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Trial record **1 of 1** for: C-08-36

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Geographic Atrophy Treatment Evaluation (GATE)

This study has been terminated.

(Treatment ineffective)

Sponsor:
Alcon Research

Information provided by (Responsible Party):
Alcon Research

ClinicalTrials.gov Identifier:
NCT00890097

First received: April 27, 2009
Last updated: June 4, 2014
Last verified: June 2014
History of Changes

Full Text View | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Results First Received: June 4, 2014

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor); Primary Purpose: Treatment
Conditions:	Geographic Atrophy Age-Related Macular Degeneration
Interventions:	Drug: AL-8309B Ophthalmic Solution Drug: AL-8309B Vehicle

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
Subjects were recruited from 48 study centers located in 14 countries.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
This reporting group includes all enrolled subjects (772). A subject was considered enrolled if they met all of the inclusion criteria and none of the exclusion criteria.

Reporting Groups

	Description
AL-8309B 1.0%	AL-8309B 1.0% Ophthalmic Solution, 1 drop in each eye twice daily for 30 months, up to a maximum of 36 months
AL-8309B 1.75%	AL-8309B 1.75% Ophthalmic Solution, 1 drop in each eye twice daily, for 30 months up to a maximum of 36 months
Vehicle	AL-8309B Vehicle, 1 drop in each eye twice daily, for 30 months up to a maximum of 36 months

Participant Flow: Overall Study

	AL-8309B 1.0%	AL-8309B 1.75%	Vehicle
STARTED	252	259	261
COMPLETED	184	173	184
NOT COMPLETED	68	86	77
Adverse Event	21	32	28
Decision Unrelated to an Adverse Event	15	12	17
Withdrew Consent	9	6	9
Lost to Follow-up	5	5	5
Noncompliance	0	4	4
Sponsor Decision	7	11	7
Did not attend final visit	2	3	0
Subject Decision	3	2	6
Randomization Error	2	0	0
Failed inclusion criteria	3	4	0
Transportation	0	2	0
Subject Moved	0	4	0
Protocol Deviation	1	1	1

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
This analysis population includes all enrolled subjects (772).

Reporting Groups

	Description
AL-8309B 1.0%	AL-8309B 1.0% Ophthalmic Solution, 1 drop in each eye twice daily for 30 months, up to a maximum of 36 months
AL-8309B 1.75%	AL-8309B 1.75% Ophthalmic Solution, 1 drop in each eye twice daily, for 30 months up to a maximum of 36 months
Vehicle	AL-8309B Vehicle, 1 drop in each eye twice daily, for 30 months up to a maximum of 36 months
Total	Total of all reporting groups

Baseline Measures

	AL-8309B 1.0%	AL-8309B 1.75%	Vehicle	Total
Number of Participants [units: participants]	252	259	261	772
Age [units: years] Mean (Standard Deviation)	77.9 (8.0)	78.3 (7.7)	78.8 (7.1)	78.3 (7.6)
Gender [units: participants]				
Female	130	162	147	439
Male	122	97	114	333

Region of Enrollment [units: participants]				
United States	111	112	116	339
France	28	27	29	84
Switzerland	21	21	21	63
Germany	18	20	19	57
Australia	16	18	16	50
Israel	13	15	15	43
Italy	12	15	14	41
Austria	13	13	14	40
Belgium	7	6	6	19
United Kingdom	4	3	3	10
Ireland	3	3	3	9
Japan	3	2	3	8
Portugal	2	3	2	7
Canada	1	1	0	2

Outcome Measures

1. Primary: Mean Annualized Lesion Enlargement Rate From Baseline as Assessed With Fundus Autofluorescence Imaging [Time Frame: Baseline, up to Month 30]

Hide Outcome Measure 1

Measure Type	Primary
Measure Title	Mean Annualized Lesion Enlargement Rate From Baseline as Assessed With Fundus Autofluorescence Imaging
Measure Description	The size of the retinal lesion was measured using the Heidelberg Retinal Angiography system at Baseline, Month 6, Month 12, Month 15, Month 18, Month 24, and Month 30. Images were collected in both eyes; however, one eye from each subject was chosen as the study eye, and only data for the study eye were used for the efficacy analysis. Results were estimated from a longitudinal random effects regression model. A greater lesion growth rate may indicate a faster progression of the disease.
Time Frame	Baseline, up to Month 30
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
This analysis population included all treated subjects. A subject was considered treated if they had a first or last dosing date in the database.

Reporting Groups

	Description
AL-8309B 1.0%	AL-8309B 1.0% Ophthalmic Solution, 1 drop in each eye twice daily for 30 months, up to a maximum of 36 months
AL-8309B 1.75%	AL-8309B 1.75% Ophthalmic Solution, 1 drop in each eye twice daily, for 30 months up to a maximum of 36 months
Vehicle	AL-8309B Vehicle, 1 drop in each eye twice daily, for 30 months up to a maximum of 36 months

Measured Values

	AL-8309B 1.0%	AL-8309B 1.75%	

			Vehicle
Number of Participants Analyzed [units: participants]	**250**	**258**	**260**
Mean Annualized Lesion Enlargement Rate From Baseline as Assessed With Fundus Autofluorescence Imaging [units: square millimeters per year] Mean (95% Confidence Interval)	**1.725 (1.595 to 1.855)**	**1.758 (1.626 to 1.890)**	**1.707 (1.585 to 1.830)**

No statistical analysis provided for Mean Annualized Lesion Enlargement Rate From Baseline as Assessed With Fundus Autofluorescence Imaging

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Adverse events were collected for the duration of the study (3 years, 2 month). Adverse events were obtained as solicited comments from the study subjects and as observations by the study Investigator as outlined in the study protocol.
Additional Description	This analysis population includes all treated subjects (768).

