)				
Week 4	-0.17 (-0.38 to 0.05)	-0.85 (-1.07 to -0.63)		
Week 8	-0.26 (-0.49 to -0.02)	-1.06 (-1.30 to -0.82)		
Week 16	-0.17 (-0.38 to 0.05)	-1.09 (-1.31 to -0.87)		
Week 24	-0.19 (-0.42 to 0.03)	-1.01 (-1.24 to -0.78)		
Week 36	-0.83 (-1.07 to -0.59)	-1.09 (-1.32 to -0.85)		
Week 52	-0.97 (-1.25 to -0.69)	-1.31 (-1.60 to -1.03)		
Week 64	-0.40 (-0.66 to -0.13)	-0.85 (-1.12 to -0.58)		
Week 76	-0.48 (-0.76 to -0.20)	-0.54 (-0.83 to -0.25)		

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in Average Daily Nasal Congestion Score (NCS)

End point title	Change From Baseline in Average Daily Nasal Congestion Score (NCS)[2]

End point description:

The Nasal Congestion Score (NCS) was assessed daily by the participant via an electronic diary as the response to the following question: Is your nose blocked? The four available response options were scored from 0 (no symptoms) to 3 (severe symptoms): 0 = Not at all; 1 = Mild; 2 = Moderate; and 3 = Severe. For each study day, a score was calculated using an average of the prior 7 days among the available days within the pre-specified window (For Week 24: Study Days 155 to 186), excluding the study day itself, if a value had been recorded by the subject on at least 4 of the prior 7 days; otherwise, the 7-day prior average for that study day was to be considered missing. One calculated (non-missing) 7-day prior average was selected for analysis according to the study day with nearest proximity to Week 24 (Study Day 168), with the earlier selected in the case of a tie. Baseline was defined as the (non-missing) 7-day interval ending on the latest day prior to randomization.

End point type	Primary

End point timeframe:

Baseline, Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48, 52, 56, 60, 64, 68, 72, and 76

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive statistics was planned to be reported in the endpoint.

End point values	Received placebo in GA39688 or GA39855	Received omalizumab in GA39688 or GA39855		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	126	123		
Units: Score on a scale				
arithmetic mean (confidence interval 95%)				
Week 4	-0.17 (-0.27 to -0.07)	-0.39 (-0.50 to -0.29)		
Week 8	-0.25 (-0.38 to -0.13)	-0.73 (-0.85 to -0.60)		
Week 12	-0.31 (-0.44 to -0.18)	-0.81 (-0.94 to -0.68)		
Week 16	-0.32 (-0.46 to -0.19)	-0.88 (-1.02 to -0.74)		
Week 20	-0.34 (-0.48 to -0.20)	-0.85 (-1.00 to -0.71)		
Week 24	-0.31 (-0.46 to -0.16)	-0.85 (-1.00 to -0.70)		
Week 28	-0.61 (-0.76 to -0.47)	-0.88 (-1.03 to -0.73)		
Week 32	-0.72 (-0.87 to -0.57)	-0.90 (-1.05 to -0.75)		
Week 36	-0.74 (-0.89 to -0.59)	-0.98 (-1.13 to -0.82)		
Week 40	-0.73 (-0.88 to -0.59)	-1.02 (-1.17 to -0.87)		
Week 44	-0.89 (-1.05 to -0.73)	-1.04 (-1.20 to -0.88)		
Week 48	-0.94 (-1.10 to -0.79)	-1.04 (-1.20 to -0.88)		
Week 52	-0.99 (-1.14 to -0.83)	-1.12 (-1.28 to -0.96)		
Week 56	-0.80 (-0.97 to -0.64)	-0.98 (-1.14 to -0.81)		
Week 60	-0.71 (-0.87 to -0.54)	-0.88 (-1.05 to -0.71)		
Week 64	-0.63 (-0.80 to -0.46)	-0.88 (-1.05 to -0.71)		
Week 68	-0.64 (-0.80 to -0.47)	-0.78 (-0.95 to -0.62)		
Week 72	-0.56 (-0.73 to -0.40)	-0.71 (-0.87 to -0.54)		
Week 76	-0.58 (-0.76 to -0.41)	-0.65 (-0.83 to -0.48)		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects with Adverse Events (AE) and Serious Adverse Events (SAE)

End point title	Percentage of Subjects with Adverse Events (AE) and Serious Adverse Events (SAE)[3]

End point description:

A serious adverse event was defined as any adverse event that met any of the following criteria: was fatal; was life-threatening; required or prolonged inpatient hospitalization; resulted in persistent or significant disability/incapacity; was a congenital anomaly/birth defect in a neonate/infant born to a mother exposed to the study drug; or, was a significant medical event in the investigator's judgment. Multiple occurrences of the same serious adverse event in one individual were counted once.

