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Trial record **1 of 1** for: C-10-083

Previous Study | Return to List | Next Study

ESBA1008 Safety, Tolerability and Effects in Wet Age-Related Macular Degeneration (AMD) Patients

This study has been completed.

Sponsor:
Alcon Research

Information provided by (Responsible Party):
Alcon Research

ClinicalTrials.gov Identifier:
NCT01304693

First received: February 24, 2011
Last updated: July 7, 2014
Last verified: July 2014
History of Changes

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

Results First Received: April 7, 2014

Study Type:	Interventional
Study Design:	Allocation: Randomized; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Outcomes Assessor); Primary Purpose: Treatment
Condition:	Exudative Age-Related Macular Degeneration
Interventions:	Biological: ESBA1008 solution Biological: Ranibizumab 0.5 mg

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 51 investigational centers located in the United States, Europe, Israel, and Australia.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
Of the 376 enrolled, 182 were exited as screen failures prior to exposure to randomization and exposure to the study drug. This reporting group includes all patients who were randomized, received study drug, and completed at least 1 scheduled on-therapy study visit (ITT) (194).

Reporting Groups

	Description
ESBA1008 Dose A	Single intravitreal injection with 6-month follow-up
ESBA1008 Dose B	Single intravitreal injection with 6-month follow-up
ESBA1008 Dose C	Single intravitreal injection with 6-month follow-up
ESBA1008 Dose D	Single intravitreal injection with 6-month follow-up
Lucentis	Single intravitreal injection with 6-month follow-up

Participant Flow: Overall Study

	ESBA1008 Dose A	ESBA1008 Dose B	ESBA1008 Dose C	ESBA1008 Dose D	Lucentis
STARTED	10	35	48	40	61
COMPLETED	10	35	47	39	60
NOT COMPLETED	0	0	1	1	1
Adverse Event	0	0	0	0	1
Decision Unrelated to an Adverse Event	0	0	1	1	0

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 patients who were randomized, received study drug, and completed at least 1 scheduled on-therapy study visit (ITT).

Reporting Groups

	Description
ESBA1008 Dose A	Single intravitreal injection with 6-month follow-up
ESBA1008 Dose B	Single intravitreal injection with 6-month follow-up
ESBA1008 Dose C	Single intravitreal injection with 6-month follow-up
ESBA1008 Dose D	Single intravitreal injection with 6-month follow-up
Lucentis	Single intravitreal injection with 6-month follow-up
Total	Total of all reporting groups

Baseline Measures

	ESBA1008 Dose A	ESBA1008 Dose B	ESBA1008 Dose C	ESBA1008 Dose D	Lucentis	Total
Number of Participants [units: participants]	10	35	48	40	61	194
Age [1] [units: years] Mean (Standard Deviation)	75.9 (6.9)	78.5 (8.3)	75.2 (7.7)	74.5 (9.8)	77.8 (8.1)	76.5 (8.4)
Gender [units: participants]						
Female	6	15	27	25	33	106
Male	4	20	21	15	28	88

[1] This analysis population includes all patients who were randomized, received study drug, and completed at least 1 scheduled on-therapy study visit (Intent-to-Treat).

Outcome Measures

Hide All Outcome Measures

1. Primary: Change From Baseline at Month 1 in Central Subfield Thickness (CSFT) as Measured by Spectral Domain Ocular Coherence Tomography (SD-OCT) [Time Frame: Baseline, Month 1]

Measure Type	Primary
Measure Title	Change From Baseline at Month 1 in Central Subfield Thickness (CSFT) as Measured by Spectral Domain Ocular Coherence Tomography (SD-OCT)
Measure Description	CSFT is a retinal thickness measurement and was measured with SD-OCT. A thickening of the retina is characteristic of wet AMD, and a reduction in CSFT may indicate an improvement in ocular health. One eye (ie, study eye) contributed to the mean.
Time Frame	Baseline, Month 1
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 includes all patients who were randomized, received study drug, and completed at least 1 scheduled on-therapy study visit (ITT). Efficacy data from visits occurring after standard of care (SoC) were censored and replaced based on LOCF,i.e. by the data observed at the time of the SoC decision.