Reporting Groups

	Description
AL-8309B 1.0%	AL-8309B 1.0% Ophthalmic Solution, 1 drop in each eye twice daily for 30 months, up to a maximum of 36 months
AL-8309B 1.75%	AL-8309B 1.75% Ophthalmic Solution, 1 drop in each eye twice daily, for 30 months up to a maximum of 36 months
Vehicle	AL-8309B Vehicle, 1 drop in each eye twice daily, for 30 months up to a maximum of 36 months

Serious Adverse Events

	AL-8309B 1.0%	AL-8309B 1.75%	Vehicle
Total, serious adverse events			
# participants affected / at risk	**86/250 (34.40%)**	**96/258 (37.21%)**	**85/260 (32.69%)**
Blood and lymphatic system disorders			
Anaemia † 1			
# participants affected / at risk	**1/250 (0.40%)**	**3/258 (1.16%)**	**0/260 (0.00%)**
Iron deficiency anaemia † 1			
# participants affected / at risk	**0/250 (0.00%)**	**1/258 (0.39%)**	**0/260 (0.00%)**
Cardiac disorders			
Acute coronary syndrome † 1			
# participants affected / at risk	**1/250 (0.40%)**	**1/258 (0.39%)**	**0/260 (0.00%)**
Angina pectoris † 1			
# participants affected / at risk	**4/250 (1.60%)**	**3/258 (1.16%)**	**1/260 (0.38%)**
Angina unstable † 1			
# participants affected / at risk	**1/250 (0.40%)**	**0/258 (0.00%)**	**0/260 (0.00%)**
Arrhythmia † 1			
# participants affected / at risk	**0/250 (0.00%)**	**0/258 (0.00%)**	**1/260 (0.38%)**
Arrhythmia supraventricular † 1			
# participants affected / at risk	**0/250 (0.00%)**	**0/258 (0.00%)**	**1/260 (0.38%)**
Atrial fibrillation † 1			

# participants affected / at risk	4/250 (1.60%)	3/258 (1.16%)	5/260 (1.92%)
Atrial flutter † 1			
# participants affected / at risk	1/250 (0.40%)	0/258 (0.00%)	0/260 (0.00%)
Atrioventricular block complete † 1			
# participants affected / at risk	1/250 (0.40%)	1/258 (0.39%)	0/260 (0.00%)
Atrioventricular block second degree † 1			
# participants affected / at risk	0/250 (0.00%)	0/258 (0.00%)	1/260 (0.38%)
Bundle branch block † 1			
# participants affected / at risk	0/250 (0.00%)	0/258 (0.00%)	1/260 (0.38%)
Cardiac arrest † 1			
# participants affected / at risk	1/250 (0.40%)	0/258 (0.00%)	0/260 (0.00%)
Cardiac disorder † 1			
# participants affected / at risk	1/250 (0.40%)	0/258 (0.00%)	0/260 (0.00%)
Cardiac failure † 1			
# participants affected / at risk	2/250 (0.80%)	4/258 (1.55%)	0/260 (0.00%)
Cardiac failure acute † 1			
# participants affected / at risk	0/250 (0.00%)	1/258 (0.39%)	0/260 (0.00%)
Cardiac failure congestive † 1			
# participants affected / at risk	4/250 (1.60%)	3/258 (1.16%)	1/260 (0.38%)
Coronary artery disease † 1			
# participants affected / at risk	0/250 (0.00%)	2/258 (0.78%)	1/260 (0.38%)
Coronary artery occlusion † 1			
# participants affected / at risk	1/250 (0.40%)	0/258 (0.00%)	0/260 (0.00%)
Myocardial infarction † 1			
# participants affected / at risk	4/250 (1.60%)	0/258 (0.00%)	0/260 (0.00%)
Myocardial ischaemia † 1			
# participants affected / at risk	1/250 (0.40%)	0/258 (0.00%)	0/260 (0.00%)
Sick sinus syndrome † 1			
# participants affected / at risk	0/250 (0.00%)	1/258 (0.39%)	0/260 (0.00%)
Sinus arrhythmia † 1			
# participants affected / at risk	0/250 (0.00%)	1/258 (0.39%)	0/260 (0.00%)
Tachycardia † 1			
# participants affected / at risk	0/250 (0.00%)	1/258 (0.39%)	0/260 (0.00%)
Ventricular tachycardia † 1			
# participants affected / at risk	0/250 (0.00%)	0/258 (0.00%)	2/260 (0.77%)
Congenital, familial and genetic disorders			
Choledochal cyst † 1			
# participants affected / at risk	0/250 (0.00%)	1/258 (0.39%)	0/260 (0.00%)
Endocrine disorders			
Goitre † 1			
# participants affected / at risk	0/250 (0.00%)	1/258 (0.39%)	0/260 (0.00%)
Eye disorders			
Cataract † 1			
# participants affected / at risk	0/250 (0.00%)	0/258 (0.00%)	1/260 (0.38%)