End point type	Primary

End point timeframe:

From Start to End (Weeks 24 to 52) of OLE Study

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive statistics was planned to be reported in the endpoint.

End point values	Received placebo in GA39688 or GA39855	Received omalizumab in GA39688 or GA39855		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	126[4]	123[5]		
Units: Percentage of Subjects				
number (not applicable)				
With at least one AE	49.6	43.5		
With at least one SAE	4.8	2.4		

Notes:

[4] - n=125; One subject randomized to the placebo arm in a parent study accidently received omalizumab.
[5] - n=124; One subject randomized to the placebo arm in a parent study accidently received omalizumab.

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects with Adverse Events Leading to Discontinuation of Omalizumab

End point title	Percentage of Subjects with Adverse Events Leading to Discontinuation of Omalizumab[6]

End point description:

A serious adverse event was defined as any adverse event that met any of the following criteria: was fatal; was life-threatening; required or prolonged inpatient hospitalization; resulted in persistent or significant disability/incapacity; was a congenital anomaly/birth defect in a neonate/infant born to a mother exposed to the study drug; or, was a significant medical event in the investigator's judgment. Multiple occurrences of the same serious adverse event in one individual were counted once.

End point type	Primary

End point timeframe:

From Start to End (Weeks 24 to 76) of OLE Study

Notes:

[6] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive statistics was planned to be reported in the endpoint.

End point values	Received placebo in GA39688 or GA39855	Received omalizumab in GA39688 or GA39855		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	126[7]	123[8]		
Units: Percentage of Subjects				
number (not applicable)	0.8	0.0		

Notes:

[7] - n=125; One subject randomized to the placebo arm in a parent study accidently received omalizumab.

[8] - n=124; One subject randomized to the placebo arm in a parent study accidently received omalizumab.

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Average Daily Total Nasal Symptom Score (TNSS)

End point title	Change From Baseline in Average Daily Total Nasal Symptom Score (TNSS)

End point description:

The Total Nasal Symptom Score (TNSS) was defined as the sum of the four individual scores for Nasal Congestion Score, Anterior Rhinorrhea Score, Posterior Rhinorrhea Score, and Sense of Smell Score, ranging from 0 (no symptoms) to 12 (most severe symptoms), assessed daily by the subject via an electronic diary. For each study day, a score was calculated using an average of the prior 7 days among the available days within the pre-specified window (For Week 24: Study Days 155 to 186), excluding the study day itself, if a value had been recorded by the subject on at least 4 of the prior 7 days; otherwise, the 7-day prior average for that study day was to be considered missing. One calculated (non-missing) 7-day prior average was selected for analysis according to the study day with nearest proximity to Week 24 (Study Day 168), with the earlier selected in the case of a tie. Baseline was defined as the (non-missing) 7-day interval ending on the latest day prior to randomization.

End point type	Secondary

End point timeframe:

Baseline, Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48, 52, 56, 60, 64, 68, 72, and 76

End point values	Received placebo in GA39688 or GA39855	Received omalizumab in GA39688 or GA39855		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	126	123		
Units: Score on a Scale				
arithmetic mean (confidence interval 95%)				
Week 4	-0.50 (-0.80 to -0.19)	-1.44 (-1.75 to -1.13)		
Week 8	-0.72 (-1.09 to -0.34)	-2.44 (-2.82 to -2.06)		
Week 12	-0.82 (-1.22 to -0.41)	-2.73 (-3.14 to -2.32)		
Week 16	-0.87 (-1.30 to -0.43)	-2.84 (-3.29 to -2.40)		
Week 20	-0.93 (-1.36 to -0.49)	-2.84 (-3.27 to -2.40)		

Week 24	-0.92 (-1.37 to -0.47)	-2.82 (-3.27 to -2.36)		
Week 28	-1.80 (-2.25 to -1.34)	-2.94 (-3.40 to -2.48)		
Week 32	-2.19 (-2.64 to -1.74)	-3.14 (-3.60 to -2.68)		
Week 36	-2.22 (-2.69 to -1.76)	-3.24 (-3.71 to -2.77)		
Week 40	-2.32 (-2.77 to -1.86)	-3.40 (-3.87 to -2.94)		
Week 44	-2.72 (-3.21 to -2.24)	-3.52 (-4.02 to -3.03)		
Week 48	-2.84 (-3.32 to -2.36)	-3.49 (-3.98 to -3.00)		
Week 52	-3.01 (-3.49 to -2.53)	-3.83 (-4.31 to -3.34)		
Week 56	-2.54 (-3.04 to -2.04)	-3.23 (-3.74 to -2.72)		
Week 60	-2.27 (-2.78 to -1.76)	-2.90 (-3.42 to -2.38)		
Week 64	-1.94 (-2.44 to -1.43)	-2.97 (-3.49 to -2.46)		
Week 68	-1.83 (-2.33 to -1.33)	-2.59 (-3.09 to -2.08)		
Week 72	-1.59 (-2.10 to -1.08)	-2.37 (-2.88 to -1.85)		
Week 76	-1.63 (-2.19 to -1.08)	-2.18 (-2.74 to -1.62)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Loss of Sense of Smell Score