Reporting Groups

	Description
ESBA1008 Dose A	Single intravitreal injection with 6-month follow-up
ESBA1008 Dose B	Single intravitreal injection with 6-month follow-up
ESBA1008 Dose C	Single intravitreal injection with 6-month follow-up
ESBA1008 Dose D	Single intravitreal injection with 6-month follow-up
Lucentis	Single intravitreal injection with 6-month follow-up

Measured Values

	ESBA1008 Dose A	ESBA1008 Dose B	ESBA1008 Dose C	ESBA1008 Dose D	Lucentis
Number of Participants Analyzed [units: participants]	**10**	**35**	**48**	**40**	**61**
Change From Baseline at Month 1 in Central Subfield Thickness (CSFT) as Measured by Spectral Domain Ocular Coherence Tomography (SD-OCT) [units: microns] Mean (Standard Deviation)	**-142.3 (78.8)**	**-181.6 (107.2)**	**-175.6 (138.9)**	**-174.9 (101.3)**	**-159.4 (110.1)**

No statistical analysis provided for Change From Baseline at Month 1 in Central Subfield Thickness (CSFT) as Measured by Spectral Domain Ocular Coherence Tomography (SD-OCT)

2. Secondary: Duration of Effect Measured by the Time From Randomization to Receipt of Standard of Care as Determined by the Investigator Based on Protocol Criteria [Time Frame: Time to event, up to Month 6]

Measure Type	Secondary
Measure Title	Duration of Effect Measured by the Time From Randomization to Receipt of Standard of Care as Determined by the Investigator Based on Protocol Criteria
Measure Description	Standard of care (SOC) therapy for exudative AMD was implemented if any protocol-specified criteria relating to CSFT, best-corrected visual acuity, or clinically significant intraocular hemorrhages in the study eye were met, in the opinion of the Investigator.

Time Frame	Time to event, up to Month 6
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.
ITT: All patients who were randomized, received study drug, and completed at least 1 scheduled on-therapy study visit.

Reporting Groups

	Description
ESBA1008 Dose A	Single intravitreal injection with 6-month follow-up
ESBA1008 Dose B	Single intravitreal injection with 6-month follow-up
ESBA1008 Dose C	Single intravitreal injection with 6-month follow-up
ESBA1008 Dose D	Single intravitreal injection with 6-month follow-up
Lucentis	Single intravitreal injection with 6-month follow-up

Measured Values

	ESBA1008 Dose A	ESBA1008 Dose B	ESBA1008 Dose C	ESBA1008 Dose D	Lucentis
Number of Participants Analyzed [units: participants]	**10**	**35**	**48**	**40**	**61**
Duration of Effect Measured by the Time From Randomization to Receipt of Standard of Care as Determined by the Investigator Based on Protocol Criteria [units: Days] Median (Inter-Quartile Range)	**45 (30 to 60)**	**75 (45 to 120)**	**67.5 (37.5 to 120)**	**75 (37.5 to 150)**	**45 (25 to 75)**

No statistical analysis provided for Duration of Effect Measured by the Time From Randomization to Receipt of Standard of Care as Determined by the Investigator Based on Protocol Criteria

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Adverse events were collected for the duration of the study (2 years, 5 months). An AE was considered to be any untoward medical occurrence in a patient exposed to study drug. The AE did not have to have had a causal relationship with the study drug.
Additional Description	This analysis population includes all patients exposed to the study drug, as treated. It should be noted that 6 patients were misdosed: 1 randomized to ESBA1008 B received ESBA1008 A; 1 randomized to ESBA1008 C received ESBA1008 B; and 4 randomized to ESBA1008 B received ESBA1008 D.

Reporting Groups

	Description
ESBA1008 Dose A	Single intravitreal injection with 6-month follow-up
ESBA1008 Dose B	Single intravitreal injection with 6-month follow-up
ESBA1008 Dose C	Single intravitreal injection with 6-month follow-up
ESBA1008 Dose D	Single intravitreal injection with 6-month follow-up
Lucentis	Single intravitreal injection with 6-month follow-up