Macular oedema † [1]			
# participants affected / at risk	**0/250 (0.00%)**	**1/258 (0.39%)**	**0/260 (0.00%)**
Retinal artery occlusion † [1]			
# participants affected / at risk	**0/250 (0.00%)**	**0/258 (0.00%)**	**1/260 (0.38%)**
Retinal detachment † [1]			
# participants affected / at risk	**0/250 (0.00%)**	**1/258 (0.39%)**	**0/260 (0.00%)**
Visual acuity reduced † [1]			
# participants affected / at risk	**1/250 (0.40%)**	**1/258 (0.39%)**	**3/260 (1.15%)**
Gastrointestinal disorders			
Abdominal pain † [1]			
# participants affected / at risk	**1/250 (0.40%)**	**0/258 (0.00%)**	**0/260 (0.00%)**
Diarrhoea † [1]			
# participants affected / at risk	**0/250 (0.00%)**	**0/258 (0.00%)**	**1/260 (0.38%)**
Gastritis † [1]			
# participants affected / at risk	**1/250 (0.40%)**	**1/258 (0.39%)**	**0/260 (0.00%)**
Gastrointestinal haemorrhage † [1]			
# participants affected / at risk	**1/250 (0.40%)**	**2/258 (0.78%)**	**0/260 (0.00%)**
Haematemesis † [1]			
# participants affected / at risk	**0/250 (0.00%)**	**1/258 (0.39%)**	**0/260 (0.00%)**
Inguinal hernia † [1]			
# participants affected / at risk	**0/250 (0.00%)**	**1/258 (0.39%)**	**1/260 (0.38%)**
Intestinal obstruction † [1]			
# participants affected / at risk	**0/250 (0.00%)**	**0/258 (0.00%)**	**1/260 (0.38%)**
Intra-abdominal haematoma † [1]			
# participants affected / at risk	**0/250 (0.00%)**	**1/258 (0.39%)**	**0/260 (0.00%)**
Intussusception † [1]			
# participants affected / at risk	**1/250 (0.40%)**	**0/258 (0.00%)**	**0/260 (0.00%)**
Nausea † [1]			
# participants affected / at risk	**1/250 (0.40%)**	**0/258 (0.00%)**	**0/260 (0.00%)**
Pancreatitis † [1]			
# participants affected / at risk	**2/250 (0.80%)**	**0/258 (0.00%)**	**0/260 (0.00%)**
Pancreatitis acute † [1]			
# participants affected / at risk	**0/250 (0.00%)**	**1/258 (0.39%)**	**1/260 (0.38%)**
Rectal haemorrhage † [1]			
# participants affected / at risk	**0/250 (0.00%)**	**1/258 (0.39%)**	**0/260 (0.00%)**
Retroperitoneal haemorrhage † [1]			
# participants affected / at risk	**0/250 (0.00%)**	**1/258 (0.39%)**	**0/260 (0.00%)**
Small intestinal obstruction † [1]			
# participants affected / at risk	**0/250 (0.00%)**	**0/258 (0.00%)**	**1/260 (0.38%)**
Umbilical hernia † [1]			
# participants affected / at risk	**0/250 (0.00%)**	**1/258 (0.39%)**	**0/260 (0.00%)**
Vomiting † [1]			
# participants affected / at risk	**1/250 (0.40%)**	**0/258 (0.00%)**	**0/260 (0.00%)**
General disorders			

Asthenia † 1			
# participants affected / at risk	**1/250 (0.40%)**	**0/258 (0.00%)**	**2/260 (0.77%)**
Chest discomfort † 1			
# participants affected / at risk	**0/250 (0.00%)**	**0/258 (0.00%)**	**1/260 (0.38%)**
Chest pain † 1			
# participants affected / at risk	**3/250 (1.20%)**	**1/258 (0.39%)**	**0/260 (0.00%)**
Death † 1			
# participants affected / at risk	**0/250 (0.00%)**	**1/258 (0.39%)**	**0/260 (0.00%)**
General physical health deterioration † 1			
# participants affected / at risk	**0/250 (0.00%)**	**0/258 (0.00%)**	**1/260 (0.38%)**
Impaired healing † 1			
# participants affected / at risk	**0/250 (0.00%)**	**0/258 (0.00%)**	**1/260 (0.38%)**
Inflammation † 1			
# participants affected / at risk	**0/250 (0.00%)**	**1/258 (0.39%)**	**0/260 (0.00%)**
Non-cardiac chest pain † 1			
# participants affected / at risk	**1/250 (0.40%)**	**0/258 (0.00%)**	**1/260 (0.38%)**
Pain † 1			
# participants affected / at risk	**2/250 (0.80%)**	**0/258 (0.00%)**	**0/260 (0.00%)**
Pyrexia † 1			
# participants affected / at risk	**0/250 (0.00%)**	**1/258 (0.39%)**	**0/260 (0.00%)**
Hepatobiliary disorders			
Bile duct stone † 1			
# participants affected / at risk	**0/250 (0.00%)**	**1/258 (0.39%)**	**0/260 (0.00%)**
Biliary tract disorder † 1			
# participants affected / at risk	**0/250 (0.00%)**	**1/258 (0.39%)**	**0/260 (0.00%)**
Cholangitis † 1			
# participants affected / at risk	**0/250 (0.00%)**	**1/258 (0.39%)**	**0/260 (0.00%)**
Cholecystitis acute † 1			
# participants affected / at risk	**1/250 (0.40%)**	**0/258 (0.00%)**	**0/260 (0.00%)**
Cirrhosis alcoholic † 1			
# participants affected / at risk	**0/250 (0.00%)**	**1/258 (0.39%)**	**0/260 (0.00%)**
Hepatic cirrhosis † 1			
# participants affected / at risk	**0/250 (0.00%)**	**1/258 (0.39%)**	**0/260 (0.00%)**
Immune system disorders			
Anaphylactic shock † 1			
# participants affected / at risk	**0/250 (0.00%)**	**1/258 (0.39%)**	**0/260 (0.00%)**
Infections and infestations			
Appendicitis † 1			
# participants affected / at risk	**1/250 (0.40%)**	**1/258 (0.39%)**	**0/260 (0.00%)**
Bronchitis † 1			
# participants affected / at risk	**1/250 (0.40%)**	**0/258 (0.00%)**	**0/260 (0.00%)**
Cellulitis † 1			
# participants affected / at risk	**1/250 (0.40%)**	**0/258 (0.00%)**	**1/260 (0.38%)**
Dacryocystitis † 1			