End point title	Change From Baseline in Loss of Sense of Smell Score

End point description:

The Sense of Smell Score was assessed daily by the subject via an electronic diary as the response to the following question: Is your sense of smell reduced? The four available response options were scored from 0 (no symptoms) to 3 (severe symptoms): 0 = Not at all; 1 = Mild; 2 = Moderate; and 3 = Severe. For each study day, a score was calculated using an average of the prior 7 days among the available days within the pre-specified window (For Week 24: Study Days 155 to 186), excluding the study day itself, if a value had been recorded by the subject on at least 4 of the prior 7 days; otherwise, the 7-day prior average for that study day was to be considered missing. One calculated (non-missing) 7-day prior average was selected for analysis according to the study day with nearest proximity to Week 24 (Study Day 168), with the earlier selected in the case of a tie. Baseline was defined as the (non-missing) 7-day interval ending on the latest day prior to randomization.

End point type	Secondary

End point timeframe:

Baseline, Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48, 52, 56, 60, 64, 68, 72, and 76

End point values	Received placebo in GA39688 or GA39855	Received omalizumab in GA39688 or GA39855		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	126	123		
Units: Score on a Scale				
arithmetic mean (confidence interval 95%)				
Week 4	-0.07 (-0.16 to 0.02)	-0.22 (-0.31 to -0.13)		
Week 8	-0.14 (-0.25 to -0.03)	-0.43 (-0.55 to -0.32)		
Week 12	-0.14 (-0.27 to -0.02)	-0.57 (-0.70 to -0.45)		
Week 16	-0.19 (-0.33 to -0.06)	-0.58 (-0.72 to -0.44)		
Week 20	-0.21 (-0.35 to -0.08)	-0.58 (-0.72 to -0.45)		
Week 24	-0.23 (-0.36 to -0.09)	-0.56 (-0.70 to -0.43)		
Week 28	-0.26 (-0.40 to -0.12)	-0.58 (-0.72 to -0.44)		
Week 32	-0.39 (-0.54 to -0.24)	-0.65 (-0.80 to -0.50)		
Week 36	-0.39 (-0.54 to -0.25)	-0.63 (-0.77 to -0.48)		
Week 40	-0.42 (-0.57 to -0.27)	-0.66 (-0.81 to -0.51)		
Week 44	-0.51 (-0.67 to -0.36)	-0.70 (-0.85 to -0.54)		
Week 48	-0.54 (-0.70 to -0.38)	-0.70 (-0.86 to -0.54)		
Week 52	-0.60 (-0.76 to -0.43)	-0.76 (-0.92 to -0.59)		
Week 56	-0.54 (-0.69 to -0.38)	-0.62 (-0.78 to -0.46)		
Week 60	-0.50 (-0.65 to -0.34)	-0.56 (-0.71 to -0.40)		
Week 64	-0.41 (-0.57 to -0.26)	-0.53 (-0.68 to -0.37)		
Week 68	-0.39 (-0.53 to -0.24)	-0.44 (-0.59 to -0.30)		
Week 72	-0.35 (-0.49 to -0.21)	-0.42 (-0.56 to -0.28)		
Week 76	-0.35 (-0.50 to -0.20)	-0.39 (-0.54 to -0.24)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Average Daily Posterior Rhinorrhea Score

End point title	Change From Baseline in Average Daily Posterior Rhinorrhea Score

End point description:

The Posterior Rhinorrhea Score was assessed daily by the subject via an electronic diary as the response

to the following question: Do you feel dripping at the back of the nose? The four available response options were scored from 0 (no symptoms) to 3 (severe symptoms): 0=Not at all; 1=Mild; 2=Moderate; and 3=Severe. For each study day, a score was calculated using an average of the prior 7 days among available days within a pre-specified window (For Week 24: Study Days 155 to 186), excluding the study day itself, if a value had been recorded by the subject on at least 4 of the prior 7 days, otherwise the 7-day prior average for that study day was to be considered missing. One calculated (non-missing) 7-day prior average was selected for analysis according to the study day with nearest proximity to Week 24 (Study Day 168), with the earlier selected in the case of a tie. Baseline was defined as the (non-missing) 7-day interval ending on the latest day prior to randomization.

