ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
Release Date: 08/14/2012

ClinicalTrials.gov ID: NCT01054170

Study Identification

Unique Protocol ID:	D0520C00014
Brief Title:	Effect on Structural Changes in Airways, Measured by MSCT, of Twice Daily 60mg AZD9668 for 12 Weeks in Chronic Obstructive Pulmonary Disease (COPD) Patients
Official Title:	A 12-week, Phase II, Double-blind, Placebo-Controlled, Randomised, Parallel-Group, Multi-Centre Study to Assess the Effect of 60mg AZD9668 Administered Orally Twice Daily on Structural Changes in the Airways by Multi-Slice Computed Tomography in Patients With Chronic Obstructive Pulmonary Disease.
Secondary IDs:	

Study Status

Record Verification:	August 2012
Overall Status:	Completed
Study Start:	January 2010
Primary Completion:	November 2010 [Actual]
Study Completion:	November 2010 [Actual]

Sponsor/Collaborators

Sponsor:	AstraZeneca
Responsible Party:	Sponsor
Collaborators:	

Oversight

FDA Regulated?:	No
IND/IDE Protocol?:	No
Review Board:	Approval Status: Approved Approval Number: 23 Nov 2009 Board Name: Queen's University Health Sciences & Affilited Teaching Hospitals Research Ethics Board Board Affiliation: Queen's University Health Sciences and Affiliated Teaching Hospitals Phone: + 1-613-533-6081 Email: clarkaf@queensu.ca
Data Monitoring?:	Yes
Plan to Share Data?:	
Oversight Authorities:	Canada: Health Canada Denmark: Danish Medicines Agency Netherlands: The Central Committee on Research Involving Human Subjects (CCMO) Romania: National Medicines Agency Ukraine: Ministry of Health

Study Description

Brief Summary:	The primary objective of the study is to evaluate structural changes effected by AD9668 in the airways of adults with Chronic Obstructive Pulmonary Disease (COPD) by Multi-Slice Computed Tomography (MSCT)
Detailed Description:	

Conditions

Conditions:	Chronic Obstructive Pulmonary Disease (COPD)
Keywords:	Chronic obstructive pulmonary lung respiratory disease efficacy placebo-controlled COPD FEV1 St Georges Respiratory Questionnaire Computed Tomography

MSCT

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 2
Intervention Model:	Parallel Assignment
Number of Arms:	2
Masking:	Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor)
Allocation:	Randomized
Endpoint Classification:	Efficacy Study
Enrollment:	52 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: AZD9668	Drug: AZD9668 2 x 30 mg oral tablets twice daily (bid) for 12 weeks
Placebo Comparator: Placebo	Drug: Placebo 2 x matched placebo to oral tablet twice daily (bid) for 12 weeks

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age:	50 Years
Maximum Age:	80 Years
Gender:	Both
Accepts Healthy Volunteers?:	No
Criteria:	Inclusion Criteria:

- Diagnosis of COPD with symptoms over 1 year
- FEV1/FVC < 70% and FEV1 >= 40 and < =70 % of predicted post-bronchodilator

- Ex-smokers for at least 12 months

Exclusion Criteria:

- Past history or current evidence of clinically significant heart disease
- Current diagnosis of asthma
- Worsening of COPD requiring hospitalisation and/or treatment with antibiotics and/or an increase in inhaled steroid dose and/or oral steroids within 4 weeks of study visit 1b

Contacts/Locations

Study Officials: Professor Asger Dirksen
Study Principal Investigator
Gentofte Hospital, Department of Lung Medicine

Locations: Canada, Ontario
Research Site
Kingston, Ontario, Canada

Canada, Quebec
Research Site
Quebec, Quebec, Canada

Denmark
Research Site
Hellerup, Denmark

Research Site
Hvidovre, Denmark

Research Site
Odensec, Denmark

Netherlands
Research Site
Breda, Netherlands

Research Site
Nieuwegein, Netherlands

Romania
Research Site
Bucuresti, Romania

Ukraine

Research Site
Kyiv, Ukraine

References

Citations:

Links:

Study Data/Documents:

Study Results

Participant Flow

Recruitment Details	First patient enrolled: 06 January 2010; Last patient completed: 17 November 2010; Twelve centres across 5 countries participated in this study: Canada (2), Denmark (3), The Netherlands (2), Romania (2) and Ukraine (3).
Pre-Assignment Details	Tiotropium maintenance therapy and reliever medication were commenced at screening, except for patients on inhaled corticosteroids (ICS, ICS/LABA) who were required to stop these at enrolment and commence on tiotropium and reliever medication at the same time. These patients received tiotropium for a period of at least 3 weeks before screening.

Reporting Groups

	Description
AZD9668	AZD9668 2x30mg bid
Placebo	Placebo 2 tablets bid

Overall Study

	AZD9668	Placebo
Started	25	27
Completed	21	21
Not Completed	4	6
Protocol Violation	1	0
Withdrawal by Subject	3	2

	AZD9668	Placebo
Adverse Event	0	4

Baseline Characteristics

Reporting Groups

	Description
AZD9668	AZD9668 2x30mg bid
Placebo	Placebo 2 tablets bid

Baseline Measures

	AZD9668	Placebo	Total
Number of Participants	25	27	52
Age, Continuous [units: years] Mean (Standard Deviation)	7.2 (65)	7.7 (66)	7.45 (131)
Gender, Male/Female [units: Participants]			
Female	6	10	16
Male	19	17	36

Outcome Measures

1. Primary Outcome Measure:

Measure Title	AWT-Pi10 (Airway Wall Thickness of a Theoretical Airway With an Internal Perimeter of 10 mm)
Measure Description	AWT-Pi10 (mm) as a measure of structural changes in airways. End of treatment Least Squares Mean.
Time Frame	Measured after 12 weeks treatment (day 84)
Safety Issue?	No

Analysis Population Description

The efficacy analysis set for each outcome measure includes those patients who received at least one dose of investigational product and for whom a baseline and at least one post-randomisation measurement is available for that outcome measure. Patients were analysed by to randomised treatment in accordance with the intention to treat principle.

Reporting Groups

	Description
AZD9668	AZD9668 2x30mg bid
Placebo	Placebo 2 tablets bid

Measured Values

	AZD9668	Placebo
Number of Participants Analyzed	17	19
AWT-Pi10 (Airway Wall Thickness of a Theoretical Airway With an Internal Perimeter of 10 mm) [units: mm] Least Squares Mean (Standard Error)	3.84 (0.021)	3.83 (0.017)

2. Secondary Outcome Measure:

Measure Title	5th Generation Wall Area Percentage
Measure Description	5th Generation Wall Area Percentage as a measure of structural changes in airways. End of treatment Least Squares Mean.
Time Frame	Measured after 12 weeks treatment (day 84)
Safety Issue?	No

Analysis Population Description

The efficacy analysis set for each outcome measure includes those patients who received at least one dose of investigational product and for whom a baseline and at least one post-randomisation measurement is available for that outcome measure. Patients were analysed by to randomised treatment in accordance with the intention to treat principle.

Reporting Groups

	Description
AZD9668	AZD9668 2x30mg bid
Placebo	Placebo 2 tablets bid

Measured Values

	AZD9668	Placebo
Number of Participants Analyzed	17	19
5th Generation Wall Area Percentage	66.21 (0.275)	65.94 (0.234)

	AZD9668	Placebo
[units: Percentage Area] Least Squares Mean (Standard Error)		

3. Secondary Outcome Measure:

Measure Title	Air Trapping Index (ATI) on Expiratory Scans
Measure Description	ATI Percentage as a measure of structural changes in airways. End of treatment Least Squares Mean.
Time Frame	Measured after 12 weeks treatment (day 84)
Safety Issue?	No

Analysis Population Description

The efficacy analysis set for each outcome measure includes those patients who received at least one dose of investigational product and for whom a baseline and at least one post-randomisation measurement is available for that outcome measure. Patients were analysed by to randomised treatment in accordance with the intention to treat principle.

Reporting Groups

	Description
AZD9668	AZD9668 2x30mg bid
Placebo	Placebo 2 tablets bid

Measured Values

	AZD9668	Placebo
Number of Participants Analyzed	15	13
Air Trapping Index (ATI) on Expiratory Scans [units: ATI Percentage] Least Squares Mean (Standard Error)	54.56 (1.706)	57.12 (1.599)

4. Secondary Outcome Measure:

Measure Title	Pre-bronchodilator Inspiratory Capacity (IC)
Measure Description	Inspiratory Capacity (L) as a measure of lung function. End of treatment Least Squares Mean.
Time Frame	Measured after 12 weeks treatment (day 84)

Safety Issue?	No

Analysis Population Description

The efficacy analysis set for each outcome measure includes those patients who received at least one dose of investigational product and for whom a baseline and at least one post-randomisation measurement is available for that outcome measure. Patients were analysed by to randomised treatment in accordance with the intention to treat principle.

Reporting Groups

	Description
AZD9668	AZD9668 2x30mg bid
Placebo	Placebo 2 tablets bid

Measured Values

	AZD9668	Placebo
Number of Participants Analyzed	24	23
Pre-bronchodilator Inspiratory Capacity (IC) [units: L] Least Squares Mean (Standard Error)	2.56 (0.154)	2.39 (0.153)

5. Secondary Outcome Measure:

Measure Title	Pre-bronchodilator Total Lung Capacity (TLC)
Measure Description	Total Lung Capacity (L) as a measure of lung function. End of treatment Least Squares Mean.
Time Frame	Measured after 12 weeks treatment (day 84)
Safety Issue?	No

Analysis Population Description

The efficacy analysis set for each outcome measure includes those patients who received at least one dose of investigational product and for whom a baseline and at least one post-randomisation measurement is available for that outcome measure. Patients were analysed by to randomised treatment in accordance with the intention to treat principle.

Reporting Groups

	Description
AZD9668	AZD9668 2x30mg bid
Placebo	Placebo 2 tablets bid

Measured Values

	AZD9668	Placebo
Number of Participants Analyzed	24	23
Pre-bronchodilator Total Lung Capacity (TLC) [units: L] Least Squares Mean (Standard Error)	7.03 (0.178)	6.92 (0.177)

6. Secondary Outcome Measure:

Measure Title	Pre-bronchodilator Functional Residual Capacity (FRC)
Measure Description	Functional Residual Capacity (L) as a measure of lung function. End of treatment Least Squares Mean.
Time Frame	Measured after 12 weeks treatment (day 84)
Safety Issue?	No

Analysis Population Description

The efficacy analysis set for each outcome measure includes those patients who received at least one dose of investigational product and for whom a baseline and at least one post-randomisation measurement is available for that outcome measure. Patients were analysed by to randomised treatment in accordance with the intention to treat principle.

Reporting Groups

	Description
AZD9668	AZD9668 2x30mg bid
Placebo	Placebo 2 tablets bid

Measured Values

	AZD9668	Placebo
Number of Participants Analyzed	23	23
Pre-bronchodilator Functional Residual Capacity (FRC) [units: L] Least Squares Mean (Standard Error)	4.41 (0.165)	4.21 (0.158)

7. Secondary Outcome Measure:

Measure Title	Pre-bronchodilator Residual Volume (RV)
Measure Description	Residual volume (L) as a measure of lung function. End of treatment Least Squares Mean.
Time Frame	Measured after 12 weeks treatment (day 84)
Safety Issue?	No

Analysis Population Description

The efficacy analysis set for each outcome measure includes those patients who received at least one dose of investigational product and for whom a baseline and at least one post-randomisation measurement is available for that outcome measure. Patients were analysed by to randomised treatment in accordance with the intention to treat principle.

Reporting Groups

	Description
AZD9668	AZD9668 2x30mg bid
Placebo	Placebo 2 tablets bid

Measured Values

	AZD9668	Placebo
Number of Participants Analyzed	24	23
Pre-bronchodilator Residual Volume (RV) [units: L] Least Squares Mean (Standard Error)	3.64 (0.161)	3.73 (0.161)

8. Secondary Outcome Measure:

Measure Title	Pre-bronchodilator Specific Airway Conductance (SGaw)
Measure Description	Specific Airway Conductance as a measure of lung function. End of treatment Least Squares Mean.
Time Frame	Measured after 12 weeks treatment (day 84)
Safety Issue?	No

Analysis Population Description

The efficacy analysis set for each outcome measure includes those patients who received at least one dose of investigational product and for whom a baseline and at least one post-randomisation measurement is available for that outcome measure. Patients were analysed by to randomised treatment in accordance with the intention to treat principle.

Reporting Groups

	Description
AZD9668	AZD9668 2x30mg bid
Placebo	Placebo 2 tablets bid

Measured Values

	AZD9668	Placebo
Number of Participants Analyzed	24	23
Pre-bronchodilator Specific Airway Conductance (SGaw) [units: 1/[s*kPa]] Least Squares Mean (Standard Error)	0.52 (0.034)	0.48 (0.034)

9. Secondary Outcome Measure:

Measure Title	Pre-bronchodilator Diffusion Capacity of Carbon Monoxide (DLco)
Measure Description	Capacity of Carbon Monoxide as a measure of lung function. End of treatment Least Squares Mean.
Time Frame	Measured after 12 weeks treatment (day 84)
Safety Issue?	No

Analysis Population Description

The efficacy analysis set for each outcome measure includes those patients who received at least one dose of investigational product and for whom a baseline and at least one post-randomisation measurement is available for that outcome measure. Patients were analysed by to randomised treatment in accordance with the intention to treat principle.

Reporting Groups

	Description
AZD9668	AZD9668 2x30mg bid
Placebo	Placebo 2 tablets bid

Measured Values

	AZD9668	Placebo
Number of Participants Analyzed	23	23
Pre-bronchodilator Diffusion Capacity of Carbon Monoxide (DLco)	5.49 (0.204)	5.67 (0.209)

	AZD9668	Placebo
[units: mmol/kPa*min] Least Squares Mean (Standard Error)		

10. Secondary Outcome Measure:

Measure Title	Pre-bronchodilator Forced Expiratory Volume in 1 Second (FEV1)
Measure Description	Forced Expiratory Volume in 1 second (L) as a measure of lung function, measured before bronchodilator (salbutamol) use in the clinic. End of treatment value or Last Observation Carried Forward (LOCF).
Time Frame	Measured after 12 weeks treatment (day 84)
Safety Issue?	No

Analysis Population Description

The efficacy analysis set for each outcome measure includes those patients who received at least one dose of investigational product and for whom a baseline and at least one post-randomisation measurement is available for that outcome measure. Patients were analysed by to randomised treatment in accordance with the intention to treat principle.

Reporting Groups

	Description
AZD9668	AZD9668 2x30mg bid
Placebo	Placebo 2 tablets bid

Measured Values

	AZD9668	Placebo
Number of Participants Analyzed	25	27
Pre-bronchodilator Forced Expiratory Volume in 1 Second (FEV1) [units: L] Least Squares Mean (Standard Error)	1.51 (0.048)	1.49 (0.050)

11. Secondary Outcome Measure:

Measure Title	Post-bronchodilator Forced Expiratory Volume in 1 Second (FEV1)
Measure Description	Forced Expiratory Volume in 1 second (L) as a measure of lung function, measured after bronchodilator (salbutamol) use in the clinic. End of treatment value or Last Observation Carried Forward (LOCF).

Time Frame	Measured after 12 weeks treatment (day 84)
Safety Issue?	No

Analysis Population Description

The efficacy analysis set for each outcome measure includes those patients who received at least one dose of investigational product and for whom a baseline and at least one post-randomisation measurement is available for that outcome measure. Patients were analysed by to randomised treatment in accordance with the intention to treat principle.

Reporting Groups

	Description
AZD9668	AZD9668 2x30mg bid
Placebo	Placebo 2 tablets bid

Measured Values

	AZD9668	Placebo
Number of Participants Analyzed	21	23
Post-bronchodilator Forced Expiratory Volume in 1 Second (FEV1) [units: L] Least Squares Mean (Standard Error)	1.60 (0.050)	1.58 (0.050)

12. Secondary Outcome Measure:

Measure Title	Pre-bronchodilator Forced Vital Capacity (FVC)
Measure Description	Forced Vital Capacity (L) as a measure of lung function, measured before bronchodilator (salbutamol) use in the clinic. End of treatment value or Last Observation Carried Forward (LOCF).
Time Frame	Measured after 12 weeks treatment (day 84)
Safety Issue?	No

Analysis Population Description

The efficacy analysis set for each outcome measure includes those patients who received at least one dose of investigational product and for whom a baseline and at least one post-randomisation measurement is available for that outcome measure. Patients were analysed by to randomised treatment in accordance with the intention to treat principle.

Reporting Groups

	Description
AZD9668	AZD9668 2x30mg bid
Placebo	Placebo 2 tablets bid

Measured Values

	AZD9668	Placebo
Number of Participants Analyzed	25	27
Pre-bronchodilator Forced Vital Capacity (FVC) [units: L] Least Squares Mean (Standard Error)	3.25 (0.084)	3.14 (0.083)

13. Secondary Outcome Measure:

Measure Title	Post-bronchodilator Forced Vital Capacity (FVC)
Measure Description	Forced Vital Capacity (L) as a measure of lung function, measured after bronchodilator (salbutamol) use in the clinic. End of treatment value or Last Observation Carried Forward (LOCF).
Time Frame	Measured after 12 weeks treatment (day 84)
Safety Issue?	No

Analysis Population Description

The efficacy analysis set for each outcome measure includes those patients who received at least one dose of investigational product and for whom a baseline and at least one post-randomisation measurement is available for that outcome measure. Patients were analysed by to randomised treatment in accordance with the intention to treat principle.

Reporting Groups

	Description
AZD9668	AZD9668 2x30mg bid
Placebo	Placebo 2 tablets bid

Measured Values

	AZD9668	Placebo
Number of Participants Analyzed	21	23
Post-bronchodilator Forced Vital Capacity (FVC) [units: L]	3.34 (0.083)	3.34 (0.080)

	AZD9668	Placebo
Least Squares Mean (Standard Error)		

14. Secondary Outcome Measure:

Measure Title	Pre-bronchodilator Slow Vital Capacity (SVC)
Measure Description	Slow Vital Capacity (L) as a measure of lung function, measured before bronchodilator (salbutamol) use in the clinic. End of treatment value or Last Observation Carried Forward (LOCF).
Time Frame	Measured after 12 weeks treatment (day 84)
Safety Issue?	No

Analysis Population Description

The efficacy analysis set for each outcome measure includes those patients who received at least one dose of investigational product and for whom a baseline and at least one post-randomisation measurement is available for that outcome measure. Patients were analysed by to randomised treatment in accordance with the intention to treat principle.

Reporting Groups

	Description
AZD9668	AZD9668 2x30mg bid
Placebo	Placebo 2 tablets bid

Measured Values

	AZD9668	Placebo
Number of Participants Analyzed	25	27
Pre-bronchodilator Slow Vital Capacity (SVC) [units: L] Least Squares Mean (Standard Error)	3.42 (0.069)	3.38 (0.068)

15. Secondary Outcome Measure:

Measure Title	Post-bronchodilator Slow Vital Capacity (SVC)
Measure Description	Slow Vital capacity (L) as a measure of lung function, measured after bronchodilator (salbutamol) use in the clinic. End of treatment value or Last Observation Carried Forward (LOCF).
Time Frame	Measured after 12 weeks treatment (day 84)

Safety Issue?	No

Analysis Population Description

The efficacy analysis set for each outcome measure includes those patients who received at least one dose of investigational product and for whom a baseline and at least one post-randomisation measurement is available for that outcome measure. Patients were analysed by to randomised treatment in accordance with the intention to treat principle.

Reporting Groups

	Description
AZD9668	AZD9668 2x30mg bid
Placebo	Placebo 2 tablets bid

Measured Values

	AZD9668	Placebo
Number of Participants Analyzed	21	23
Post-bronchodilator Slow Vital Capacity (SVC) [units: L] Least Squares Mean (Standard Error)	3.56 (0.063)	3.44 (0.061)

16. Secondary Outcome Measure:

Measure Title	Peak Expiratory Flow (PEF) Morning (Daily Recordings)
Measure Description	Peak Expiratory Flow (L/min) as a measure of lung function, measured at home by the patient each morning.
Time Frame	Average from measurements recorded daily by patient in last 6 weeks of treatment.
Safety Issue?	No

Analysis Population Description

The efficacy analysis set for each outcome measure includes those patients who received at least one dose of investigational product and for whom a baseline and at least one post-randomisation measurement is available for that outcome measure. Patients were analysed by to randomised treatment in accordance with the intention to treat principle.

Reporting Groups

	Description
AZD9668	AZD9668 2x30mg bid
Placebo	Placebo 2 tablets bid

Measured Values

	AZD9668	Placebo
Number of Participants Analyzed	25	27
Peak Expiratory Flow (PEF) Morning (Daily Recordings) [units: L/min] Least Squares Mean (Standard Error)	255.82 (9.956)	244.16 (9.871)

17. Secondary Outcome Measure:

Measure Title	Peak Expiratory Flow (PEF) Evening (Daily Recordings)
Measure Description	Peak Expiratory Flow (L/min) as a measure of lung function, measured at home by the patient each evening .
Time Frame	Average from measurements recorded daily by patient in last 6 weeks of treatment.
Safety Issue?	No

Analysis Population Description

The efficacy analysis set for each outcome measure includes those patients who received at least one dose of investigational product and for whom a baseline and at least one post-randomisation measurement is available for that outcome measure. Patients were analysed by to randomised treatment in accordance with the intention to treat principle.

Reporting Groups

	Description
AZD9668	AZD9668 2x30mg bid
Placebo	Placebo 2 tablets bid

Measured Values

	AZD9668	Placebo
Number of Participants Analyzed	25	27
Peak Expiratory Flow (PEF) Evening (Daily Recordings) [units: L/min] Least Squares Mean (Standard Error)	264.15 (10.02)	254.31 (9.966)

18. Secondary Outcome Measure:

Measure Title	Forced Expiratory Volume in 1 Second (FEV1) Morning (Daily Recordings)
Measure Description	Forced Expiratory Volume in 1 second (L) as a measure of lung function, measured at home by the patient each morning.
Time Frame	Average from measurements recorded daily by patient in last 6 weeks of treatment.
Safety Issue?	No

Analysis Population Description

The efficacy analysis set for each outcome measure includes those patients who received at least one dose of investigational product and for whom a baseline and at least one post-randomisation measurement is available for that outcome measure. Patients were analysed by to randomised treatment in accordance with the intention to treat principle.

Reporting Groups

	Description
AZD9668	AZD9668 2x30mg bid
Placebo	Placebo 2 tablets bid

Measured Values

	AZD9668	Placebo
Number of Participants Analyzed	25	27
Forced Expiratory Volume in 1 Second (FEV1) Morning (Daily Recordings) [units: L] Least Squares Mean (Standard Error)	1.49 (0.065)	1.29 (0.066)

19. Secondary Outcome Measure:

Measure Title	Forced Expiratory Volume in 1 Second (FEV1) Evening (Daily Recordings)
Measure Description	Forced Expiratory Volume in 1 second (L) as a measure of lung function, measured at home by the patient each evening.
Time Frame	Average from measurements recorded daily by patient in last 6 weeks of treatment.
Safety Issue?	No

Analysis Population Description

The efficacy analysis set for each outcome measure includes those patients who received at least one dose of investigational product and for whom a baseline and at least one post-randomisation measurement is available for that outcome measure. Patients were analysed by to randomised treatment in accordance with the intention to treat principle.

Reporting Groups

	Description
AZD9668	AZD9668 2x30mg bid
Placebo	Placebo 2 tablets bid

Measured Values

	AZD9668	Placebo
Number of Participants Analyzed	25	27
Forced Expiratory Volume in 1 Second (FEV1) Evening (Daily Recordings) [units: L] Least Squares Mean (Standard Error)	1.51 (0.062)	1.30 (0.064)

20. Secondary Outcome Measure:

Measure Title	Breathlessness, Cough and Sputum Scale (BCSS) Total Score
Measure Description	Breathlessness, Cough and Sputum Scale, patient reported questionnaire as a measure of respiratory symptoms (reported on a 0 (best health status) to 12 (worst possible status) scale).
Time Frame	Average from measurements recorded daily by patient in last 6 weeks of treatment.
Safety Issue?	No

Analysis Population Description

The efficacy analysis set for each outcome measure includes those patients who received at least one dose of investigational product and for whom a baseline and at least one post-randomisation measurement is available for that outcome measure. Patients were analysed by to randomised treatment in accordance with the intention to treat principle.

Reporting Groups

	Description
AZD9668	AZD9668 2x30mg bid
Placebo	Placebo 2 tablets bid

Measured Values

	AZD9668	Placebo
Number of Participants Analyzed	25	27
Breathlessness, Cough and Sputum Scale (BCSS) Total Score [units: Total Score] Least Squares Mean (Standard Error)	2.33 (0.319)	3.36 (0.301)

21. Secondary Outcome Measure:

Measure Title	EXAcerbations of Chronic Pulmonary Disease Tool (EXACT) Total Score
Measure Description	EXAcerbations of Chronic pulmonary disease Tool, patient questionnaire as a measure of respiratory symptoms (reported as units on a 0 (best health status) to 100 (worst possible status) scale).
Time Frame	Average from measurements recorded daily by patient in last 6 weeks of treatment.
Safety Issue?	No

Analysis Population Description

The efficacy analysis set for each outcome measure includes those patients who received at least one dose of investigational product and for whom a baseline and at least one post-randomisation measurement is available for that outcome measure. Patients were analysed by to randomised treatment in accordance with the intention to treat principle.

Reporting Groups

	Description
AZD9668	AZD9668 2x30mg bid
Placebo	Placebo 2 tablets bid

Measured Values

	AZD9668	Placebo
Number of Participants Analyzed	25	26
EXAcerbations of Chronic Pulmonary Disease Tool (EXACT) Total Score [units: Total Score] Least Squares Mean (Standard Error)	28.48 (2.065)	33.26 (2.013)

22. Secondary Outcome Measure:

Measure Title	St George's Respiratory Questionnaire for COPD Patients (SGRQ-C) Overall Score
Measure Description	St George's Respiratory Questionnaire for Chronic Obstructive Pulmonary Disease, as a measure of Quality of Life (reported on a % scale from 0 (best health status) to 100(worst possible status)).
Time Frame	Measured after 12 weeks treatment (day 84)
Safety Issue?	No

Analysis Population Description

The efficacy analysis set for each outcome measure includes those patients who received at least one dose of investigational product and for whom a baseline and at least one post-randomisation measurement is available for that outcome measure. Patients were analysed by to randomised treatment in accordance with the intention to treat principle.