# participants affected / at risk	0/250 (0.00%)	1/258 (0.39%)	0/260 (0.00%)
Diverticulitis † 1			
# participants affected / at risk	4/250 (1.60%)	0/258 (0.00%)	0/260 (0.00%)
Echinococciasis † 1			
# participants affected / at risk	0/250 (0.00%)	0/258 (0.00%)	1/260 (0.38%)
Gastroenteritis † 1			
# participants affected / at risk	1/250 (0.40%)	0/258 (0.00%)	2/260 (0.77%)
Gastroenteritis viral † 1			
# participants affected / at risk	1/250 (0.40%)	0/258 (0.00%)	0/260 (0.00%)
Labyrinthitis † 1			
# participants affected / at risk	0/250 (0.00%)	0/258 (0.00%)	1/260 (0.38%)
Lobar pneumonia † 1			
# participants affected / at risk	0/250 (0.00%)	0/258 (0.00%)	1/260 (0.38%)
Localised infection † 1			
# participants affected / at risk	1/250 (0.40%)	1/258 (0.39%)	0/260 (0.00%)
Lower respiratory tract infection † 1			
# participants affected / at risk	0/250 (0.00%)	0/258 (0.00%)	2/260 (0.77%)
Lung infection † 1			
# participants affected / at risk	0/250 (0.00%)	0/258 (0.00%)	1/260 (0.38%)
Pancreatic abscess † 1			
# participants affected / at risk	0/250 (0.00%)	1/258 (0.39%)	0/260 (0.00%)
Pneumonia † 1			
# participants affected / at risk	3/250 (1.20%)	9/258 (3.49%)	5/260 (1.92%)
Pyelonephritis acute † 1			
# participants affected / at risk	0/250 (0.00%)	1/258 (0.39%)	0/260 (0.00%)
Sepsis † 1			
# participants affected / at risk	1/250 (0.40%)	3/258 (1.16%)	1/260 (0.38%)
Sinusitis † 1			
# participants affected / at risk	1/250 (0.40%)	0/258 (0.00%)	0/260 (0.00%)
Urinary tract infection † 1			
# participants affected / at risk	0/250 (0.00%)	3/258 (1.16%)	1/260 (0.38%)
Urosepsis † 1			
# participants affected / at risk	0/250 (0.00%)	0/258 (0.00%)	1/260 (0.38%)
Injury, poisoning and procedural complications			
Alcohol poisoning † 1			
# participants affected / at risk	1/250 (0.40%)	0/258 (0.00%)	0/260 (0.00%)
Arthropod bite † 1			
# participants affected / at risk	0/250 (0.00%)	0/258 (0.00%)	1/260 (0.38%)
Fall † 1			
# participants affected / at risk	0/250 (0.00%)	1/258 (0.39%)	1/260 (0.38%)
Injury † 1			
# participants affected / at risk	16/250 (6.40%)	14/258 (5.43%)	15/260 (5.77%)
Intraocular lens dislocation † 1			
# participants affected / at risk	1/250 (0.40%)	0/258 (0.00%)	0/260 (0.00%)

Overdose † 1			
# participants affected / at risk	**2/250 (0.80%)**	**0/258 (0.00%)**	**0/260 (0.00%)**
Post procedural complication † 1			
# participants affected / at risk	**0/250 (0.00%)**	**1/258 (0.39%)**	**0/260 (0.00%)**
Skin laceration † 1			
# participants affected / at risk	**0/250 (0.00%)**	**1/258 (0.39%)**	**0/260 (0.00%)**
Subdural haematoma † 1			
# participants affected / at risk	**1/250 (0.40%)**	**0/258 (0.00%)**	**1/260 (0.38%)**
Investigations			
Arthroscopy † 1			
# participants affected / at risk	**1/250 (0.40%)**	**0/258 (0.00%)**	**0/260 (0.00%)**
Catheterisation cardiac † 1			
# participants affected / at risk	**2/250 (0.80%)**	**1/258 (0.39%)**	**1/260 (0.38%)**
Endoscopy † 1			
# participants affected / at risk	**1/250 (0.40%)**	**0/258 (0.00%)**	**0/260 (0.00%)**
Investigation † 1			
# participants affected / at risk	**0/250 (0.00%)**	**0/258 (0.00%)**	**2/260 (0.77%)**
Oxygen saturation decreased † 1			
# participants affected / at risk	**0/250 (0.00%)**	**0/258 (0.00%)**	**1/260 (0.38%)**
Renal function test abnormal † 1			
# participants affected / at risk	**1/250 (0.40%)**	**0/258 (0.00%)**	**0/260 (0.00%)**
Metabolism and nutrition disorders			
Dehydration † 1			
# participants affected / at risk	**0/250 (0.00%)**	**0/258 (0.00%)**	**1/260 (0.38%)**
Hyponatraemia † 1			
# participants affected / at risk	**0/250 (0.00%)**	**0/258 (0.00%)**	**1/260 (0.38%)**
Musculoskeletal and connective tissue disorders			
Arthralgia † 1			
# participants affected / at risk	**1/250 (0.40%)**	**0/258 (0.00%)**	**2/260 (0.77%)**
Arthritis † 1			
# participants affected / at risk	**0/250 (0.00%)**	**1/258 (0.39%)**	**0/260 (0.00%)**
Costochondritis † 1			
# participants affected / at risk	**0/250 (0.00%)**	**0/258 (0.00%)**	**1/260 (0.38%)**
Intervertebral disc degeneration † 1			
# participants affected / at risk	**0/250 (0.00%)**	**1/258 (0.39%)**	**0/260 (0.00%)**
Intervertebral disc disorder † 1			
# participants affected / at risk	**0/250 (0.00%)**	**0/258 (0.00%)**	**1/260 (0.38%)**
Intervertebral disc protrusion † 1			
# participants affected / at risk	**1/250 (0.40%)**	**0/258 (0.00%)**	**0/260 (0.00%)**
Kyphosis † 1			
# participants affected / at risk	**0/250 (0.00%)**	**1/258 (0.39%)**	**0/260 (0.00%)**
Musculoskeletal chest pain † 1			
# participants affected / at risk	**1/250 (0.40%)**	**0/258 (0.00%)**	**0/260 (0.00%)**
Osteoarthritis † 1			

# participants affected / at risk	2/250 (0.80%)	5/258 (1.94%)	2/260 (0.77%)
Osteoporosis † 1			
# participants affected / at risk	1/250 (0.40%)	1/258 (0.39%)	0/260 (0.00%)
Osteoporotic fracture † 1			
# participants affected / at risk	0/250 (0.00%)	0/258 (0.00%)	1/260 (0.38%)
Rheumatoid arthritis † 1			
# participants affected / at risk	1/250 (0.40%)	0/258 (0.00%)	0/260 (0.00%)
Rotator cuff syndrome † 1			
# participants affected / at risk	0/250 (0.00%)	0/258 (0.00%)	1/260 (0.38%)
Spinal column stenosis † 1			
# participants affected / at risk	2/250 (0.80%)	0/258 (0.00%)	0/260 (0.00%)
Temporomandibular joint syndrome † 1			
# participants affected / at risk	0/250 (0.00%)	1/258 (0.39%)	0/260 (0.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma † 1			
# participants affected / at risk	2/250 (0.80%)	0/258 (0.00%)	0/260 (0.00%)
Bladder cancer † 1			
# participants affected / at risk	1/250 (0.40%)	0/258 (0.00%)	0/260 (0.00%)
Breast cancer † 1			
# participants affected / at risk	0/250 (0.00%)	0/258 (0.00%)	1/260 (0.38%)
Breast cancer metastatic † 1			
# participants affected / at risk	0/250 (0.00%)	1/258 (0.39%)	0/260 (0.00%)
Bronchial carcinoma † 1			
# participants affected / at risk	0/250 (0.00%)	1/258 (0.39%)	0/260 (0.00%)
Cardiac valve fibroelastoma † 1			
# participants affected / at risk	0/250 (0.00%)	0/258 (0.00%)	1/260 (0.38%)
Colon cancer metastatic † 1			
# participants affected / at risk	1/250 (0.40%)	0/258 (0.00%)	1/260 (0.38%)
Endometrial cancer † 1			
# participants affected / at risk	0/250 (0.00%)	1/258 (0.39%)	0/260 (0.00%)
Hepatic neoplasm malignant non-resectable † 1			
# participants affected / at risk	1/250 (0.40%)	0/258 (0.00%)	0/260 (0.00%)
Lung adenocarcinoma stage III † 1			
# participants affected / at risk	0/250 (0.00%)	1/258 (0.39%)	0/260 (0.00%)
Lung adenocarcinoma stage IV † 1			
# participants affected / at risk	0/250 (0.00%)	1/258 (0.39%)	0/260 (0.00%)
Lung neoplasm malignant † 1			
# participants affected / at risk	0/250 (0.00%)	1/258 (0.39%)	1/260 (0.38%)
Malignant melanoma † 1			
# participants affected / at risk	0/250 (0.00%)	1/258 (0.39%)	0/260 (0.00%)
Metastases to abdominal cavity † 1			
# participants affected / at risk	0/250 (0.00%)	1/258 (0.39%)	0/260 (0.00%)
Metastases to central nervous system † 1			
# participants affected / at risk	0/250 (0.00%)	0/258 (0.00%)	1/260 (0.38%)

Metastases to lung † 1			
# participants affected / at risk	**0/250 (0.00%)**	**1/258 (0.39%)**	**0/260 (0.00%)**
Multiple myeloma † 1			
# participants affected / at risk	**0/250 (0.00%)**	**1/258 (0.39%)**	**0/260 (0.00%)**
Myelodysplastic syndrome † 1			
# participants affected / at risk	**0/250 (0.00%)**	**1/258 (0.39%)**	**0/260 (0.00%)**
Neoplasm malignant † 1			
# participants affected / at risk	**3/250 (1.20%)**	**1/258 (0.39%)**	**0/260 (0.00%)**
Pancreatic carcinoma non-resectable † 1			
# participants affected / at risk	**0/250 (0.00%)**	**0/258 (0.00%)**	**1/260 (0.38%)**
Parathyroid tumour benign † 1			
# participants affected / at risk	**1/250 (0.40%)**	**0/258 (0.00%)**	**0/260 (0.00%)**
Prostate cancer † 1			
# participants affected / at risk	**2/250 (0.80%)**	**0/258 (0.00%)**	**0/260 (0.00%)**
Renal cell carcinoma † 1			
# participants affected / at risk	**0/250 (0.00%)**	**1/258 (0.39%)**	**0/260 (0.00%)**
Squamous cell carcinoma of skin † 1			
# participants affected / at risk	**0/250 (0.00%)**	**1/258 (0.39%)**	**0/260 (0.00%)**
Thyroid adenoma † 1			
# participants affected / at risk	**0/250 (0.00%)**	**0/258 (0.00%)**	**1/260 (0.38%)**
Thyroid neoplasm † 1			
# participants affected / at risk	**0/250 (0.00%)**	**1/258 (0.39%)**	**0/260 (0.00%)**
Ureteric cancer metastatic † 1			
# participants affected / at risk	**0/250 (0.00%)**	**0/258 (0.00%)**	**1/260 (0.38%)**
Nervous system disorders			
Altered state of consciousness † 1			
# participants affected / at risk	**0/250 (0.00%)**	**0/258 (0.00%)**	**1/260 (0.38%)**
Carpal tunnel syndrome † 1			
# participants affected / at risk	**1/250 (0.40%)**	**0/258 (0.00%)**	**0/260 (0.00%)**
Cerebral artery occlusion † 1			
# participants affected / at risk	**0/250 (0.00%)**	**1/258 (0.39%)**	**0/260 (0.00%)**
Cerebral haematoma † 1			
# participants affected / at risk	**1/250 (0.40%)**	**0/258 (0.00%)**	**0/260 (0.00%)**
Cerebral haemorrhage † 1			
# participants affected / at risk	**1/250 (0.40%)**	**0/258 (0.00%)**	**0/260 (0.00%)**
Cerebrovascular accident † 1			
# participants affected / at risk	**3/250 (1.20%)**	**4/258 (1.55%)**	**3/260 (1.15%)**
Convulsion † 1			
# participants affected / at risk	**1/250 (0.40%)**	**0/258 (0.00%)**	**0/260 (0.00%)**
Dementia † 1			
# participants affected / at risk	**1/250 (0.40%)**	**0/258 (0.00%)**	**1/260 (0.38%)**
Dizziness † 1			
# participants affected / at risk	**0/250 (0.00%)**	**0/258 (0.00%)**	**1/260 (0.38%)**
Dysarthria † 1			

# participants affected / at risk	0/250 (0.00%)	0/258 (0.00%)	1/260 (0.38%)
Extrapyramidal disorder † 1			
# participants affected / at risk	0/250 (0.00%)	1/258 (0.39%)	0/260 (0.00%)
Grand mal convulsion † 1			
# participants affected / at risk	1/250 (0.40%)	0/258 (0.00%)	0/260 (0.00%)
Haemorrhage intracranial † 1			
# participants affected / at risk	0/250 (0.00%)	0/258 (0.00%)	2/260 (0.77%)
Headache † 1			
# participants affected / at risk	0/250 (0.00%)	0/258 (0.00%)	1/260 (0.38%)
Ischaemic stroke † 1			
# participants affected / at risk	0/250 (0.00%)	1/258 (0.39%)	0/260 (0.00%)
Loss of consciousness † 1			
# participants affected / at risk	2/250 (0.80%)	0/258 (0.00%)	0/260 (0.00%)
Nerve compression † 1			
# participants affected / at risk	0/250 (0.00%)	1/258 (0.39%)	0/260 (0.00%)
Parkinson's disease † 1			
# participants affected / at risk	0/250 (0.00%)	0/258 (0.00%)	1/260 (0.38%)
Sciatica † 1			
# participants affected / at risk	0/250 (0.00%)	1/258 (0.39%)	0/260 (0.00%)
Subarachnoid haemorrhage † 1			
# participants affected / at risk	0/250 (0.00%)	0/258 (0.00%)	1/260 (0.38%)
Syncope † 1			
# participants affected / at risk	1/250 (0.40%)	2/258 (0.78%)	2/260 (0.77%)
Syringomyelia † 1			
# participants affected / at risk	0/250 (0.00%)	0/258 (0.00%)	1/260 (0.38%)
Transient ischaemic attack † 1			
# participants affected / at risk	4/250 (1.60%)	2/258 (0.78%)	2/260 (0.77%)
Psychiatric disorders			
Confusional state † 1			
# participants affected / at risk	0/250 (0.00%)	0/258 (0.00%)	1/260 (0.38%)
Depression † 1			
# participants affected / at risk	1/250 (0.40%)	0/258 (0.00%)	0/260 (0.00%)
Depression suicidal † 1			
# participants affected / at risk	0/250 (0.00%)	1/258 (0.39%)	0/260 (0.00%)
Disorientation † 1			
# participants affected / at risk	0/250 (0.00%)	1/258 (0.39%)	1/260 (0.38%)
Hallucination, visual † 1			
# participants affected / at risk	0/250 (0.00%)	0/258 (0.00%)	1/260 (0.38%)
Major depression † 1			
# participants affected / at risk	0/250 (0.00%)	1/258 (0.39%)	1/260 (0.38%)
Mental status changes † 1			
# participants affected / at risk	1/250 (0.40%)	1/258 (0.39%)	0/260 (0.00%)
Schizophrenia † 1			
# participants affected / at risk	1/250 (0.40%)	0/258 (0.00%)	0/260 (0.00%)

Renal and urinary disorders			
Bladder disorder † 1			
# participants affected / at risk	**0/250 (0.00%)**	**1/258 (0.39%)**	**0/260 (0.00%)**
Haematuria † 1			
# participants affected / at risk	**0/250 (0.00%)**	**1/258 (0.39%)**	**1/260 (0.38%)**
Hydronephrosis † 1			
# participants affected / at risk	**1/250 (0.40%)**	**0/258 (0.00%)**	**0/260 (0.00%)**
Nephrolithiasis † 1			
# participants affected / at risk	**1/250 (0.40%)**	**0/258 (0.00%)**	**0/260 (0.00%)**
Pelvi-ureteric obstruction † 1			
# participants affected / at risk	**1/250 (0.40%)**	**0/258 (0.00%)**	**0/260 (0.00%)**
Renal failure † 1			
# participants affected / at risk	**0/250 (0.00%)**	**1/258 (0.39%)**	**0/260 (0.00%)**
Renal failure acute † 1			
# participants affected / at risk	**1/250 (0.40%)**	**1/258 (0.39%)**	**1/260 (0.38%)**
Renal failure chronic † 1			
# participants affected / at risk	**1/250 (0.40%)**	**0/258 (0.00%)**	**0/260 (0.00%)**
Urinary retention † 1			
# participants affected / at risk	**1/250 (0.40%)**	**0/258 (0.00%)**	**0/260 (0.00%)**
Reproductive system and breast disorders			
Benign prostatic hyperplasia † 1			
# participants affected / at risk	**1/250 (0.40%)**	**3/258 (1.16%)**	**1/260 (0.38%)**
Ovarian cyst † 1			
# participants affected / at risk	**0/250 (0.00%)**	**1/258 (0.39%)**	**0/260 (0.00%)**
Prostatomegaly † 1			
# participants affected / at risk	**1/250 (0.40%)**	**1/258 (0.39%)**	**0/260 (0.00%)**
Vaginal fistula † 1			
# participants affected / at risk	**1/250 (0.40%)**	**0/258 (0.00%)**	**0/260 (0.00%)**
Respiratory, thoracic and mediastinal disorders			
Asthma † 1			
# participants affected / at risk	**0/250 (0.00%)**	**0/258 (0.00%)**	**3/260 (1.15%)**
Atelectasis † 1			
# participants affected / at risk	**1/250 (0.40%)**	**0/258 (0.00%)**	**0/260 (0.00%)**
Chronic obstructive pulmonary disease † 1			
# participants affected / at risk	**1/250 (0.40%)**	**4/258 (1.55%)**	**1/260 (0.38%)**
Dyspnoea † 1			
# participants affected / at risk	**2/250 (0.80%)**	**1/258 (0.39%)**	**0/260 (0.00%)**
Dyspnoea exertional † 1			
# participants affected / at risk	**0/250 (0.00%)**	**1/258 (0.39%)**	**0/260 (0.00%)**
Hypoxia † 1			
# participants affected / at risk	**0/250 (0.00%)**	**1/258 (0.39%)**	**0/260 (0.00%)**
Lung disorder † 1			
# participants affected / at risk	**1/250 (0.40%)**	**1/258 (0.39%)**	**0/260 (0.00%)**
Pneumonia aspiration † 1			

# participants affected / at risk	0/250 (0.00%)	0/258 (0.00%)	1/260 (0.38%)
Pulmonary congestion † 1			
# participants affected / at risk	0/250 (0.00%)	0/258 (0.00%)	1/260 (0.38%)
Pulmonary embolism † 1			
# participants affected / at risk	1/250 (0.40%)	0/258 (0.00%)	3/260 (1.15%)
Respiratory acidosis † 1			
# participants affected / at risk	0/250 (0.00%)	1/258 (0.39%)	0/260 (0.00%)
Respiratory arrest † 1			
# participants affected / at risk	0/250 (0.00%)	0/258 (0.00%)	1/260 (0.38%)
Respiratory failure † 1			
# participants affected / at risk	0/250 (0.00%)	0/258 (0.00%)	2/260 (0.77%)
Sleep apnoea syndrome † 1			
# participants affected / at risk	1/250 (0.40%)	0/258 (0.00%)	0/260 (0.00%)
Skin and subcutaneous tissue disorders			
Angioedema † 1			
# participants affected / at risk	1/250 (0.40%)	0/258 (0.00%)	0/260 (0.00%)
Surgical and medical procedures			
Angioplasty † 1			
# participants affected / at risk	0/250 (0.00%)	1/258 (0.39%)	0/260 (0.00%)
Aortic aneurysm repair † 1			
# participants affected / at risk	0/250 (0.00%)	1/258 (0.39%)	0/260 (0.00%)
Aortic valve repair † 1			
# participants affected / at risk	0/250 (0.00%)	0/258 (0.00%)	1/260 (0.38%)
Aortic valve replacement † 1			
# participants affected / at risk	0/250 (0.00%)	1/258 (0.39%)	0/260 (0.00%)
Appendicectomy † 1			
# participants affected / at risk	0/250 (0.00%)	1/258 (0.39%)	0/260 (0.00%)
Bunion operation † 1			
# participants affected / at risk	0/250 (0.00%)	0/258 (0.00%)	1/260 (0.38%)
Cardiac pacemaker insertion † 1			
# participants affected / at risk	0/250 (0.00%)	0/258 (0.00%)	1/260 (0.38%)
Cardioversion † 1			
# participants affected / at risk	0/250 (0.00%)	0/258 (0.00%)	1/260 (0.38%)
Haemorrhoid operation † 1			
# participants affected / at risk	1/250 (0.40%)	0/258 (0.00%)	0/260 (0.00%)
Hip arthroplasty † 1			
# participants affected / at risk	0/250 (0.00%)	2/258 (0.78%)	1/260 (0.38%)
Hip surgery † 1			
# participants affected / at risk	0/250 (0.00%)	0/258 (0.00%)	1/260 (0.38%)
Inguinal hernia repair † 1			
# participants affected / at risk	0/250 (0.00%)	0/258 (0.00%)	1/260 (0.38%)
Intraocular lens implant † 1			
# participants affected / at risk	1/250 (0.40%)	0/258 (0.00%)	0/260 (0.00%)
Intrathecal pump insertion † 1			

# participants affected / at risk	1/250 (0.40%)	0/258 (0.00%)	0/260 (0.00%)
Joint arthroplasty † 1			
# participants affected / at risk	0/250 (0.00%)	0/258 (0.00%)	1/260 (0.38%)
Keratoplasty † 1			
# participants affected / at risk	0/250 (0.00%)	1/258 (0.39%)	0/260 (0.00%)
Knee arthroplasty † 1			
# participants affected / at risk	2/250 (0.80%)	1/258 (0.39%)	0/260 (0.00%)
Knee operation † 1			
# participants affected / at risk	0/250 (0.00%)	1/258 (0.39%)	1/260 (0.38%)
Malignant tumour excision † 1			
# participants affected / at risk	0/250 (0.00%)	1/258 (0.39%)	0/260 (0.00%)
Radiotherapy to eye † 1			
# participants affected / at risk	1/250 (0.40%)	0/258 (0.00%)	0/260 (0.00%)
Salivary gland operation † 1			
# participants affected / at risk	0/250 (0.00%)	1/258 (0.39%)	0/260 (0.00%)
Scoliosis surgery † 1			
# participants affected / at risk	1/250 (0.40%)	0/258 (0.00%)	0/260 (0.00%)
Spinal operation † 1			
# participants affected / at risk	0/250 (0.00%)	0/258 (0.00%)	1/260 (0.38%)
Vasodilation procedure † 1			
# participants affected / at risk	0/250 (0.00%)	0/258 (0.00%)	1/260 (0.38%)
Vascular disorders			
Aortic aneurysm † 1			
# participants affected / at risk	0/250 (0.00%)	1/258 (0.39%)	0/260 (0.00%)
Aortic stenosis † 1			
# participants affected / at risk	1/250 (0.40%)	1/258 (0.39%)	0/260 (0.00%)
Arterial occlusive disease † 1			
# participants affected / at risk	0/250 (0.00%)	1/258 (0.39%)	1/260 (0.38%)
Circulatory collapse † 1			
# participants affected / at risk	0/250 (0.00%)	0/258 (0.00%)	1/260 (0.38%)
Deep vein thrombosis † 1			
# participants affected / at risk	2/250 (0.80%)	0/258 (0.00%)	0/260 (0.00%)
Haemorrhage † 1			
# participants affected / at risk	0/250 (0.00%)	1/258 (0.39%)	0/260 (0.00%)
Hypertension † 1			
# participants affected / at risk	1/250 (0.40%)	0/258 (0.00%)	0/260 (0.00%)
Hypertensive crisis † 1			
# participants affected / at risk	0/250 (0.00%)	2/258 (0.78%)	0/260 (0.00%)
Hypotension † 1			
# participants affected / at risk	0/250 (0.00%)	0/258 (0.00%)	1/260 (0.38%)
Peripheral arterial occlusive disease † 1			
# participants affected / at risk	1/250 (0.40%)	0/258 (0.00%)	0/260 (0.00%)
Peripheral vascular disorder † 1			
# participants affected / at risk	0/250 (0.00%)	0/258 (0.00%)	1/260 (0.38%)

Temporal arteritis † 1			
# participants affected / at risk	**0/250 (0.00%)**	**0/258 (0.00%)**	**1/260 (0.38%)**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA

Other Adverse Events

Hide Other Adverse Events

Time Frame	Adverse events were collected for the duration of the study (3 years, 2 month). Adverse events were obtained as solicited comments from the study subjects and as observations by the study Investigator as outlined in the study protocol.
Additional Description	This analysis population includes all treated subjects (768).

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
AL-8309B 1.0%	AL-8309B 1.0% Ophthalmic Solution, 1 drop in each eye twice daily for 30 months, up to a maximum of 36 months
AL-8309B 1.75%	AL-8309B 1.75% Ophthalmic Solution, 1 drop in each eye twice daily, for 30 months up to a maximum of 36 months
Vehicle	AL-8309B Vehicle, 1 drop in each eye twice daily, for 30 months up to a maximum of 36 months

Other Adverse Events

	AL-8309B 1.0%	AL-8309B 1.75%	Vehicle
Total, other (not including serious) adverse events			
# participants affected / at risk	**207/250 (82.80%)**	**212/258 (82.17%)**	**207/260 (79.62%)**
Eye disorders			
Blepharitis † 1			
# participants affected / at risk	**15/250 (6.00%)**	**19/258 (7.36%)**	**7/260 (2.69%)**
Cataract † 1			
# participants affected / at risk	**30/250 (12.00%)**	**23/258 (8.91%)**	**23/260 (8.85%)**
Choroidal neovascularisation † 1			
# participants affected / at risk	**20/250 (8.00%)**	**20/258 (7.75%)**	**16/260 (6.15%)**
Eye irritation † 1			
# participants affected / at risk	**20/250 (8.00%)**	**27/258 (10.47%)**	**9/260 (3.46%)**
Eye pain † 1			
# participants affected / at risk	**16/250 (6.40%)**	**21/258 (8.14%)**	**11/260 (4.23%)**
Lacrimation increased † 1			
# participants affected / at risk	**8/250 (3.20%)**	**15/258 (5.81%)**	**3/260 (1.15%)**
Macular degeneration † 1			
# participants affected / at risk	**18/250 (7.20%)**	**20/258 (7.75%)**	**14/260 (5.38%)**
Retinal haemorrhage † 1			
# participants affected / at risk	**14/250 (5.60%)**	**16/258 (6.20%)**	**21/260 (8.08%)**
Visual acuity reduced † 1			
# participants affected / at risk	**101/250 (40.40%)**	**107/258 (41.47%)**	**109/260 (41.92%)**

Gastrointestinal disorders			
Constipation † 1			
# participants affected / at risk	**13/250 (5.20%)**	**4/258 (1.55%)**	**13/260 (5.00%)**
Gastrooesophageal reflux disease † 1			
# participants affected / at risk	**15/250 (6.00%)**	**11/258 (4.26%)**	**9/260 (3.46%)**
Nausea † 1			
# participants affected / at risk	**15/250 (6.00%)**	**8/258 (3.10%)**	**8/260 (3.08%)**
General disorders			
Oedema peripheral † 1			
# participants affected / at risk	**14/250 (5.60%)**	**4/258 (1.55%)**	**11/260 (4.23%)**
Infections and infestations			
Bronchitis † 1			
# participants affected / at risk	**15/250 (6.00%)**	**21/258 (8.14%)**	**28/260 (10.77%)**
Influenza † 1			
# participants affected / at risk	**7/250 (2.80%)**	**8/258 (3.10%)**	**14/260 (5.38%)**
Nasopharyngitis † 1			
# participants affected / at risk	**19/250 (7.60%)**	**19/258 (7.36%)**	**22/260 (8.46%)**
Urinary tract infection † 1			
# participants affected / at risk	**20/250 (8.00%)**	**28/258 (10.85%)**	**19/260 (7.31%)**
Injury, poisoning and procedural complications			
Injury † 1			
# participants affected / at risk	**34/250 (13.60%)**	**38/258 (14.73%)**	**31/260 (11.92%)**
Musculoskeletal and connective tissue disorders			
Arthralgia † 1			
# participants affected / at risk	**6/250 (2.40%)**	**15/258 (5.81%)**	**9/260 (3.46%)**
Back pain † 1			
# participants affected / at risk	**13/250 (5.20%)**	**12/258 (4.65%)**	**17/260 (6.54%)**
Osteoarthritis † 1			
# participants affected / at risk	**14/250 (5.60%)**	**21/258 (8.14%)**	**12/260 (4.62%)**
Nervous system disorders			
Headache † 1			
# participants affected / at risk	**19/250 (7.60%)**	**15/258 (5.81%)**	**9/260 (3.46%)**
Psychiatric disorders			
Depression † 1			
# participants affected / at risk	**10/250 (4.00%)**	**9/258 (3.49%)**	**18/260 (6.92%)**
Vascular disorders			
Hypertension † 1			
# participants affected / at risk	**24/250 (9.60%)**	**30/258 (11.63%)**	**36/260 (13.85%)**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data
No text entered.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.
There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.
The agreement is: ☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo. ☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo. ☑ Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed. **Restriction Description:** Sponsor reserves the right of prior review of any publication or presentation of information related to the study.

Results Point of Contact:

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No publications provided

Responsible Party:	Alcon Research
ClinicalTrials.gov Identifier:	NCT00890097 History of Changes
Other Study ID Numbers:	**C-08-36**
Study First Received:	April 27, 2009
Results First Received:	June 4, 2014
Last Updated:	June 4, 2014
Health Authority:	United States: Food and Drug Administration