End point type	Secondary

End point timeframe:

Baseline, Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48, 52, 56, 60, 64, 68, 72, and 76

End point values	Received placebo in GA39688 or GA39855	Received omalizumab in GA39688 or GA39855		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	126	123		
Units: Score on a Scale				
arithmetic mean (confidence interval 95%)				
Week 4	-0.13 (-0.23 to -0.03)	-0.35 (-0.44 to -0.25)		
Week 8	-0.13 (-0.24 to -0.02)	-0.58 (-0.70 to -0.47)		
Week 12	-0.14 (-0.25 to -0.02)	-0.60 (-0.72 to -0.48)		
Week 16	-0.11 (-0.24 to 0.02)	-0.63 (-0.76 to -0.50)		
Week 20	-0.14 (-0.27 to -0.02)	-0.64 (-0.77 to -0.51)		
Week 24	-0.15 (-0.29 to -0.02)	-0.66 (-0.79 to -0.52)		
Week 28	-0.36 (-0.49 to -0.22)	-0.67 (-0.81 to -0.53)		
Week 32	-0.46 (-0.60 to -0.32)	-0.72 (-0.86 to -0.58)		
Week 36	-0.46 (-0.60 to -0.32)	-0.76 (-0.90 to -0.62)		
Week 40	-0.49 (-0.62 to -0.36)	-0.77 (-0.91 to -0.64)		
Week 44	-0.58 (-0.72 to -0.44)	-0.80 (-0.94 to -0.65)		
Week 48	-0.60 (-0.74 to -0.46)	-0.77 (-0.91 to -0.62)		
Week 52	-0.62 (-0.75 to -0.48)	-0.87 (-1.00 to -0.73)		
Week 56	-0.52 (-0.66 to -0.38)	-0.74 (-0.88 to -0.59)		
Week 60	-0.47 (-0.62 to -0.33)	-0.70 (-0.85 to -0.55)		
Week 64	-0.38 (-0.52 to -0.23)	-0.78 (-0.93 to -0.63)		
Week 68	-0.37 (-0.52 to -0.21)	-0.66 (-0.81 to -0.50)		
Week 72	-0.27 (-0.42 to -0.11)	-0.61 (-0.76 to -0.45)		

Week 76	-0.28 (-0.44 to -0.12)	-0.53 (-0.70 to -0.37)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Average Daily Anterior Rhinorrhea Score

End point title	Change From Baseline in Average Daily Anterior Rhinorrhea Score

End point description:

The Anterior Rhinorrhea Score was assessed daily by the subject via an electronic diary as the response to the following question: Do you have a runny nose? The four available response options were scored from 0 (no symptoms) to 3 (severe symptoms): 0=Not at all; 1=Mild; 2=Moderate; and 3=Severe. For each study day, a score was calculated using an average of the prior 7 days among available days within a pre-specified window (For Week 24: Study Days 155 to 186), excluding the study day itself, if a value had been recorded by the subject on at least 4 of the prior 7 days, otherwise the 7-day prior average for that study day was to be considered missing. One calculated (non-missing) 7-day prior average was selected for analysis according to the study day with nearest proximity to Week 24 (Study Day 168), with the earlier selected in the case of a tie. Baseline was defined as the (non-missing) 7-day interval ending on the latest day prior to randomization.

End point type	Secondary

End point timeframe:

Baseline, Weeks 4, 8, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48, 52, 56, 60, 64, 68, 72, and 76

End point values	Received placebo in GA39688 or GA39855	Received omalizumab in GA39688 or GA39855		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	126	123		
Units: Score on a Scale				
arithmetic mean (confidence interval 95%)				
Week 4	-0.13 (-0.23 to -0.03)	-0.47 (-0.57 to -0.37)		
Week 8	-0.21 (-0.32 to -0.09)	-0.68 (-0.80 to -0.57)		
Week 12	-0.24 (-0.36 to -0.13)	-0.73 (-0.85 to -0.61)		
Week 16	-0.26 (-0.38 to -0.13)	-0.74 (-0.87 to -0.61)		
Week 20	-0.24 (-0.37 to -0.11)	-0.74 (-0.87 to -0.61)		
Week 24	-0.24 (-0.38 to -0.11)	-0.73 (-0.87 to -0.59)		
Week 28	-0.58 (-0.71 to -0.45)	-0.80 (-0.93 to -0.66)		
Week 32	-0.65 (-0.77 to -0.52)	-0.84 (-0.97 to -0.71)		
Week 36	-0.66 (-0.79 to -0.52)	-0.85 (-0.99 to -0.71)		