Serious Adverse Events

	ESBA1008 Dose A	ESBA1008 Dose B	ESBA1008 Dose C	ESBA1008 Dose D	Lucentis
Total, serious adverse events					
# participants affected / at risk	**0/11 (0.00%)**	**4/31 (12.90%)**	**3/47 (6.38%)**	**3/44 (6.82%)**	**7/61 (11.48%)**
Cardiac disorders					
Acute myocardial infarction † 1					
# participants affected / at risk	**0/11 (0.00%)**	**0/31 (0.00%)**	**0/47 (0.00%)**	**1/44 (2.27%)**	**0/61 (0.00%)**
Eye disorders					
Visual acuity reduced † 1					
# participants affected / at risk	**0/11 (0.00%)**	**1/31 (3.23%)**	**0/47 (0.00%)**	**1/44 (2.27%)**	**0/61 (0.00%)**
Gastrointestinal disorders					
Pancreatitis acute † 1					
# participants affected / at risk	**0/11 (0.00%)**	**0/31 (0.00%)**	**0/47 (0.00%)**	**1/44 (2.27%)**	**0/61 (0.00%)**
General disorders					
Multi-organ failure † 1					
# participants affected / at risk	**0/11 (0.00%)**	**0/31 (0.00%)**	**0/47 (0.00%)**	**1/44 (2.27%)**	**0/61 (0.00%)**
Hepatobiliary disorders					
Hepatitis † 1					
# participants affected / at risk	**0/11 (0.00%)**	**0/31 (0.00%)**	**1/47 (2.13%)**	**0/44 (0.00%)**	**0/61 (0.00%)**
Infections and infestations					
Cellulitis † 1					
# participants affected / at risk	**0/11 (0.00%)**	**0/31 (0.00%)**	**0/47 (0.00%)**	**0/44 (0.00%)**	**1/61 (1.64%)**
Endophthalmitis † 1					
# participants affected / at risk	**0/11 (0.00%)**	**0/31 (0.00%)**	**0/47 (0.00%)**	**0/44 (0.00%)**	**1/61 (1.64%)**
Pneumonia † 1					
# participants affected / at risk	**0/11 (0.00%)**	**0/31 (0.00%)**	**0/47 (0.00%)**	**0/44 (0.00%)**	**2/61 (3.28%)**
Injury, poisoning and procedural complications					
Post-procedural haematoma † 1					
# participants affected / at risk	**0/11 (0.00%)**	**0/31 (0.00%)**	**0/47 (0.00%)**	**1/44 (2.27%)**	**0/61 (0.00%)**
Nervous system disorders					
Cerebrovascular accident † 1					
# participants affected / at risk	**0/11 (0.00%)**	**1/31 (3.23%)**	**0/47 (0.00%)**	**0/44 (0.00%)**	**1/61 (1.64%)**
Syncope † 1					
# participants affected / at risk	**0/11 (0.00%)**	**1/31 (3.23%)**	**0/47 (0.00%)**	**0/44 (0.00%)**	**0/61 (0.00%)**
Transient ischaemic attack † 1					
# participants affected / at risk	**0/11 (0.00%)**	**1/31 (3.23%)**	**0/47 (0.00%)**	**0/44 (0.00%)**	**0/61 (0.00%)**
Vertebrobasilar insufficiency † 1					
# participants affected / at risk	**0/11 (0.00%)**	**0/31 (0.00%)**	**1/47 (2.13%)**	**0/44 (0.00%)**	**0/61 (0.00%)**
Respiratory, thoracic and mediastinal disorders					

Pulmonary oedema † 1					
# participants affected / at risk	**0/11 (0.00%)**	**1/31 (3.23%)**	**0/47 (0.00%)**	**0/44 (0.00%)**	**0/61 (0.00%)**
Chronic obstructive pulmonary disease † 1					
# participants affected / at risk	**0/11 (0.00%)**	**0/31 (0.00%)**	**1/47 (2.13%)**	**0/44 (0.00%)**	**0/61 (0.00%)**
Acute respiratory failure † 1					
# participants affected / at risk	**0/11 (0.00%)**	**0/31 (0.00%)**	**0/47 (0.00%)**	**1/44 (2.27%)**	**0/61 (0.00%)**
Dyspnoea † 1					
# participants affected / at risk	**0/11 (0.00%)**	**0/31 (0.00%)**	**0/47 (0.00%)**	**0/44 (0.00%)**	**1/61 (1.64%)**
Skin and subcutaneous tissue disorders					
Blister † 1					
# participants affected / at risk	**0/11 (0.00%)**	**0/31 (0.00%)**	**1/47 (2.13%)**	**0/44 (0.00%)**	**0/61 (0.00%)**
Surgical and medical procedures					
Aortic bypass † 1					
# participants affected / at risk	**0/11 (0.00%)**	**0/31 (0.00%)**	**0/47 (0.00%)**	**0/44 (0.00%)**	**1/61 (1.64%)**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 13.0

