ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
Release Date: 12/02/2015

ClinicalTrials.gov ID: NCT01185080

Study Identification

Unique Protocol ID:	D0540C00014
Brief Title:	Efficacy Study in Allergic Rhinitis Patients After Intranasal Administration of AZD8848
Official Title:	A Double-blind, Placebo Controlled, Randomised, Parallel Group Phase IIa Study to Investigate the Efficacy, Tolerability, and Safety of Different Dosing Regimens of AZD8848 Administered Intranasally to Seasonal Allergic Rhinitis Patients Out of Pollen Season in a Nasal Allergen Challenge Model
Secondary IDs:	2010-020747-13 [EudraCT Number]

Study Status

Record Verification:	December 2015
Overall Status:	Completed
Study Start:	September 2010
Primary Completion:	December 2010 [Actual]
Study Completion:	January 2012 [Actual]

Sponsor/Collaborators

Sponsor:	AstraZeneca
Responsible Party:	Sponsor
Collaborators:	

Oversight

FDA Regulated?:	No

IND/IDE Protocol?:	No
Review Board:	Approval Status: Approved Approval Number: 2010/319 Board Name: Regionala etikprövningsnämnden in Lund, Sweden Board Affiliation: Regionala etikprövningsnämnden in Lund, Sweden Phone: +46 46 222 41 80 Email:
Data Monitoring?:	No
Plan to Share Data?:	
Oversight Authorities:	Sweden: Medical Products Agency

Study Description

Brief Summary:	The primary purpose of this study is to investigate effect, tolerability and safety of different dosing regimens of AZD8848 administered intranasally to seasonal allergic rhinitis patients out of season in an allergen challenge model.
Detailed Description:	A double-blind, placebo controlled, randomised, parallel group phase IIa study to investigate the efficacy, tolerability, and safety of different dosing regimens of AZD8848 administered intranasally to seasonal allergic rhinitis patients out of pollen season in a nasal allergen challenge model

Conditions

Conditions:	Allergic Rhinitis
Keywords:	AZD8848 allergic rhinitis efficacy tolerability safety nasal symptoms

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 2
Intervention Model:	Parallel Assignment
Number of Arms:	3

Masking:	Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor)
Allocation:	Randomized
Endpoint Classification:	Efficacy Study
Enrollment:	93 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: 1. AZD8848 20 µg AZD8848 three times weekly	Drug: AZD8848 Nasal spray solution, intranasal, three times weekly for one month
Placebo Comparator: 2. Placebo Placebo three times weekly	Drug: Placebo Nasal spray solution, intranasal, three times weekly for one month
Experimental: 3. AZD8848 and placebo 60 µg AZD8848 once weekly and placebo twice weekly	Drug: AZD8848 and placebo Nasal spray solution, intranasal, three times weekly for one month

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age:	18 Years
Maximum Age:	55 Years
Gender:	Both
Accepts Healthy Volunteers?:	No
Criteria:	Inclusion Criteria:

- Seasonal allergic rhinitis patients out of pollen season
- Have a history and presence of birch and/or timothy grass pollen induced seasonal allergic rhinitis for at least the previous 2 years (verified by a positive skin prick test)
- Patients with need of treatment for their nasal symptoms during the pollen season

Exclusion Criteria:

- Symptomatic perennial allergic or non-allergic rhinitis
- Family history of autoimmune disease A history of asthma

Contacts/Locations

Study Officials: Lennart Greiff, MD, PhD
Study Principal Investigator
Lund University Hospital, Sweden

Sam Lindgren, MD, PhD
Study Director
AstraZeneca R&D Lund, Sweden

Locations: Sweden
Research Site
Lund, Malmohus Lan, Sweden

Research Site
Helsingborg, Sweden

References

Citations:

Links: URL: http://filehosting.pharmacm.com/DownloadService.ashx?client=CTR_MED_7111&studyid=192&fil...
Description CSR Synopsis

URL: http://filehosting.pharmacm.com/DownloadService.ashx?client=CTR_MED_7111&studyid=192&fil...
Description Protocol

Study Data/Documents:

Study Results

Participant Flow

Recruitment Details	There were 93 patients enrolled in the study, who 83 of them were randomized. Of the 10 patients who were not randomized, 3 patients due to "patient decision" and 7 patients due to "Eligibility criteria not fulfilled" were not randomized.