Week 40	-0.71 (-0.85 to -0.57)	-0.93 (-1.07 to -0.79)		
Week 44	-0.77 (-0.91 to -0.63)	-0.96 (-1.10 to -0.82)		
Week 48	-0.80 (-0.95 to -0.66)	-0.94 (-1.09 to -0.80)		
Week 52	-0.85 (-0.98 to -0.71)	-1.06 (-1.19 to -0.92)		
Week 56	-0.71 (-0.85 to -0.56)	-0.89 (-1.03 to -0.74)		
Week 60	-0.61 (-0.76 to -0.46)	-0.75 (-0.90 to -0.60)		
Week 64	-0.54 (-0.69 to -0.39)	-0.77 (-0.92 to -0.61)		
Week 68	-0.47 (-0.62 to -0.32)	-0.69 (-0.84 to -0.54)		
Week 72	-0.43 (-0.59 to -0.28)	-0.62 (-0.77 to -0.46)		
Week 76	-0.45 (-0.62 to -0.29)	-0.57 (-0.74 to -0.40)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Health-Related Quality of Life (HRQoL) as Assessed by the Total Sino-Nasal Outcome Test (SNOT)-22 Score

End point title	Change From Baseline in Health-Related Quality of Life (HRQoL) as Assessed by the Total Sino-Nasal Outcome Test (SNOT)-22 Score

End point description:

The SNOT-22 Questionnaire, a disease specific HRQoL measure, comprises a list of 22 symptoms and social or emotional consequences of the nasal disorder. Every subject was asked to rate how severe each problem had been for them over the past 2 weeks on a scale from 0 (no problem at all) 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 less disease and better HRQoL. A negative score indicates a decrease (or improvement) from the baseline score.

End point type	Secondary

End point timeframe:

Baseline, Weeks 4, 8, 16, 24, 36, 52, 64, and 76

End point values	Received placebo in GA39688 or GA39855	Received omalizumab in GA39688 or GA39855		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	126	123		
Units: Score on a Scale				
arithmetic mean (confidence interval 95%)				
Week 4	-8.43 (-10.82 to -6.04)	-17.86 (-20.28 to -15.44)		
Week 8	-8.85 (-11.56 to -6.15)	-21.74 (-24.47 to -19.01)		

Week 16	-8.52 (-11.32 to -5.72)	-24.56 (-27.40 to -21.73)		
Week 24	-7.76 (-10.73 to -4.80)	-23.56 (-26.55 to -20.57)		
Week 36	-17.87 (-20.91 to -14.83)	-25.42 (-28.51 to -22.34)		
Week 52	-22.39 (-25.39 to -19.40)	-28.47 (-31.52 to -25.42)		
Week 64	-17.02 (-20.31 to -13.72)	-22.66 (-26.01 to -19.31)		
Week 76	-15.37 (-18.79 to -11.95)	-19.44 (-22.89 to -15.99)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in European Quality of Life 5-Dimension 5-Level Questionnaire (EQ-5D-5L) Visual Analogue Scale (VAS) Score

End point title	Change From Baseline in European Quality of Life 5-Dimension 5-Level Questionnaire (EQ-5D-5L) Visual Analogue Scale (VAS) Score

End point description:

The EQ-5D-5L contains a visual analog score (VAS), providing a global assessment of health. The EQ-VAS questionnaire is a self-reported questionnaire that measures health state. The VAS is a 100 mm scale from worst (0 mm) to best (100 mm) health the subject can imagine.

End point type	Secondary

End point timeframe:

Baseline, Weeks 16, 24, 36, 52, 64, and 76

End point values	Received placebo in GA39688 or GA39855	Received omalizumab in GA39688 or GA39855		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	126	123		
Units: Score on a Scale				
arithmetic mean (standard deviation)				
Week 16	-0.6 (± 20.8)	6.4 (± 16.7)		
Week 24	2.3 (± 19.6)	7.9 (± 16.9)		
Week 36	7.4 (± 20.0)	9.3 (± 16.1)		
Week 52	8.5 (± 22.2)	10.8 (± 17.9)		
Week 64	5.3 (± 21.4)	5.3 (± 18.4)		
Week 76	2.8 (± 20.4)	4.4 (± 20.8)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Reporting "No Problem" in the European Quality of Life 5-Dimension 5-Level Questionnaire (EQ-5D-5L) Subdomains

End point title	Percentage of Subjects Reporting "No Problem" in the European Quality of Life 5-Dimension 5-Level Questionnaire (EQ-5D-5L) Subdomains

End point description:

The EQ-5D-5L contains five domains: Mobility, Self-Care, Usual activity, Pain/Discomfort, and Anxiety/Depression, providing a global assessment of health. Each item is rated by the subject on a five-point scale indicating the followings: Level 1 - no problem; Level 2 - slight problems; Level 3 - moderate problems; Level 4 - severe problems; Level 5 - extreme problems.