Other Adverse Events

Hide Other Adverse Events

Time Frame	Adverse events were collected for the duration of the study (2 years, 5 months). An AE was considered to be any untoward medical occurrence in a patient exposed to study drug. The AE did not have to have had a causal relationship with the study drug.
Additional Description	This analysis population includes all patients exposed to the study drug, as treated. It should be noted that 6 patients were misdosed: 1 randomized to ESBA1008 B received ESBA1008 A; 1 randomized to ESBA1008 C received ESBA1008 B; and 4 randomized to ESBA1008 B received ESBA1008 D.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
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ESBA1008 Dose B	Single intravitreal injection with 6-month follow-up
ESBA1008 Dose C	Single intravitreal injection with 6-month follow-up
ESBA1008 Dose D	Single intravitreal injection with 6-month follow-up
Lucentis	Single intravitreal injection with 6-month follow-up

Other Adverse Events

	ESBA1008 Dose A	ESBA1008 Dose B	ESBA1008 Dose C	ESBA1008 Dose D	Lucentis
Total, other (not including serious) adverse events					
# participants affected / at risk	**1/11 (9.09%)**	**10/31 (32.26%)**	**17/47 (36.17%)**	**16/44 (36.36%)**	**13/61 (21.31%)**

Eye disorders					
Conjunctival haemorrhage † 1					
# participants affected / at risk	**0/11 (0.00%)**	**3/31 (9.68%)**	**3/47 (6.38%)**	**8/44 (18.18%)**	**2/61 (3.28%)**
Retinal haemorrhage † 1					
# participants affected / at risk	**0/11 (0.00%)**	**1/31 (3.23%)**	**2/47 (4.26%)**	**1/44 (2.27%)**	**4/61 (6.56%)**
Visual acuity reduced † 1					
# participants affected / at risk	**0/11 (0.00%)**	**2/31 (6.45%)**	**1/47 (2.13%)**	**2/44 (4.55%)**	**3/61 (4.92%)**
Eye pain † 1					
# participants affected / at risk	**0/11 (0.00%)**	**0/31 (0.00%)**	**4/47 (8.51%)**	**1/44 (2.27%)**	**1/61 (1.64%)**
Infections and infestations					
Nasopharnygitis † 1					
# participants affected / at risk	**1/11 (9.09%)**	**0/31 (0.00%)**	**3/47 (6.38%)**	**3/44 (6.82%)**	**2/61 (3.28%)**
Urinary tract infection † 1					
# participants affected / at risk	**0/11 (0.00%)**	**4/31 (12.90%)**	**1/47 (2.13%)**	**2/44 (4.55%)**	**0/61 (0.00%)**
Bronchitis † 1					
# participants affected / at risk	**0/11 (0.00%)**	**0/31 (0.00%)**	**3/47 (6.38%)**	**0/44 (0.00%)**	**3/61 (4.92%)**
Pneumonia † 1					
# participants affected / at risk	**0/11 (0.00%)**	**1/31 (3.23%)**	**0/47 (0.00%)**	**0/44 (0.00%)**	**3/61 (4.92%)**
Musculoskeletal and connective tissue disorders					
Back pain † 1					
# participants affected / at risk	**0/11 (0.00%)**	**0/31 (0.00%)**	**3/47 (6.38%)**	**0/44 (0.00%)**	**1/61 (1.64%)**
Vascular disorders					
Hypertension † 1					
# participants affected / at risk	**0/11 (0.00%)**	**1/31 (3.23%)**	**5/47 (10.64%)**	**2/44 (4.55%)**	**0/61 (0.00%)**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 13.0

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:	NCT01304693 History of Changes
Other Study ID Numbers:	**C-10-083**
Study First Received:	February 24, 2011
Results First Received:	April 7, 2014
Last Updated:	July 7, 2014
Health Authority:	United States: Food and Drug Administration Australia: Department of Health and Ageing Therapeutic Goods Administration Austria : Federal Ministry for Labour, Health, and Social Affairs Germany: Federal Institute for Drugs and Medical Devices France: Afssaps - Agence française de sécurité sanitaire des produits de santé (Saint-Denis) Israel: Ethics Commission