Reporting Groups

	Description
AZD9668	AZD9668 2x30mg bid
Placebo	Placebo 2 tablets bid

Measured Values

	AZD9668	Placebo
Number of Participants Analyzed	25	23
St George's Respiratory Questionnaire for COPD Patients (SGRQ-C) Overall Score [units: Scores on a scale] Least Squares Mean (Standard Error)	35.64 (2.364)	39.61 (2.389)

23. Secondary Outcome Measure:

Measure Title	Percentage of Reliever Free Days in Last Six Weeks of Treatment
Measure Description	Percentage of reliever free days in last 6 weeks on treatment.
Time Frame	Average from measurements recorded daily by patient in last 6 weeks of treatment.
Safety Issue?	No

Analysis Population Description

The efficacy analysis set for each outcome measure includes those patients who received at least one dose of investigational product and for whom a baseline and at least one post-randomisation measurement is available for that outcome measure. Patients were analysed by to randomised treatment in accordance with the intention to treat principle.

Reporting Groups

	Description
AZD9668	AZD9668 2x30mg bid
Placebo	Placebo 2 tablets bid

Measured Values

	AZD9668	Placebo
Number of Participants Analyzed	25	27
Percentage of Reliever Free Days in Last Six Weeks of Treatment [units: percentage of days] Least Squares Mean (Standard Error)	34.23 (6.394)	26.43 (6.001)

24. Secondary Outcome Measure:

Measure Title	Exacerbations
Measure Description	Number of patients experiencing disease exacerbations on treatment.
Time Frame	Exacerbations were recorded at all study visits (after 1, 4, 8, and 12 weeks of treatment and at follow up)
Safety Issue?	No

Analysis Population Description

The efficacy analysis set for each outcome measure includes those patients who received at least one dose of investigational product and for whom a baseline and at least one post-randomisation measurement is available for that outcome measure. Patients were analysed by to randomised treatment in accordance with the intention to treat principle.

Reporting Groups

	Description
AZD9668	AZD9668 2x30mg bid
Placebo	Placebo 2 tablets bid

Measured Values

	AZD9668	Placebo
Number of Participants Analyzed	25	27
Exacerbations	0	5

	AZD9668	Placebo
[units: Participants]		

Reported Adverse Events

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

Reporting Groups

	Description
AZD9668	AZD9668 2x30mg bid
Placebo	Placebo 2 tablets bid

Serious Adverse Events

	AZD9668	Placebo
	Affected/At Risk (%)	Affected/At Risk (%)
Total	0/25 (0%)	1/27 (3.7%)
Injury, poisoning and procedural complications		
POST PROCEDURAL COMPLICATION [A] †	0/25 (0%)	1/27 (3.7%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA 13.1

Other Adverse Events

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

	AZD9668	Placebo
	Affected/At Risk (%)	Affected/At Risk (%)
Total	8/25 (32%)	8/27 (29.63%)
Gastrointestinal disorders		
DRY MOUTH [A] †	0/25 (0%)	2/27 (7.41%)

	AZD9668	Placebo
	Affected/At Risk (%)	Affected/At Risk (%)
General disorders		
ASTHENIA [B] †	0/25 (0%)	2/27 (7.41%)
Infections and infestations		
NASOPHARYNGITIS [A] †	5/25 (20%)	2/27 (7.41%)
Nervous system disorders		
DIZZINESS [B] †	2/25 (8%)	0/27 (0%)
Respiratory, thoracic and mediastinal disorders		
BRONCHIAL WALL THICKENING [A] †	1/25 (4%)	2/27 (7.41%)
COUGH [A] †	0/25 (0%)	3/27 (11.11%)
DYSPNOEA [A] †	0/25 (0%)	2/27 (7.41%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA (13.1)
B Term from vocabulary, MedDRA 13.1

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:

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

There is NOT 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.

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