End point type	Secondary

End point timeframe:

Baseline, Weeks 16, 24, 36, 52, 64 and 76

End point values	Received placebo in GA39688 or GA39855	Received omalizumab in GA39688 or GA39855		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	126	123		
Units: Percentage of Subjects				
number (not applicable)				
Baseline Usual activities	57.9	59.5		
Baseline Mobility	67.5	68.6		
Baseline Self-care	83.3	90.9		
Baseline Pain/Discomfort	27.0	27.3		
Baseline Anxiety/Depression	49.2	47.9		
Week 16 Usual activities	54.0	75.6		
Week 16 Mobility	60.5	79.7		
Week 16 Self-care	84.7	91.1		
Week 16 Pain/Discomfort	32.2	48.0		
Week 16 Anxiety/Depression	48.4	57.7		
Week 24 Usual activities	60.8	69.9		
Week 24 Mobility	66.4	74.0		
Week 24 Self-care	87.2	89.4		
Week 24 Pain/Discomfort	29.6	51.2		
Week 24 Anxiety/Depression	47.2	60.2		
Week 36 Usual activities	60.3	74.8		
Week 36 Mobility	69.4	75.6		
Week 36 Self-care	83.5	90.8		
Week 36 Pain/Discomfort	40.5	48.7		
Week 36 Anxiety/Depression	55.4	68.9		
Week 52 Usual activities	65.5	74.6		
Week 52 Mobility	72.3	71.9		
Week 52 Self-care	87.4	91.2		
Week 52 Pain/Discomfort	40.3	56.1		
Week 52 Anxiety/Depression	62.2	70.2		
Week 64 Usual activities	62.9	72.1		
Week 64 Mobility	62.1	70.3		

Week 64 Self-care	84.5	90.1		
Week 64 Pain/Discomfort	32.8	47.7		
Week 64 Anxiety/Depression	50.9	61.3		
Week 76 Usual activities	64.6	71.4		
Week 76 Mobility	66.4	76.8		
Week 76 Self-care	85.0	89.3		
Week 76 Pain/Discomfort	34.5	48.2		
Week 76 Anxiety/Depression	51.3	58.0		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Asthma Quality of Life Questionnaire (AQLQ) Score (in subjects with comorbid asthma only)

End point title	Change From Baseline in Asthma Quality of Life Questionnaire (AQLQ) Score (in subjects with comorbid asthma only)

End point description:

The AQLQ is a 32-item participant-reported measure of asthma-related quality of life (QoL) with a total score (the mean of all 32 responses) ranging from 1 (severely impaired) to 7 (not impaired at all); a higher score indicates a better QoL. An increase of at least 0.5 points in the AQLQ score was considered the minimal important difference for improvement in QoL.

End point type	Secondary

End point timeframe:

Baseline, Weeks 16, 24, 36, 52, 64, and 76

End point values	Received placebo in GA39688 or GA39855	Received omalizumab in GA39688 or GA39855		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	69	73		
Units: Score on a Scale				
arithmetic mean (standard deviation)				
Week 16	0.05 (± 1.14)	0.77 (± 1.15)		
Week 24	-0.01 (± 0.94)	0.84 (± 1.25)		
Week 36	0.50 (± 1.05)	0.84 (± 1.27)		
Week 52	0.52 (± 1.10)	0.95 (± 1.23)		
Week 64	0.34 (± 1.12)	0.66 (± 1.35)		
Week 76	0.27 (± 1.15)	0.42 (± 1.57)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Sense of Smell, as Assessed by The University

of Pennsylvania Smell Identification Test (UPSIT) Score

End point title	Change From Baseline in Sense of Smell, as Assessed by The University of Pennsylvania Smell Identification Test (UPSIT) Score

End point description:

The UPSIT is a 40-question instrument that measures an individual's ability to detect odors and ranges from 0 to 40, with a higher score indicating a better sense of smell. It is a self-administered "scratch-and-sniff" test provided in booklets that have 40 microencapsulated odorants, each with a multiple-choice option for the response. The number of correct responses is summed to provide a total score.