Reporting Groups

	Description
AZD8848 20 µg x3	20 µg AZD8848 three times weekly
Placebo	Placebo three times weekly
AZD8848 60 µg	60 µg AZD8848 once weekly and placebo twice weekly

Overall Study

	AZD8848 20 µg x3	Placebo	AZD8848 60 µg
Started	50	16	17
Completed	49	15	16
Not Completed	1	1	1
Adverse Event	1	1	0
Personal reasons	0	0	1

Baseline Characteristics

Reporting Groups

	Description
AZD8848 20 µg x3	20 µg AZD8848 three times weekly
Placebo	Placebo three times weekly
AZD8848 60 µg	60 µg AZD8848 once weekly and placebo twice weekly

Baseline Measures

	AZD8848 20 µg x3	Placebo	AZD8848 60 µg	Total
Number of Participants	50	16	17	83
Age, Continuous [units: years] Mean (Full Range)	29.7 (18 to 53)	28.8 (20 to 46)	31.0 (19 to 47)	29.8 (18 to 53)
Gender, Male/Female [units: Participants]				
Female	6	2	2	10
Male	44	14	15	73

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Mean of Reflective (10 Min) Total Nasal Symptom Score (TNSS)
Measure Description	Mean of Reflective Total Nasal Symptom Score (absolute values) for symptoms over the last 10 minutes after allergen challenge, collected during clinic visits. The Mean is calculated over the Allergen challenge period, which is a seven day period. Each individual symptom is scored 0 to 3, which 0 = Absence of symptoms, 1 = Mild symptoms, 2 = Moderate symptoms and 3 = Severe symptoms. The scores of each individual symptom (runny nose, blocked nose and the maximum score of nasal itching or sneezing) will be added together to give a TNSS of 0 to 9. TNSS Score 0 indicates better outcome and TNSS score 9 indicates worse outcome. Allergen challenge period starts 24 hrs post last dose (visit 15). Number of Participants Analyzed is based on all patients with evaluable efficacy and/or biomarker data from the challenge period (Visit 15).
Time Frame	During 1st day to 7th day of Allergen challenge period.
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
AZD8848 20 µg x3	20 µg AZD8848 three times weekly
Placebo	Placebo three times weekly
AZD8848 60 µg	60 µg AZD8848 once weekly and placebo twice weekly

Measured Values

	AZD8848 20 µg x3	Placebo	AZD8848 60 µg
Number of Participants Analyzed	50	15	16
Mean of Reflective (10 Min) Total Nasal Symptom Score (TNSS) [units: Scores on a scale] Least Squares Mean (Full Range)	4.52 (1.43 to 7.71)	4.97 (2.86 to 6.43)	4.69 (3.14 to 7.00)

2. Primary Outcome Measure:

Measure Title	Mean of Reflective (10 Min) Total Nasal Symptom Score (TNSS)

Measure Description	Mean of Reflective Total Nasal Symptom Score (absolute values) for symptoms over the last 10 minutes after allergen challenge, collected during clinic visits. The Mean is calculated over 4th day to 7th day of the Allergen challenge period. Each individual symptom is scored 0 to 3, which 0 = Absence of symptoms, 1 = Mild symptoms, 2 = Moderate symptoms and 3 = Severe symptoms. The scores of each individual symptom (runny nose, blocked nose and the maximum score of nasal itching or sneezing) will be added together to give a TNSS of 0 to 9. TNSS Score 0 indicates better outcome and TNSS score 9 indicates worse outcome. Allergen challenge period starts 24 hrs post last dose. Number of Participants Analyzed is based on all patients with evaluable efficacy and/or biomarker data from the challenge period (Visit 15).
Time Frame	During 4th day to 7th day of Allergen challenge period.
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
AZD8848 20 µg x3	20 µg AZD8848 three times weekly
Placebo	Placebo three times weekly
AZD8848 60 µg	60 µg AZD8848 once weekly and placebo twice weekly

Measured Values

	AZD8848 20 µg x3	Placebo	AZD8848 60 µg
Number of Participants Analyzed	49	15	16
Mean of Reflective (10 Min) Total Nasal Symptom Score (TNSS) [units: Scores on a scale] Least Squares Mean (Full Range)	4.45 (1.25 to 8.25)	5.36 (3.25 to 8.00)	4.42 (2.75 to 7.50)

3. Primary Outcome Measure:

Measure Title	Mean of Morning Measurements of Reflective (12 Hrs) Total Nasal Symptom Score (TNSS)

Measure Description	Mean of morning measurements of Reflective Total Nasal Symptom Score (absolute values) of symptoms over the last 12 hours during allergen challenge, collected in patient diary. The Mean is calculated over the evening of the 1st day to the morning of 8th day of the Allergen challenge period. Each individual symptom is scored 0 to 3, which 0 = Absence of symptoms, 1 = Mild symptoms, 2 = Moderate symptoms and 3 = Severe symptoms. The scores of each individual symptom (runny nose, blocked nose and the maximum score of nasal itching or sneezing) will be added together to give a TNSS of 0 to 9. TNSS Score 0 indicates better outcome and TNSS score 9 indicates worse outcome. Allergen challenge period starts 24 hrs post last dose. Number of Participants Analyzed is based on all patients with evaluable efficacy and/or biomarker data from the challenge period (Visit 15).
Time Frame	During evening of the 1st day to the morning of the 8th day of Allergen challenge period.
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
AZD8848 20 µg x3	20 µg AZD8848 three times weekly
Placebo	Placebo three times weekly
AZD8848 60 µg	60 µg AZD8848 once weekly and placebo twice weekly

Measured Values

	AZD8848 20 µg x3	Placebo	AZD8848 60 µg
Number of Participants Analyzed	50	14	16
Mean of Morning Measurements of Reflective (12 Hrs) Total Nasal Symptom Score (TNSS) [units: Scores on a scale] Least Squares Mean (Full Range)	1.81 (0.286 to 4.14)	2.14 (0.286 to 3.57)	1.48 (0.143 to 3.29)

4. Primary Outcome Measure:

Measure Title	Mean of Evening Measurements of Reflective (12 Hrs) Total Nasal Symptom Score (TNSS)

Measure Description	Mean of evening measurements of Reflective Total Nasal Symptom Score (absolute values) of symptoms over the last 12 hours during allergen challenge, collected in patient diary. The Mean is calculated over the evening of the 1st day to the morning of 8th day of the Allergen challenge period. Each individual symptom is scored 0 to 3, which 0 = Absence of symptoms, 1 = Mild symptoms, 2 = Moderate symptoms and 3 = Severe symptoms. The scores of each individual symptom (runny nose, blocked nose and the maximum score of nasal itching or sneezing) will be added together to give a TNSS of 0 to 9. TNSS Score 0 indicates better outcome and TNSS score 9 indicates worse outcome. Allergen challenge period starts 24 hrs post last dose. Number of Participants Analyzed is based on all patients with evaluable efficacy and/or biomarker data from the challenge period (Visit 15).
Time Frame	During the evening of the 1st day to the morning of the 8th day of Allergen challenge period.
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
AZD8848 20 µg x3	20 µg AZD8848 three times weekly
Placebo	Placebo three times weekly
AZD8848 60 µg	60 µg AZD8848 once weekly and placebo twice weekly

Measured Values

	AZD8848 20 µg x3	Placebo	AZD8848 60 µg
Number of Participants Analyzed	50	14	16
Mean of Evening Measurements of Reflective (12 Hrs) Total Nasal Symptom Score (TNSS) [units: Scores on a scale] Least Squares Mean (Full Range)	2.06 (0.143 to 4.71)	2.32 (0 to 4.57)	1.96 (0.143 to 4.43)

5. Primary Outcome Measure:

Measure Title	Mean of Peak Nasal Inspiratory Flow (PNIF) (10 Min)

Measure Description	Mean of Peak Nasal Inspiratory Flow (absolute values) recorded immediately after TNSS scoring (recall period 10 min), during Allergen challenge period. The Mean is calculated over the Allergen challenge period, which is a seven day period. The patient will breathe out as much as he can. Then a mask (Portable Inspiratory Flow Meter) will be placed over the nose and mouth and the patient will inspire forcefully through the nose while the lips remain tightly closed. The highest PNIF (L/minute) out of 3 measurements will be recorded. Allergen challenge period starts 24 hrs post last dose. Number of Participants Analyzed is based on all patients with evaluable efficacy and/or biomarker data from the challenge period (Visit 15).
Time Frame	During 1st day to 7th day of Allergen challenge period.
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
AZD8848 20 µg x3	20 µg AZD8848 three times weekly
Placebo	Placebo three times weekly
AZD8848 60 µg	60 µg AZD8848 once weekly and placebo twice weekly

Measured Values

	AZD8848 20 µg x3	Placebo	AZD8848 60 µg
Number of Participants Analyzed	50	15	16
Mean of Peak Nasal Inspiratory Flow (PNIF) (10 Min) [units: L/min] Least Squares Mean (Full Range)	117 (37.9 to 197)	127 (67.0 to 214)	129 (50.0 to 243)

6. Primary Outcome Measure:

Measure Title	Mean of Peak Nasal Inspiratory Flow (PNIF) (10 Min)
Measure Description	Mean of Peak Nasal Inspiratory Flow (absolute values) recorded immediately after TNSS scoring (recall period 10 min), during Allergen challenge period. The Mean is calculated over 4th day to 7th day of the Allergen challenge period. The patient will breathe out as much as he can. Then a mask (Portable Inspiratory Flow Meter) will be placed over the nose and mouth and the patient will inspire forcefully through the nose while the lips remain tightly closed. The highest PNIF (L/minute) out of 3 measurements will be recorded. Allergen challenge period starts 24 hrs post last dose. Number of Participants Analyzed is based on all patients with evaluable efficacy and/or biomarker data from the challenge period (Visit 15).

Time Frame	During 4th day to 7th day of Allergen challenge period.
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
AZD8848 20 µg x3	20 µg AZD8848 three times weekly
Placebo	Placebo three times weekly
AZD8848 60 µg	60 µg AZD8848 once weekly and placebo twice weekly

Measured Values

	AZD8848 20 µg x3	Placebo	AZD8848 60 µg
Number of Participants Analyzed	49	15	16
Mean of Peak Nasal Inspiratory Flow (PNIF) (10 Min) [units: L/min] Least Squares Mean (Full Range)	121 (37.5 to 200)	128 (77.5 to 220)	135 (52.5 to 245)

7. Primary Outcome Measure:

Measure Title	Mean of Morning Measurements of Peak Nasal Inspiratory Flow (PNIF) (12 Hrs)
Measure Description	Mean of morning measurements of Peak Nasal Inspiratory Flow (absolute values) of symptoms over the last 12 hours during allergen challenge, collected in patient diary. The Mean is calculated over the evening of the 1st day to the morning of 8th day of the Allergen challenge period. The patient will breathe out as much as he can. Then a mask (Portable Inspiratory Flow Meter) will be placed over the nose and mouth and the patient will inspire forcefully through the nose while the lips remain tightly closed. The highest PNIF (L/minute) out of 3 measurements will be recorded. Allergen challenge period starts 24 hrs post last dose. Number of Participants Analyzed is based on all patients with evaluable efficacy and/or biomarker data from the challenge period (Visit 15).
Time Frame	During evening of the 1st day to the morning of the 8th day of Allergen challenge period.
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
AZD8848 20 µg x3	20 µg AZD8848 three times weekly
Placebo	Placebo three times weekly
AZD8848 60 µg	60 µg AZD8848 once weekly and placebo twice weekly

Measured Values

	AZD8848 20 µg x3	Placebo	AZD8848 60 µg
Number of Participants Analyzed	50	14	16
Mean of Morning Measurements of Peak Nasal Inspiratory Flow (PNIF) (12 Hrs) [units: L/min] Least Squares Mean (Full Range)	136 (51.4 to 237)	148 (84.3 to 237)	148 (71.4 to 234)

8. Primary Outcome Measure:

Measure Title	of Evening Measurements of Peak Nasal Inspiratory Flow (PNIF) (12 Hrs)
Measure Description	Mean of evening measurements of Peak Nasal Inspiratory Flow (absolute values) of symptoms over the last 12 hours during allergen challenge, collected in patient diary. The Mean is calculated over the evening of the 1st day to the morning of 8th day of the Allergen challenge period. The patient will breathe out as much as he can. Then a mask (Portable Inspiratory Flow Meter) will be placed over the nose and mouth and the patient will inspire forcefully through the nose while the lips remain tightly closed. The highest PNIF (L/minute) out of 3 measurements will be recorded. Allergen challenge period starts 24 hrs post last dose. Number of Participants Analyzed is based on all patients with evaluable efficacy and/or biomarker data from the challenge period (Visit 15).
Time Frame	During evening of the 1st day to the morning of the 8th day of Allergen challenge period.
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
AZD8848 20 µg x3	20 µg AZD8848 three times weekly
Placebo	Placebo three times weekly

	Description
AZD8848 60 µg	60 µg AZD8848 once weekly and placebo twice weekly

Measured Values

	AZD8848 20 µg x3	Placebo	AZD8848 60 µg
Number of Participants Analyzed	50	14	16
of Evening Measurements of Peak Nasal Inspiratory Flow (PNIF) (12 Hrs) [units: L/min] Least Squares Mean (Full Range)	145 (52.9 to 222)	149 (71.4 to 253)	147 (68.6 to 251)

9. Secondary Outcome Measure:

Measure Title	Absolute Mean Value of Instantaneous Total Nasal Symptom Score (TNSS)
Measure Description	Absolute mean value of Instantaneous Total Nasal Symptom Score (TNSS) for pre-dose symptoms on visit 2, during treatment period. Treatment period is one month, which starts at visit 2 and ends at visit 14. Each individual symptom is scored 0 to 3, which 0 = Absence of symptoms, 1 = Mild symptoms, 2 = Moderate symptoms and 3 = Severe symptoms. The scores of each individual symptom (runny nose, blocked nose and the maximum score of nasal itching or sneezing) will be added together to give a TNSS of 0 to 9. TNSS Score 0 indicates better outcome and TNSS score 9 indicate worse outcome. Number of Participants Analyzed is based on all patients with evaluable efficacy and/or biomarker data at visit 2.
Time Frame	Pre-dose on visit 2 (baseline)
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
AZD8848 20 µg x3	20 µg AZD8848 three times weekly
Placebo	Placebo three times weekly
AZD8848 60 µg	60 µg AZD8848 once weekly and placebo twice weekly

Measured Values

	AZD8848 20 µg x3	Placebo	AZD8848 60 µg
Number of Participants Analyzed	50	16	17
Absolute Mean Value of Instantaneous Total Nasal Symptom Score (TNSS) [units: Scores on a scale] Mean (Standard Deviation)	0.38 (0.697)	0.75 (1.291)	0.35 (0.493)

10. Secondary Outcome Measure:

Measure Title	Absolute Mean Value of Instantaneous Total Nasal Symptom Score (TNSS)
Measure Description	Absolute mean value of Instantaneous Total Nasal Symptom Score (TNSS) for pre-dose symptoms on visit11, during treatment period. Treatment period is one month, which starts at visit 2 and ends at visit 14. Each individual symptom is scored 0 to 3, which 0 = Absence of symptoms, 1 = Mild symptoms, 2 = Moderate symptoms and 3 = Severe symptoms. The scores of each individual symptom (runny nose, blocked nose and the maximum score of nasal itching or sneezing) will be added together to give a TNSS of 0 to 9. TNSS Score 0 indicates better outcome and TNSS score 9 indicates worse outcome. Number of Participants Analyzed is based on all patients with evaluable efficacy and/or biomarker data at visit 11.
Time Frame	Pre-dose on visit 11 (end of 3rd week of treatment)
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
AZD8848 20 µg x3	20 µg AZD8848 three times weekly
Placebo	Placebo three times weekly
AZD8848 60 µg	60 µg AZD8848 once weekly and placebo twice weekly

Measured Values

	AZD8848 20 µg x3	Placebo	AZD8848 60 µg
Number of Participants Analyzed	49	15	15
Absolute Mean Value of Instantaneous Total Nasal Symptom Score (TNSS) [units: Scores on a scale]	1.20 (1.020)	0.67 (1.047)	0.80 (0.862)

	AZD8848 20 µg x3	Placebo	AZD8848 60 µg
Mean (Standard Deviation)			

11. Secondary Outcome Measure:

Measure Title	Absolute Mean Value of Peak Nasal Inspiratory Flow (PNIF)
Measure Description	Absolute mean value of Peak Nasal Inspiratory Flow (PNIF) for pre-dose symptoms on visit 2, during treatment period. Treatment period is one month, which starts at visit 2 and ends at visit 14. The patient will breathe out as much as he can. Then a mask (Portable Inspiratory Flow Meter) will be placed over the nose and mouth and the patient will inspire forcefully through the nose while the lips remain tightly closed. The highest PNIF (L/minute) out of 3 measurements will be recorded. Number of Participants Analyzed is based on all patients with evaluable efficacy and/or biomarker data at visit 2.
Time Frame	Pre-dose on visit 2 (baseline)
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
AZD8848 20 µg x3	20 µg AZD8848 three times weekly
Placebo	Placebo three times weekly
AZD8848 60 µg	60 µg AZD8848 once weekly and placebo twice weekly

Measured Values

	AZD8848 20 µg x3	Placebo	AZD8848 60 µg
Number of Participants Analyzed	50	16	17
Absolute Mean Value of Peak Nasal Inspiratory Flow (PNIF) [units: L/min] Mean (Standard Deviation)	170.4 (54.593)	176.9 (63.005)	169.4 (62.497)

12. Secondary Outcome Measure:

Measure Title	Absolute Mean Value of Peak Nasal Inspiratory Flow (PNIF)
Measure Description	Absolute mean value of Peak Nasal Inspiratory Flow (PNIF) for pre-dose symptoms on visit 11, during treatment period. Treatment period is one month, which starts at visit 2 and ends at visit 14. The patient will breathe out as much as he can. Then a mask (Portable Inspiratory Flow Meter) will be placed over the nose and mouth and the patient will inspire forcefully through the nose while the lips remain tightly closed. The highest PNIF (L/minute) out of 3 measurements will be recorded. Number of Participants Analyzed is based on all patients with evaluable efficacy and/or biomarker data at visit 11.
Time Frame	Pre-dose on visit 11 (end of 3rd week of treatment)
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
AZD8848 20 µg x3	20 µg AZD8848 three times weekly
Placebo	Placebo three times weekly
AZD8848 60 µg	60 µg AZD8848 once weekly and placebo twice weekly

Measured Values

	AZD8848 20 µg x3	Placebo	AZD8848 60 µg
Number of Participants Analyzed	49	15	15
Absolute Mean Value of Peak Nasal Inspiratory Flow (PNIF) [units: L/min] Mean (Standard Deviation)	168.1 (52.070)	191.3 (48.824)	182.7 (61.350)

13. Secondary Outcome Measure:

Measure Title	Change From Baseline of C-X-C Motif Chemokine 10 (CXCL10) in Plasma
Measure Description	Change from baseline to 24 hours after last dose (day1 visit 15) of C-X-C motif chemokine 10 (CXCL10) in plasma, expressed as a ratio. The ratio is calculated as day1 of visit 15 / baseline. Number of Participants Analyzed is based on all patients with evaluable biomarker data at visit 2 and visit15.

Time Frame	Baseline to 1st day of visit 15
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
AZD8848 20 µg x3	20 µg AZD8848 three times weekly
Placebo	Placebo three times weekly
AZD8848 60 µg	60 µg AZD8848 once weekly and placebo twice weekly

Measured Values

	AZD8848 20 µg x3	Placebo	AZD8848 60 µg
Number of Participants Analyzed	46	15	16
Change From Baseline of C-X-C Motif Chemokine 10 (CXCL10) in Plasma [units: ratio] Geometric Mean (95% Confidence Interval)	2.89 (2.45 to 3.40)	0.803 (0.6 to 1.07)	3.90 (2.96 to 5.15)

14. Secondary Outcome Measure:

Measure Title	Change From Baseline of C-X-C Motif Chemokine 10 (CXCL10) in Nasal Lavage
Measure Description	Change from baseline to 24 hours after last dose (day1 visit 15) of C-X-C motif chemokine 10 (CXCL10) in nasal lavage, expressed as a ratio. The ratio is calculated as day1 of visit 15 / baseline. Number of Participants Analyzed is based on all patients with evaluable biomarker data at visit 2 and visit 15.
Time Frame	Baseline to 1st day of visit 15
Safety Issue?	No

Analysis Population Description
[Not Specified]

Reporting Groups

	Description
AZD8848 20 µg x3	20 µg AZD8848 three times weekly

	Description
Placebo	Placebo three times weekly
AZD8848 60 µg	60 µg AZD8848 once weekly and placebo twice weekly

Measured Values

	AZD8848 20 µg x3	Placebo	AZD8848 60 µg
Number of Participants Analyzed	48	14	15
Change From Baseline of C-X-C Motif Chemokine 10 (CXCL10) in Nasal Lavage [units: ratio] Least Squares Mean (95% Confidence Interval)	30.0 (21.99 to 40.81)	1.66 (0.93 to 2.97)	26.9 (15.52 to 46.56)

Reported Adverse Events

Time Frame	[Not specified]
Additional Description	[Not specified]

Reporting Groups

	Description
AZD8848 20 µg x3	20 µg AZD8848 three times weekly
Placebo	Placebo three times weekly
AZD8848 60 µg	60 µg AZD8848 once weekly and placebo twice weekly

Serious Adverse Events

	AZD8848 20 µg x3	Placebo	AZD8848 60 µg
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	0/50 (0%)	0/16 (0%)	0/17 (0%)

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 5%

	AZD8848 20 µg x3	Placebo	AZD8848 60 µg
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	48/50 (96%)	12/16 (75%)	12/17 (70.59%)
Eye disorders			
Eczema Eyelids †	0/50 (0%)	1/16 (6.25%)	0/17 (0%)
Eye Oedema †	0/50 (0%)	0/16 (0%)	1/17 (5.88%)
Eye Pruritus [A] †	0/50 (0%)	0/16 (0%)	1/17 (5.88%)
Gastrointestinal disorders			
Abdominal pain upper [A] †	0/50 (0%)	0/16 (0%)	1/17 (5.88%)
Dry Mouth [A] †	1/50 (2%)	0/16 (0%)	1/17 (5.88%)
Gastritis [A] †	1/50 (2%)	1/16 (6.25%)	1/17 (5.88%)
Nausea [A] †	4/50 (8%)	0/16 (0%)	1/17 (5.88%)
General disorders			
Asthenia [A] †	4/50 (8%)	0/16 (0%)	1/17 (5.88%)
Chills [A] †	6/50 (12%)	0/16 (0%)	3/17 (17.65%)
Fatigue [A] †	7/50 (14%)	1/16 (6.25%)	1/17 (5.88%)
Feeling abnormal [A] †	3/50 (6%)	0/16 (0%)	1/17 (5.88%)
Irritability [A] †	0/50 (0%)	0/16 (0%)	1/17 (5.88%)
Pain [A] †	3/50 (6%)	1/16 (6.25%)	3/17 (17.65%)
Pyrexia [A] †	11/50 (22%)	0/16 (0%)	1/17 (5.88%)
Infections and infestations			
Herpes Virus Infection [A] †	3/50 (6%)	0/16 (0%)	0/17 (0%)
Nasopharyngitis [A] †	5/50 (10%)	2/16 (12.5%)	0/17 (0%)
Sinusitus [A] †	0/50 (0%)	1/16 (6.25%)	0/17 (0%)

	AZD8848 20 µg x3	Placebo	AZD8848 60 µg
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Injury, poisoning and procedural complications			
Face injury [A] †	1/50 (2%)	0/16 (0%)	2/17 (11.76%)
Musculoskeletal and connective tissue disorders			
Arthralgia [A] †	0/50 (0%)	0/16 (0%)	1/17 (5.88%)
Musculoskeletal Pain [A] †	0/50 (0%)	0/16 (0%)	1/17 (5.88%)
Myalgia [A] †	3/50 (6%)	0/16 (0%)	0/17 (0%)
Nervous system disorders			
Disgeusia [A] †	0/50 (0%)	1/16 (6.25%)	0/17 (0%)
Disturbance in attention [A] †	0/50 (0%)	1/16 (6.25%)	0/17 (0%)
Headache [A] †	20/50 (40%)	5/16 (31.25%)	3/17 (17.65%)
Migraine [A] †	0/50 (0%)	0/16 (0%)	1/17 (5.88%)
Psychiatric disorders			
Stress [A] †	0/50 (0%)	1/16 (6.25%)	0/17 (0%)
Reproductive system and breast disorders			
Dysmenorrhoea [A] †	0/50 (0%)	1/16 (6.25%)	0/17 (0%)
Respiratory, thoracic and mediastinal disorders			
Cough [A] †	4/50 (8%)	0/16 (0%)	1/17 (5.88%)
Epistaxis [A] †	24/50 (48%)	1/16 (6.25%)	6/17 (35.29%)
Nasal congestion [A] †	12/50 (24%)	1/16 (6.25%)	4/17 (23.53%)
Nasal discomfort [A] †	7/50 (14%)	0/16 (0%)	0/17 (0%)
Nasal dryness [A] †	1/50 (2%)	1/16 (6.25%)	0/17 (0%)
Nasal obstruction [A] †	14/50 (28%)	3/16 (18.75%)	4/17 (23.53%)
Oropharyngeal pain [A] †	10/50 (20%)	4/16 (25%)	9/17 (52.94%)

	AZD8848 20 µg x3	Placebo	AZD8848 60 µg
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Rhinalgia [A] †	4/50 (8%)	0/16 (0%)	0/17 (0%)
Rhinorrhoea [A] †	17/50 (34%)	3/16 (18.75%)	6/17 (35.29%)
Sneezing [A] †	7/50 (14%)	0/16 (0%)	0/17 (0%)
Throat irritation [A] †	0/50 (0%)	0/16 (0%)	2/17 (11.76%)
Skin and subcutaneous tissue disorders			
Acne [A] †	0/50 (0%)	0/16 (0%)	1/17 (5.88%)
Rash [A] †	0/50 (0%)	1/16 (6.25%)	1/17 (5.88%)
Scab [A] †	4/50 (8%)	0/16 (0%)	1/17 (5.88%)
Vascular disorders			
Hypertension [A] †	0/50 (0%)	0/16 (0%)	1/17 (5.88%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA 14.0

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

There is an agreement between PI and Sponsor (AZ) or its agents that restricts the PI's right to discuss/publish trial results after the trial is completed. The PI agrees to collaborate in good faith with AZ with regards to content and formation of any publication or disclosure to be made by PI and to pay due consideration to opinions offered by AZ

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