End point type	Secondary

End point timeframe:

Baseline, Weeks 8, 16, 24, 36, 52, 64, and 76

End point values	Received placebo in GA39688 or GA39855	Received omalizumab in GA39688 or GA39855		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	126	123		
Units: Score on a Scale				
arithmetic mean (confidence interval 95%)				
Week 8	0.49 (-0.69 to 1.67)	5.04 (3.85 to 6.23)		
Week 16	0.83 (-0.33 to 1.99)	4.31 (3.14 to 5.48)		
Week 24	0.46 (-0.71 to 1.64)	4.24 (3.04 to 5.43)		
Week 36	3.47 (2.10 to 4.84)	4.27 (2.90 to 5.65)		
Week 52	3.88 (2.57 to 5.20)	4.13 (2.78 to 5.47)		
Week 64	1.81 (0.56 to 3.06)	2.77 (1.49 to 4.05)		
Week 76	0.62 (-0.47 to 1.71)	1.42 (0.32 to 2.52)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With a Clinically Significant Change From Baseline in Laboratory Values

End point title	Percentage of Subjects With a Clinically Significant Change From Baseline in Laboratory Values

End point description:

Investigators will assess the subjects' clinical laboratory values (e.g., serum chemistry, hematology evaluations including complete blood count [CBC] with differential and platelet counts, and urinalysis values) at timepoints throughout this OLE study relative to the subjects' values at baseline from studies GA39688/GA39855 and parameters with clinically significant changes from baseline will be reported.

End point type	Secondary

End point timeframe:

Baseline, Weeks 36, 52, 64, and 76

End point values	Received placebo in GA39688 or GA39855	Received omalizumab in GA39688 or GA39855		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	126	123		
Units: Percentage of Subjects				
number (not applicable)				
Baseline OLE (Week 24)	0.0	0.0		
Week 36	0.0	0.0		
Week 52	0.0	0.0		
Week 64	0.0	0.0		
Week 76	0.0	0.0		

Statistical analyses

No statistical analyses for this end point

Secondary: Minimum Serum Concentrations (Ctrough) of Omalizumab at Specified Timepoints

End point title	Minimum Serum Concentrations (Ctrough) of Omalizumab at Specified Timepoints

End point description:

Serum concentrations of omalizumab were quantified using an enzyme-linked immunoabsorbent assay (ELISA) with a lower limit of quantification (LLOQ) of 28.0 nanograms per millilitre (ng/mL). According to the analysis plan, values below the lower limit of quantification (BLQ) were set to 14 ng/mL (i.e. half of LLOQ value).

End point type	Secondary

End point timeframe:

Predose at Weeks 36, 52, 64, and 76

End point values	Received placebo in GA39688 or GA39855	Received omalizumab in GA39688 or GA39855		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	121	123		
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
Week 36	33100 (± 83.8)	34500 (± 95.7)		
Week 52	29700 (± 133.4)	27700 (± 158.5)		
Week 64	1650 (± 199.8)	1780 (± 214.2)		

Week 76	93.3 (± 352.7)	109 (± 246.4)		

Statistical analyses

No statistical analyses for this end point

Secondary: Serum Concentration of Total Immunoglobulin E (IgE)

End point title	Serum Concentration of Total Immunoglobulin E (IgE)

End point description:

Serum concentrations of total immunoglobulin E (IgE) were measured throughout the study, as target engagement biomarkers of omalizumab, using validated quantitative immunoassays with lower limits of quantification of 2 International Units per millilitre (IU/mL), and upper limits of quantification (ULQ) of 5000 IU/mL.

End point type	Secondary

End point timeframe:

Predose at Weeks 36, 52, 64, and 76

End point values	Received placebo in GA39688 or GA39855	Received omalizumab in GA39688 or GA39855		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	126	123		
Units: IU/mL				
arithmetic mean (standard deviation)				
Week 36	665 (± 530)	522 (± 367)		
Week 52	635 (± 463)	532 (± 424)		
Week 64	390 (± 366)	335 (± 342)		
Week 76	231 (± 226)	196 (± 191)		

Statistical analyses

No statistical analyses for this end point

Secondary: Serum Concentration of Free IgE

End point title	Serum Concentration of Free IgE

End point description:

Serum concentrations of free immunoglobulin E (IgE) were measured throughout the study, as target engagement biomarkers of omalizumab, using validated quantitative immunoassays with lower limits of quantification of 0.83 International Units per millilitre (IU/mL), and upper limits of quantification (ULQ) of 62.5 IU/mL. The free IgE assay had limited range to measure circulating levels of free IgE in the presence of complexes of omalizumab-IgE. According to the analysis plan for the free IgE assay, results above ULQ were set to 62.5 IU/mL. If results for one-third or fewer of the subjects were greater than the ULQ, then all summary statistics were to be reported. However, if the results for more than one-third of subjects were greater than the ULQ, then only the median, interquartile range and minimum were calculated, and the mean, standard deviation, and maximum were non-reportable. 9999=non-

reportable

End point type	Secondary

End point timeframe:

Predose at Weeks 36, 52, 64, and 76

End point values	Received placebo in GA39688 or GA39855	Received omalizumab in GA39688 or GA39855		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	126	123		
Units: IU/mL				
arithmetic mean (standard deviation)				
Week 36	8.08 (± 4.73)	7.73 (± 6.37)		
Week 52	9.09 (± 8.81)	9.52 (± 10.8)		
Week 64	9999 (± 9999)	9999 (± 9999)		
Week 76	9999 (± 9999)	9999 (± 9999)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From Start to End (Weeks 24 to 76) of OLE Study

Adverse event reporting additional description:

One subject randomized to the placebo arm in a parent study accidently received omalizumab.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	.22.1

Reporting groups

Reporting group title	Received placebo in GA39688 or GA39855

Reporting group description:

After completion of the randomized double-blind placebo controlled studies GA39688 or GA39855, eligible subjects were enrolled into WA60169. All subjects in WA60169 received 28 weeks of open-label omalizumab as a subcutaneous injection once every 2 weeks (Q2W) or once every 4 weeks (Q4W) before entering a 24-week off-treatment observation phase of the study. Omalizumab dose during the 28 weeks open-label treatment was determined based on serum total IgE levels and body weight from the screening data from the parent studies.

Reporting group title	Received omalizumab in GA39688 or GA39855

Reporting group description:

After completion of the randomized double-blind placebo controlled studies GA39688 or GA39855, eligible subjects were enrolled into WA60169. All subjects in WA60169 received 28 weeks of open-label omalizumab as a subcutaneous injection once every 2 weeks (Q2W) or once every 4 weeks (Q4W) before entering a 24-week off-treatment observation phase of the study. Omalizumab dose during the 28 weeks open-label treatment was determined based on serum total IgE levels and body weight from the screening data from the parent studies.

Serious adverse events	Received placebo in GA39688 or GA39855	Received omalizumab in GA39688 or GA39855	
Total subjects affected by serious adverse events			
subjects affected / exposed	12 / 125 (9.60%)	8 / 124 (6.45%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Prostate cancer			
subjects affected / exposed	0 / 125 (0.00%)	1 / 124 (0.81%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Femur fracture			

subjects affected / exposed	1 / 125 (0.80%)	0 / 124 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hip fracture			
subjects affected / exposed	1 / 125 (0.80%)	0 / 124 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal compression fracture			
subjects affected / exposed	1 / 125 (0.80%)	0 / 124 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Aortic aneurysm			
subjects affected / exposed	1 / 125 (0.80%)	0 / 124 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Gastrointestinal inflammation			
subjects affected / exposed	0 / 125 (0.00%)	1 / 124 (0.81%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 125 (0.80%)	0 / 124 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileus paralytic			
subjects affected / exposed	0 / 125 (0.00%)	1 / 124 (0.81%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis acute			
subjects affected / exposed	1 / 125 (0.80%)	0 / 124 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal			

disorders			
Asthma			
subjects affected / exposed	2 / 125 (1.60%)	1 / 124 (0.81%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasal polyps			
subjects affected / exposed	0 / 125 (0.00%)	1 / 124 (0.81%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 125 (0.80%)	0 / 124 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bipolar disorder			
subjects affected / exposed	0 / 125 (0.00%)	1 / 124 (0.81%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Musculoskeletal pain			
subjects affected / exposed	0 / 125 (0.00%)	1 / 124 (0.81%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Pneumonia			
subjects affected / exposed	2 / 125 (1.60%)	0 / 124 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural infection			
subjects affected / exposed	1 / 125 (0.80%)	0 / 124 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal abscess			
alternative assessment type: Non-systematic			

subjects affected / exposed	0 / 125 (0.00%)	1 / 124 (0.81%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Testicular abscess			
subjects affected / exposed	0 / 125 (0.00%)	1 / 124 (0.81%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Received placebo in GA39688 or GA39855	Received omalizumab in GA39688 or GA39855	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	28 / 125 (22.40%)	19 / 124 (15.32%)	
Respiratory, thoracic and mediastinal disorders			
Nasal polyps			
subjects affected / exposed	13 / 125 (10.40%)	4 / 124 (3.23%)	
occurrences (all)	16	4	
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	13 / 125 (10.40%)	19 / 124 (15.32%)	
occurrences (all)	34	33	
Sinusitis			
subjects affected / exposed	13 / 125 (10.40%)	9 / 124 (7.26%)	
occurrences (all)	16	16	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported