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Novartis Clinical Trials Results

Sponsor
Alcon Research, Ltd.

Generic Drug Name
Brolucizumab

Trial Indication(s)
Exudative Age-Related Macular Degeneration

Protocol Number
C-12-006

Protocol Title
Efficacy and Safety Study of ESBA1008 Versus EYLEA®

Clinical Trial Phase
Phase 2

Phase of Drug Development

Phase 2

Study Start/End Dates
11 March 2013 to 18 August 2014

Reason for Termination

No applicable.

Study Design/Methodology
This was a prospective, randomized, double-masked, multicenter, 2-arm study. The study population was planned to include approximately 84 subjects who were 50 years of age or older with untreated active choroidal neovascularization (CNV) due to age related macular degeneration (AMD) in the study eye. The study consisted of 16 visits (Screening, Baseline [Day 0], and 14 injection

and/or assessment visits) that occurred at 4-week intervals through Week 56. Enrolled subjects were randomized 1:1 to receive ESBA1008 or EYLEA. Subjects in the ESBA1008 group received active intravitreal (IVT) injections at Day 0 and at Weeks 4, 8, 16, 24, 32, and 44 and sham injections (to maintain masking) at Weeks 40 and 48. Subjects in the EYLEA group received IVT injections at Day 0, Weeks 4, 8, 16, 24, 32, 40, and Week 48, and a sham injection at Week 44 (to maintain masking). All subjects were followed to Week 56.

Centers
Subjects were recruited from 41 investigational centers located in the US.

Objectives

Primary objective(s)

Primary Objective: To compare the efficacy of ESBA1008 6 mg/50 µL to EYLEA 2 mg/50 µL at 12 weeks (4 weeks after 3 loading doses given at 4-week intervals)

Secondary objective(s)

- To compare the efficacy of ESBA1008 6 mg/50 µL to EYLEA 2 mg/50 µL at 16 weeks (8 weeks after 3 loading doses given at 4-week intervals)
- To compare the efficacy of ESBA1008 6 mg/50 µL with the efficacy of EYLEA 2 mg/50 µL up to 56 weeks

Test Product (s), Dose(s), and Mode(s) of Administration

ESBA1008 solution, 7 intravitreal (IVT) injections, as specified in protocol.

Statistical Methods
The primary analysis data set was the full analyses set (FAS), which included all subjects who were randomized, received at least 1 treatment, had a baseline value, and had at least 1 postbaseline measurement of the primary efficacy variable, BCVA. Data for subjects included in the FAS were analyzed based on the randomized treatment assignment for each subject (“as randomized”) as well as the actual treatment received by each subject (“as treated”). The per protocol (PP) population was defined in relation to Week 12 and included all subjects in the FAS who received all 3 initial IVT injections, had no critical protocol deviations, and had a valid assessment of the primary efficacy variable (BCVA) at Week 12 (primary endpoint). Data for subjects included in the PP analysis set were analyzed based on the randomized treatment assignment for each subject. The pretreatment safety analysis set included all subjects who consented to participate in the study. The treatment emergent safety analysis set included all subjects who were randomized and received at least 1 IVT injection. Within the safety analysis sets, subjects were analyzed according to the first treatment received.

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Study Population: Key Inclusion/Exclusion Criteria

Inclusion Criteria:

- Give written informed consent; be able to make the required study visits and follow instructions.
- Diagnosis of wet age-related macular degeneration, as specified in protocol.
- Best-corrected visual acuity (BCVA) as specified in protocol
- Other protocol-specified inclusion criteria may apply.

Exclusion Criteria:

- Either eye: Any active ocular or periocular infection or active intraocular inflammation.
- Study eye: Any approved or investigational treatment for exudative AMD other than vitamin supplements.
- Study eye: Any current or history of macular or retinal disease other than exudative AMD.
- Study eye: Any concurrent intraocular condition that, in the opinion of the Investigator, could require medical or surgical intervention during the course of the study to prevent or treat vision loss, or that limits the potential to gain visual acuity with the investigational product.
- Study eye: Uncontrolled glaucoma.
- Study eye: Any ocular disease that, in the opinion of the Investigator, could compromise the visual acuity.
- Study eye: History of eye surgery, as specified in protocol.
- Study eye: Use of corticosteroids, as specified in protocol.
- Any medical condition that, in the opinion of the Investigator, would preclude scheduled study visits, completion of the study or safe administration of investigational product.
- Any screening laboratory result that, in the opinion of the Investigator, would make the patient unsuitable for study participation.
- History of hypersensitivity to any component used in the study, as assessed by the Investigator.
- Women of childbearing potential: Lactating, pregnant, plan to become pregnant, or not using adequate birth control, as specified in protocol.
- Participation in an investigational drug or device study within time period specified in protocol.
- Other protocol-defined exclusion criteria may apply.

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Participant Flow Table

Subject Disposition (All Enrolled Subjects) Overall Study

	ESBA 1008		EYLEA		Overall	
	n	(%)	n	(%)	n	(%)
Total enrolled					173	
Screen failure					83	
Randomized[a]	45		45		90	
As Randomized:						
Randomized and treated	45	(100.0)	44	(97.8)	89	(98.9)
Completed	42	(93.3)	41	(91.1)	83	(92.2)
Discontinued	3	(6.7)	4	(8.9)	7	(7.8)
Adverse event	1	(2.2)	1	(2.2)	2	(2.2)
Death	1	(2.2)	0	(0.0)	1	(1.1)
Protocol violation	0	(0.0)	2	(4.4)	2	(2.2)
Withdrawal by subject	1	(2.2)	1	(2.2)	2	(2.2)
As Treated[b]**:**						
Randomized and treated	44	(97.8)	45	(100.0)	89	(98.9)
Completed	41	(91.1)	42	(93.3)	83	(92.2)
Discontinued	3	(6.7)	3	(6.7)	6	(6.7)
Adverse event	1	(2.2)	1	(2.2)	2	(2.2)
Death	1	(2.2)	0	(0.0)	1	(1.1)
Protocol violation	0	(0.0)	1	(2.2)	1	(1.1)
Withdrawal by subject	1	(2.2)	1	(2.2)	2	(2.2)

ESBA 1008 = ESBA 1008 6 mg/50µL
EYLEA = EYLEA 2 mg/50µL
Percentages are based on the number of subjects randomized in each treatment group
[a]One subject randomized to EYLEA did not receive treatment
[b]One subject randomized to ESBA 1008 received EYLEA treatment

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Baseline Characteristics

Summary of Demographic Characteristics (Full Analysis Set/As Treated)

	ESBA 1008 (N=44)	EYLEA (N=45)	Overall (N=89)
Age (in years)			
N	44	45	89
Mean (SD)	78.8 (9.7)	77.3 (9.1)	78.0 (9.4)
Median	80.0	79.0	80.0
(Min, Max)	(58, 96)	(55, 92)	(55, 96)
Age (in years), n (%)			
<65 years	6 (13.6)	6 (13.3)	12 (13.5)
65-74 years	6 (13.6)	10 (22.2)	16 (18.0)
75-84 years	19 (43.2)	18 (40.0)	37 (41.6)
≥85 years	13 (29.5)	11 (24.4)	24 (27.0)
Gender, n (%)			
Male	16 (36.4)	20 (44.4)	36 (40.4)
Female	28 (63.6)	25 (55.6)	53 (59.6)
Race, n (%)			
White	42 (95.5)	44 (97.8)	86 (96.6)
Black or African American	1 (2.3)	0 (0.0)	1 (1.1)
Asian	1 (2.3)	1 (2.2)	2 (2.2)
Ethnicity, n (%)			
Hispanic or Latino	0 (0.0)	1 (2.2)	1 (1.1)
Not Hispanic or Latino	44 (100.0)	44 (97.8)	88 (98.9)

ESBA 1008 = ESBA 1008 6 mg/50µL
EYLEA = EYLEA 2 mg/50µL
Percentages are based on the number of subjects with available data in each subgroup category
Analysis using actual treatment received

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Primary Outcome Result

Descriptive Statistics for BCVA and Change from Baseline (No. of Letters) by Visit (Full Analysis Set/As Treated - LOCF)

			ESBA 1008 (N=44)	EYLEA (N=45)
Baseline	Observed Value	N	44	45
		Mean (SD)	54.1 (13.9)	55.6 (12.3)
		Median	59.0	56.0
		(Min, Max)	(25, 72)	(24, 72)
Week 4	Observed Value	N	44	45
		Mean (SD)	58.9 (15.9)	59.9 (14.6)
		Median	62.5	63.0
		(Min, Max)	(25, 81)	(25, 80)
	Change from Baseline	N	44	45
		Mean (SD)	4.8 (9.1)	4.3 (7.4)
		SE	1.4	1.1
		(80% CI)	(3.0, 6.6)	(2.9, 5.8)
		Median	5.0	3.0
		(Q1, Q3)	(-1.0, 10.5)	(0.0, 9.0)
		(Min, Max)	(-28, 23)	(-10, 21)
Week 8	Observed Value	N	44	45
		Mean (SD)	60.1 (17.7)	62.1 (15.1)
		Median	63.5	65.0
		(Min, Max)	(23, 85)	(26, 80)
	Change from Baseline	N	44	45
		Mean (SD)	6.0 (11.6)	6.5 (8.5)
		SE	1.7	1.3
		(80% CI)	(3.8, 8.3)	(4.9, 8.2)
		Median	5.0	5.0
		(Q1, Q3)	(0.0, 11.5)	(2.0, 12.0)
		(Min, Max)	(-31, 34)	(-19, 23)
Week 12	Observed Value	N	44	45
		Mean (SD)	59.8 (18.5)	62.4 (16.1)
		Median	63.0	66.0
		(Min, Max)	(23, 85)	(25, 83)
	Change from Baseline	N	44	45
		Mean (SD)	5.8 (12.7)	6.9 (9.3)
		SE	1.9	1.4
		(80% CI)	(3.3, 8.3)	(5.1, 8.7)
		Median	6.5	7.0
		(Q1, Q3)	(-3.0, 13.0)	(0.0, 12.0)
		(Min, Max)	(-29, 34)	(-12, 27)
Week 16	Observed Value	N	44	45
		Mean (SD)	60.1 (19.9)	62.2 (16.3)
		Median	62.5	68.0
		(Min, Max)	(22, 89)	(26, 84)

	Change from Baseline	N	44	45
		Mean (SD)	6.0 (13.3)	6.6 (9.2)
		SE	2.0	1.4
		(80% CI)	(3.4, 8.7)	(4.8, 8.4)
		Median	5.5	9.0
		(Q1, Q3)	(-2.0, 13.0)	(2.0, 12.0)
		(Min, Max)	(-22, 34)	(-11, 23)
Week 20	Observed Value	N	44	45
		Mean (SD)	61.6 (19.6)	62.8 (16.5)
		Median	63.5	67.0
		(Min, Max)	(18, 91)	(23, 83)
	Change from Baseline	N	44	45
		Mean (SD)	7.5 (14.5)	7.3 (9.4)
		SE	2.2	1.4
		(80% CI)	(4.7, 10.4)	(5.5, 9.1)
		Median	7.5	9.0
		(Q1, Q3)	(1.5, 15.5)	(0.0, 14.0)
		(Min, Max)	(-41, 40)	(-11, 26)
Week 24	Observed Value	N	44	45
		Mean (SD)	61.2 (18.8)	63.7 (16.3)
		Median	66.0	68.0
		(Min, Max)	(23, 87)	(21, 83)
	Change from Baseline	N	44	45
		Mean (SD)	7.1 (13.0)	8.2 (11.2)
		SE	2.0	1.7
		(80% CI)	(4.5, 9.6)	(6.0, 10.3)
		Median	5.5	8.0
		(Q1, Q3)	(0.0, 13.5)	(1.0, 15.0)
		(Min, Max)	(-34, 39)	(-25, 30)
Week 28	Observed Value	N	44	45
		Mean (SD)	62.4 (18.5)	62.2 (17.7)
		Median	67.0	67.0
		(Min, Max)	(23, 88)	(24, 84)
	Change from Baseline	N	44	45
		Mean (SD)	8.3 (12.2)	6.6 (12.4)
		SE	1.8	1.8
		(80% CI)	(5.9, 10.7)	(4.2, 9.0)
		Median	7.0	8.0
		(Q1, Q3)	(0.0, 14.5)	(0.0, 15.0)
		(Min, Max)	(-15, 37)	(-31, 30)
Week 32	Observed Value	N	44	45
		Mean (SD)	60.7 (20.2)	62.1 (17.7)
		Median	64.0	67.0
		(Min, Max)	(21, 89)	(15, 84)

	Change from Baseline	N	44	45
		Mean (SD)	6.7 (13.7)	6.5 (12.7)
		SE	2.1	1.9
		(80% CI)	(4.0, 9.3)	(4.1, 9.0)
		Median	6.0	7.0
		(Q1, Q3)	(-3.5, 17.0)	(0.0, 16.0)
		(Min, Max)	(-23, 38)	(-40, 34)
Week 36	Observed Value	N	44	45
		Mean (SD)	60.3 (20.9)	62.0 (18.0)
		Median	64.0	66.0
		(Min, Max)	(16, 88)	(10, 84)
	Change from Baseline	N	44	45
		Mean (SD)	6.2 (16.2)	6.4 (13.1)
		SE	2.4	2.0
		(80% CI)	(3.0, 9.4)	(3.8, 8.9)
		Median	5.0	7.0
		(Q1, Q3)	(1.0, 17.0)	(0.0, 15.0)
		(Min, Max)	(-44, 37)	(-45, 30)
Week 40	Observed Value	N	44	45
		Mean (SD)	60.4 (19.9)	61.3 (18.5)
		Median	65.5	68.0
		(Min, Max)	(23, 87)	(8, 84)
	Change from Baseline	N	44	45
		Mean (SD)	6.3 (14.9)	5.7 (13.6)
		SE	2.3	2.0
		(80% CI)	(3.4, 9.2)	(3.0, 8.3)
		Median	5.0	9.0
		(Q1, Q3)	(0.0, 15.5)	(-3.0, 15.0)
		(Min, Max)	(-37, 41)	(-47, 25)
Week 44	Observed Value	N	44	45
		Mean (SD)	61.1 (20.7)	62.1 (17.6)
		Median	65.5	67.0
		(Min, Max)	(23, 90)	(13, 85)
	Change from Baseline	N	44	45
		Mean (SD)	7.0 (15.6)	6.5 (12.0)
		SE	2.4	1.8
		(80% CI)	(3.9, 10.1)	(4.2, 8.9)
		Median	6.5	10.0
		(Q1, Q3)	(1.0, 16.0)	(0.0, 16.0)
		(Min, Max)	(-41, 37)	(-30, 24)
Week 48	Observed Value	N	44	45
		Mean (SD)	60.2 (21.3)	62.4 (18.7)
		Median	64.5	69.0
		(Min, Max)	(17, 88)	(6, 84)

	Change from Baseline	N	44	45
		Mean (SD)	6.2 (16.5)	6.8 (13.4)
		SE	2.5	2.0
		(80% CI)	(2.9, 9.4)	(4.2, 9.4)
		Median	5.0	7.0
		(Q1, Q3)	(0.0, 16.0)	(1.0, 16.0)
		(Min, Max)	(-43, 37)	(-33, 28)
Week 52	Observed Value	N	44	45
		Mean (SD)	60.1 (21.1)	62.8 (18.5)
		Median	65.0	69.0
		(Min, Max)	(23, 88)	(11, 84)
	Change from Baseline	N	44	45
		Mean (SD)	6.0 (16.4)	7.2 (13.2)
		SE	2.5	2.0
		(80% CI)	(2.8, 9.2)	(4.7, 9.8)
		Median	5.0	10.0
		(Q1, Q3)	(-2.0, 17.0)	(0.0, 15.0)
		(Min, Max)	(-39, 39)	(-37, 30)
Week 56	Observed Value	N	44	45
		Mean (SD)	59.0 (22.3)	62.8 (18.0)
		Median	64.5	69.0
		(Min, Max)	(12, 89)	(21, 85)
	Change from Baseline	N	44	45
		Mean (SD)	4.9 (17.9)	7.3 (13.4)
		SE	2.7	2.0
		(80% CI)	(1.4, 8.4)	(4.7, 9.9)
		Median	4.0	10.0
		(Q1, Q3)	(-3.5, 16.5)	(0.0, 17.0)
		(Min, Max)	(-47, 43)	(-30, 30)

ESBA 1008 = ESBA 1008 6 mg/50µL
EYLEA = EYLEA 2 mg/50µL
Change = Visit value - Baseline value, SD = Standard Deviation, SE = Standard Error, CI = Confidence Interval
Analysis using actual treatment received

Secondary Outcome Result(s)

Least Square Estimates for BCVA Change from Baseline to Week 16 (No. of Letters) Using ANOVA (Full Analysis Set/As

	ESBA 1008 (N=44)	EYLEA (N=45)	Difference (ESBA-EYLEA) 80% CI	p-value*
Mean	6.04	6.62	-0.58 (-3.72, 2.56)	0.8117
(SE)	(1.73)	(1.71)		

ESBA 1008 = ESBA 1008 6 mg/50µL
EYLEA = EYLEA 2 mg/50µL
SE = Standard Error; CI = Confidence Interval
Note: Estimates were based on the Analysis of Variance model. Baseline BCVA (<55 letters and ≥55 letters) included as class variable in the model and using observed weights
*p-values related to the treatment difference
Analysis using actual treatment received

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Descriptive Statistics for BCVA and Change from Baseline (No. of Letters) by Visit (Full Analysis Set/As Treated - LOCF)

			ESBA 1008 (N=44)	EYLEA (N=45)
Baseline	Observed Value	N	44	45
		Mean (SD)	54.1 (13.9)	55.6 (12.3)
		Median	59.0	56.0
		(Min, Max)	(25, 72)	(24, 72)
Week 4	Observed Value	N	44	45
		Mean (SD)	58.9 (15.9)	59.9 (14.6)
		Median	62.5	63.0
		(Min, Max)	(25, 81)	(25, 80)
	Change from Baseline	N	44	45
		Mean (SD)	4.8 (9.1)	4.3 (7.4)
		SE	1.4	1.1
		(80% CI)	(3.0, 6.6)	(2.9, 5.8)
		Median	5.0	3.0
		(Q1, Q3)	(-1.0, 10.5)	(0.0, 9.0)
		(Min, Max)	(-28, 23)	(-10, 21)
Week 8	Observed Value	N	44	45
		Mean (SD)	60.1 (17.7)	62.1 (15.1)
		Median	63.5	65.0
		(Min, Max)	(23, 85)	(26, 80)
	Change from Baseline	N	44	45
		Mean (SD)	6.0 (11.6)	6.5 (8.5)
		SE	1.7	1.3
		(80% CI)	(3.8, 8.3)	(4.9, 8.2)
		Median	5.0	5.0
		(Q1, Q3)	(0.0, 11.5)	(2.0, 12.0)
		(Min, Max)	(-31, 34)	(-19, 23)
Week 12	Observed Value	N	44	45
		Mean (SD)	59.8 (18.5)	62.4 (16.1)
		Median	63.0	66.0
		(Min, Max)	(23, 85)	(25, 83)
	Change from Baseline	N	44	45
		Mean (SD)	5.8 (12.7)	6.9 (9.3)
		SE	1.9	1.4
		(80% CI)	(3.3, 8.3)	(5.1, 8.7)
		Median	6.5	7.0
		(Q1, Q3)	(-3.0, 13.0)	(0.0, 12.0)
		(Min, Max)	(-29, 34)	(-12, 27)
Week 16	Observed Value	N	44	45
		Mean (SD)	60.1 (19.9)	62.2 (16.3)
		Median	62.5	68.0
		(Min, Max)	(22, 89)	(26, 84)

	Change from Baseline	N	44	45
		Mean (SD)	6.0 (13.3)	6.6 (9.2)
		SE	2.0	1.4
		(80% CI)	(3.4, 8.7)	(4.8, 8.4)
		Median	5.5	9.0
		(Q1, Q3)	(-2.0, 13.0)	(2.0, 12.0)
		(Min, Max)	(-22, 34)	(-11, 23)
Week 20	Observed Value	N	44	45
		Mean (SD)	61.6 (19.6)	62.8 (16.5)
		Median	63.5	67.0
		(Min, Max)	(18, 91)	(23, 83)
	Change from Baseline	N	44	45
		Mean (SD)	7.5 (14.5)	7.3 (9.4)
		SE	2.2	1.4
		(80% CI)	(4.7, 10.4)	(5.5, 9.1)
		Median	7.5	9.0
		(Q1, Q3)	(1.5, 15.5)	(0.0, 14.0)
		(Min, Max)	(-41, 40)	(-11, 26)
Week 24	Observed Value	N	44	45
		Mean (SD)	61.2 (18.8)	63.7 (16.3)
		Median	66.0	68.0
		(Min, Max)	(23, 87)	(21, 83)
	Change from Baseline	N	44	45
		Mean (SD)	7.1 (13.0)	8.2 (11.2)
		SE	2.0	1.7
		(80% CI)	(4.5, 9.6)	(6.0, 10.3)
		Median	5.5	8.0
		(Q1, Q3)	(0.0, 13.5)	(1.0, 15.0)
		(Min, Max)	(-34, 39)	(-25, 30)
Week 28	Observed Value	N	44	45
		Mean (SD)	62.4 (18.5)	62.2 (17.7)
		Median	67.0	67.0
		(Min, Max)	(23, 88)	(24, 84)
	Change from Baseline	N	44	45
		Mean (SD)	8.3 (12.2)	6.6 (12.4)
		SE	1.8	1.8
		(80% CI)	(5.9, 10.7)	(4.2, 9.0)
		Median	7.0	8.0
		(Q1, Q3)	(0.0, 14.5)	(0.0, 15.0)
		(Min, Max)	(-15, 37)	(-31, 30)
Week 32	Observed Value	N	44	45
		Mean (SD)	60.7 (20.2)	62.1 (17.7)
		Median	64.0	67.0
		(Min, Max)	(21, 89)	(15, 84)

	Change from Baseline	N	44	45
		Mean (SD)	6.7 (13.7)	6.5 (12.7)
		SE	2.1	1.9
		(80% CI)	(4.0, 9.3)	(4.1, 9.0)
		Median	6.0	7.0
		(Q1, Q3)	(-3.5, 17.0)	(0.0, 16.0)
		(Min, Max)	(-23, 38)	(-40, 34)
Week 36	Observed Value	N	44	45
		Mean (SD)	60.3 (20.9)	62.0 (18.0)
		Median	64.0	66.0
		(Min, Max)	(16, 88)	(10, 84)
	Change from Baseline	N	44	45
		Mean (SD)	6.2 (16.2)	6.4 (13.1)
		SE	2.4	2.0
		(80% CI)	(3.0, 9.4)	(3.8, 8.9)
		Median	5.0	7.0
		(Q1, Q3)	(1.0, 17.0)	(0.0, 15.0)
		(Min, Max)	(-44, 37)	(-45, 30)
Week 40	Observed Value	N	44	45
		Mean (SD)	60.4 (19.9)	61.3 (18.5)
		Median	65.5	68.0
		(Min, Max)	(23, 87)	(8, 84)
	Change from Baseline	N	44	45
		Mean (SD)	6.3 (14.9)	5.7 (13.6)
		SE	2.3	2.0
		(80% CI)	(3.4, 9.2)	(3.0, 8.3)
		Median	5.0	9.0
		(Q1, Q3)	(0.0, 15.5)	(-3.0, 15.0)
		(Min, Max)	(-37, 41)	(-47, 25)
Week 44	Observed Value	N	44	45
		Mean (SD)	61.1 (20.7)	62.1 (17.6)
		Median	65.5	67.0
		(Min, Max)	(23, 90)	(13, 85)
	Change from Baseline	N	44	45
		Mean (SD)	7.0 (15.6)	6.5 (12.0)
		SE	2.4	1.8
		(80% CI)	(3.9, 10.1)	(4.2, 8.9)
		Median	6.5	10.0
		(Q1, Q3)	(1.0, 16.0)	(0.0, 16.0)
		(Min, Max)	(-41, 37)	(-30, 24)
Week 48	Observed Value	N	44	45
		Mean (SD)	60.2 (21.3)	62.4 (18.7)
		Median	64.5	69.0
		(Min, Max)	(17, 88)	(6, 84)

	Change from Baseline	N	44	45
		Mean (SD)	6.2 (16.5)	6.8 (13.4)
		SE	2.5	2.0
		(80% CI)	(2.9, 9.4)	(4.2, 9.4)
		Median	5.0	7.0
		(Q1, Q3)	(0.0, 16.0)	(1.0, 16.0)
		(Min, Max)	(-43, 37)	(-33, 28)
Week 52	Observed Value	N	44	45
		Mean (SD)	60.1 (21.1)	62.8 (18.5)
		Median	65.0	69.0
		(Min, Max)	(23, 88)	(11, 84)
	Change from Baseline	N	44	45
		Mean (SD)	6.0 (16.4)	7.2 (13.2)
		SE	2.5	2.0
		(80% CI)	(2.8, 9.2)	(4.7, 9.8)
		Median	5.0	10.0
		(Q1, Q3)	(-2.0, 17.0)	(0.0, 15.0)
		(Min, Max)	(-39, 39)	(-37, 30)
Week 56	Observed Value	N	44	45
		Mean (SD)	59.0 (22.3)	62.8 (18.0)
		Median	64.5	69.0
		(Min, Max)	(12, 89)	(21, 85)
	Change from Baseline	N	44	45
		Mean (SD)	4.9 (17.9)	7.3 (13.4)
		SE	2.7	2.0
		(80% CI)	(1.4, 8.4)	(4.7, 9.9)
		Median	4.0	10.0
		(Q1, Q3)	(-3.5, 16.5)	(0.0, 17.0)
		(Min, Max)	(-47, 43)	(-30, 30)

ESBA 1008 = ESBA 1008 6 mg/50µL
EYLEA = EYLEA 2 mg/50µL
Change = Visit value - Baseline value, SD = Standard Deviation, SE = Standard Error, CI = Confidence Interval
Analysis using actual treatment received

NOVARTIS

Descriptive Statistics for Average BCVA Change from Baseline (No. of Letters) (Full Analysis Set/As Treated – LOCF)

	ESBA 1008 (N=44)	EYLEA (N=45)
Average change from Week 12 over the period of Week 16 to Week 24		
N	44	45
Mean (SD)	1.1 (5.4)	0.5 (4.7)
SE	0.8	0.7
(80% CI)	(0.0, 2.2)	(-0.4, 1.4)
Median	0.7	0.0
(Q1, Q3)	(-2.5, 3.7)	(-2.0, 2.7)
(Min, Max)	(-9, 18)	(-12, 12)
Average change from Week 12 over the period of Week 16 to Week 40		
N	44	45
Mean (SD)	1.1 (6.3)	-0.1 (7.3)
SE	0.9	1.1
(80% CI)	(-0.1, 2.3)	(-1.5, 1.3)
Median	1.2	0.1
(Q1, Q3)	(-4.0, 4.8)	(-2.7, 2.6)
(Min, Max)	(-11, 20)	(-32, 16)
Average change from Week 12 over the period of Week 16 to Week 56		
N	44	45
Mean (SD)	0.8 (7.0)	-0.0 (8.1)
SE	1.0	1.2
(80% CI)	(-0.6, 2.2)	(-1.6, 1.5)
Median	0.9	-0.1
(Q1, Q3)	(-3.5, 4.2)	(-3.1, 3.1)
(Min, Max)	(-16, 20)	(-37, 18)

ESBA 1008 = ESBA 1008 6 mg/50µL
EYLEA = EYLEA 2 mg/50µL
SD = Standard Deviation, SE = Standard Error, CI = Confidence Interval
Analysis using actual treatment received

NOVARTIS

Descriptive Statistics for 1-Month BCVA Changes (No. of Letters) Following No Treatment for 1-Month (Full Analysis Set/As Treated - LOCF)

		ESBA 1008 (N=44)	EYLEA (N=45)
Change from Week 12 to Week 16	N	44	45
	Mean (SD)	0.3 (5.7)	-0.2 (5.1)
	SE	0.9	0.8
	(80% CI)	(-0.8, 1.4)	(-1.2, 0.7)
	Median	0.0	0.0
	(Q1, Q3)	(-3.0, 3.0)	(-2.0, 2.0)
	(Min, Max)	(-12, 16)	(-15, 10)
Change from Week 20 to Week 24	N	44	45
	Mean (SD)	-0.4 (4.8)	0.9 (5.5)
	SE	0.7	0.8
	(80% CI)	(-1.4, 0.5)	(-0.2, 2.0)
	Median	-1.0	0.0
	(Q1, Q3)	(-3.0, 2.5)	(-2.0, 4.0)
	(Min, Max)	(-14, 16)	(-16, 13)
Change from Week 28 to Week 32	N	44	45
	Mean (SD)	-1.7 (4.6)	-0.1 (3.6)
	SE	0.7	0.5
	(80% CI)	(-2.6, -0.8)	(-0.8, 0.6)
	Median	0.0	0.0
	(Q1, Q3)	(-4.5, 1.0)	(-1.0, 2.0)
	(Min, Max)	(-17, 7)	(-9, 12)
Change from Week 36 to Week 40	N	44	45
	Mean (SD)	0.1 (7.3)	-0.7 (4.0)
	SE	1.1	0.6
	(80% CI)	(-1.3, 1.6)	(-1.5, 0.1)
	Median	0.0	0.0
	(Q1, Q3)	(-3.0, 2.0)	(-2.0, 1.0)
	(Min, Max)	(-11, 39)	(-11, 8)

		ESBA 1008 (N=44)	EYLEA (N=45)
Change from Week 44 to Week 48	N		45
	Mean (SD)		0.2 (4.2)
	SE		0.6
	(80% CI)		(-0.6, 1.1)
	Median		0.0
	(Q1, Q3)		(-3.0, 2.0)
	(Min, Max)		(-10, 12)
Change from Week 48 to Week 52	N	44	
	Mean (SD)	-0.1 (4.3)	
	SE	0.6	
	(80% CI)	(-1.0, 0.7)	
	Median	0.0	
	(Q1, Q3)	(-2.0, 2.0)	
	(Min, Max)	(-17, 11)	
Change from Week 52 to Week 56	N		45
	Mean (SD)		0.0 (4.2)
	SE		0.6
	(80% CI)		(-0.8, 0.8)
	Median		0.0
	(Q1, Q3)		(-2.0, 2.0)
	(Min, Max)		(-8, 13)

ESBA 1008 = ESBA 1008 6 mg/50µL
EYLEA = EYLEA 2 mg/50µL
SD = Standard Deviation, SE = Standard Error, CI = Confidence Interval
Analysis using actual treatment received

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Descriptive Statistics for 1-Month BCVA Changes (No. of Letters) Following Treatment (Full Analysis Set/As Treated - LOCF)

		ESBA 1008 (N=44)	EYLEA (N=45)
Change from Week 16 to Week 20	N	44	45
	Mean (SD)	1.5 (5.7)	0.6 (5.1)
	SE	0.9	0.8
	(80% CI)	(0.4, 2.6)	(-0.3, 1.6)
	Median	1.0	0.0
	(Q1, Q3)	(-1.0, 5.0)	(-2.0, 3.0)
	(Min, Max)	(-19, 12)	(-14, 18)
Change from Week 24 to Week 28	N	44	45
	Mean (SD)	1.2 (5.6)	-1.6 (7.7)
	SE	0.8	1.1
	(80% CI)	(0.1, 2.3)	(-3.0, -0.1)
	Median	1.0	0.0
	(Q1, Q3)	(-0.5, 2.5)	(-3.0, 1.0)
	(Min, Max)	(-13, 28)	(-43, 13)
Change from Week 32 to Week 36	N	44	45
	Mean (SD)	-0.5 (7.9)	-0.2 (5.1)
	SE	1.2	0.8
	(80% CI)	(-2.0, 1.1)	(-1.1, 0.8)
	Median	0.0	0.0
	(Q1, Q3)	(-2.0, 2.0)	(-4.0, 3.0)
	(Min, Max)	(-40, 11)	(-12, 10)
Change from Week 40 to Week 44	N		45
	Mean (SD)		0.8 (5.2)
	SE		0.8
	(80% CI)		(-0.2, 1.8)
	Median		0.0
	(Q1, Q3)		(-2.0, 3.0)
	(Min, Max)		(-12, 17)
Change from Week 44 to Week 48	N	44	
	Mean (SD)	-0.8 (4.2)	
	SE	0.6	
	(80% CI)	(-1.7, -0.0)	
	Median	-0.5	
	(Q1, Q3)	(-2.0, 1.5)	
	(Min, Max)	(-16, 8)	

		ESBA 1008 (N=44)	EYLEA (N=45)
Change from Week 48 to Week 52	N		45
	Mean (SD)		0.5 (3.6)
	SE		0.5
	(80% CI)		(-0.2, 1.2)
	Median		0.0
	(Q1, Q3)		(-2.0, 2.0)
	(Min, Max)		(-9, 10)

ESBA 1008 = ESBA 1008 6 mg/50µL
EYLEA = EYLEA 2 mg/50µL
SD = Standard Deviation, SE = Standard Error, CI = Confidence Interval
Analysis using actual treatment received

Descriptive Statistics for 2-Months BCVA Changes (No. of Letters) Following No Treatment for 1 Months in ESBA Treatment Group (Full Analysis Set/As Treated - LOCF)

		ESBA 1008 (N=44)
Change from Week 36 to Week 44	N	44
	Mean (SD)	0.8 (7.1)
	SE	1.1
	(80% CI)	(-0.6, 2.2)
	Median	0.0
	(Q1, Q3)	(-2.0, 2.0)
	(Min, Max)	(-14, 36)
Change from Week 48 to Week 56	N	44
	Mean (SD)	-1.3 (5.0)
	SE	0.8
	(80% CI)	(-2.2, -0.3)
	Median	-1.0
	(Q1, Q3)	(-3.0, 1.0)
	(Min, Max)	(-17, 14)
Average of change from Week 36 to 44 and Week 48 to Week 56	N	44
	Mean (SD)	-0.2 (4.4)
	SE	0.7
	(80% CI)	(-1.1, 0.6)
	Median	0.0
	(Q1, Q3)	(-1.8, 1.3)
	(Min, Max)	(-14, 18)

ESBA 1008 = ESBA 1008 6 mg/50µL
SD = Standard Deviation, SE = Standard Error, CI = Confidence Interval
Analysis using actual treatment received

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Descriptive Statistics for CSFT and Change from Baseline (µm) by Visit (Full Analysis Set/As Treated - LOCF)

			ESBA 1008 (N=44)	EYLEA (N=45)
Baseline	Observed Value	N	44	45
		Mean (SD)	490.1 (149.2)	495.7 (144.6)
		Median	472.0	476.0
		(Min, Max)	(241, 926)	(231, 907)
Week 4	Observed Value	N	44	45
		Mean (SD)	305.4 (74.7)	342.8 (94.4)
		Median	292.0	322.0
		(Min, Max)	(188, 522)	(209, 603)
	Change from Baseline	N	44	45
		Mean (SD)	-184.7 (118.9)	-153.0 (95.1)
		SE	17.9	14.2
		(80% CI)	(-208.0, -161.3)	(-171.4, -134.5)
		Median	-162.5	-141.0
		(Q1, Q3)	(-241.5, -95.0)	(-218.0, -83.0)
		(Min, Max)	(-540, -27)	(-390, -17)

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			ESBA 1008 (N=44)	EYLEA (N=45)
Week 8	Observed Value	N	44	45
		Mean (SD)	291.6 (73.4)	319.6 (94.9)
		Median	272.0	286.0
		(Min, Max)	(186, 522)	(212, 685)
	Change from Baseline	N	44	45
		Mean (SD)	-198.5 (117.6)	-176.1 (106.5)
		SE	17.7	15.9
		(80% CI)	(-221.6, -175.4)	(-196.8, -155.5)
		Median	-182.0	-182.0
		(Q1, Q3)	(-256.0, -95.0)	(-253.0, -91.0)
		(Min, Max)	(-549, -51)	(-435, -3)
Week 12	Observed Value	N	44	45
		Mean (SD)	290.6 (76.4)	309.6 (91.1)
		Median	273.5	279.0
		(Min, Max)	(182, 508)	(206, 672)
	Change from Baseline	N	44	45
		Mean (SD)	-199.5 (126.7)	-186.2 (113.6)
		SE	19.1	16.9
		(80% CI)	(-224.3, -174.6)	(-208.2, -164.1)
		Median	-188.5	-180.0
		(Q1, Q3)	(-259.0, -92.0)	(-267.0, -92.0)
		(Min, Max)	(-572, 24)	(-466, -23)
Week 16	Observed Value	N	44	45
		Mean (SD)	301.7 (94.2)	332.5 (111.8)
		Median	282.0	310.0
		(Min, Max)	(181, 587)	(202, 822)
	Change from Baseline	N	44	45
		Mean (SD)	-188.4 (121.0)	-163.2 (116.4)
		SE	18.2	17.4
		(80% CI)	(-212.1, -164.6)	(-185.8, -140.6)
		Median	-183.0	-130.0
		(Q1, Q3)	(-260.0, -93.0)	(-245.0, -65.0)
		(Min, Max)	(-567, 35)	(-432, 15)
Week 20	Observed Value	N	44	45
		Mean (SD)	283.1 (67.3)	310.9 (100.4)
		Median	268.5	283.0
		(Min, Max)	(180, 462)	(197, 798)
	Change from Baseline	N	44	45
		Mean (SD)	-207.0 (123.2)	-184.8 (118.5)
		SE	18.6	17.7
		(80% CI)	(-231.2, -182.8)	(-207.8, -161.8)
		Median	-189.0	-166.0
		(Q1, Q3)	(-261.5, -119.0)	(-269.0, -91.0)
		(Min, Max)	(-565, -34)	(-442, 15)

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			ESBA 1008 (N=44)	EYLEA (N=45)
Week 40	Observed Value	N	44	45
		Mean (SD)	289.5 (85.6)	320.5 (111.0)
		Median	275.0	283.0
		(Min, Max)	(163, 555)	(195, 862)
	Change from Baseline	N	44	45
		Mean (SD)	-200.6 (143.6)	-175.2 (124.1)
		SE	21.7	18.5
		(80% CI)	(-228.8, -172.4)	(-199.3, -151.1)
		Median	-181.5	-164.0
		(Q1, Q3)	(-270.0, -97.0)	(-240.0, -70.0)
		(Min, Max)	(-569, 108)	(-451, 38)
Week 44	Observed Value	N	44	45
		Mean (SD)	294.0 (76.0)	311.1 (105.0)
		Median	289.5	274.0
		(Min, Max)	(177, 508)	(190, 749)
	Change from Baseline	N	44	45
		Mean (SD)	-196.1 (120.2)	-184.6 (121.7)
		SE	18.1	18.1
		(80% CI)	(-219.7, -172.5)	(-208.2, -161.0)
		Median	-173.0	-166.0
		(Q1, Q3)	(-265.0, -105.0)	(-264.0, -82.0)
		(Min, Max)	(-522, -12)	(-439, 29)
Week 48	Observed Value	N	44	45
		Mean (SD)	277.1 (70.1)	320.0 (97.9)
		Median	275.0	282.0
		(Min, Max)	(163, 490)	(193, 634)
	Change from Baseline	N	44	45
		Mean (SD)	-213.0 (129.7)	-175.7 (124.3)
		SE	19.6	18.5
		(80% CI)	(-238.4, -187.5)	(-199.8, -151.6)
		Median	-188.0	-148.0
		(Q1, Q3)	(-270.5, -121.0)	(-260.0, -74.0)
		(Min, Max)	(-586, -21)	(-457, 22)
Week 52	Observed Value	N	44	45
		Mean (SD)	279.6 (69.3)	297.0 (79.1)
		Median	273.5	274.0
		(Min, Max)	(177, 490)	(192, 608)
	Change from Baseline	N	44	45
		Mean (SD)	-210.5 (130.6)	-198.8 (123.4)
		SE	19.7	18.4
		(80% CI)	(-236.1, -184.9)	(-222.7, -174.8)
		Median	-188.5	-164.0
		(Q1, Q3)	(-272.5, -124.0)	(-296.0, -89.0)
		(Min, Max)	(-585, -10)	(-456, -4)

			ESBA 1008 (N=44)	EYLEA (N=45)
Week 56	Observed Value	N	44	45
		Mean (SD)	293.3 (78.1)	315.4 (102.9)
		Median	297.5	285.0
		(Min, Max)	(155, 520)	(190, 765)
	Change from Baseline	N	44	45
		Mean (SD)	-196.8 (135.4)	-180.4 (121.6)
		SE	20.4	18.1
		(80% CI)	(-223.4, -170.2)	(-204.0, -156.8)
		Median	-178.0	-152.0
		(Q1, Q3)	(-272.5, -98.5)	(-254.0, -85.0)
		(Min, Max)	(-592, 27)	(-460, 24)

ESBA 1008 = ESBA 1008 6 mg/50µL
EYLEA = EYLEA 2 mg/50µL
Change = Visit value - Baseline value, SD = Standard Deviation, SE = Standard Error, CI = Confidence Interval
Analysis using actual treatment received

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Safety Results

C-12-006, Safety Set Incidence of Nonocular Serious Treatment Emergent Adverse Events (TEAE) by System Organ Class and Preferred Term

	ESBA 1008 (N=44)			EYLEA (N=45)		
	n	(%)	E	n	(%)	E
Any Event	10	(22.7)	11	8	(17.8)	14
Injury, poisoning and procedural complications	2	(4.5)	2	2	(4.4)	3
Arthropod bite	1	(2.3)	1	0	(0.0)	0
Humerus fracture	0	(0.0)	0	1	(2.2)	1
Incisional hernia	0	(0.0)	0	1	(2.2)	1
Lower limb fracture	1	(2.3)	1	0	(0.0)	0
Subdural haematoma	0	(0.0)	0	1	(2.2)	1
Cardiac disorders	1	(2.3)	1	2	(4.4)	2
Atrial fibrillation	0	(0.0)	0	2	(4.4)	2
Myocardial ischaemia	1	(2.3)	1	0	(0.0)	0
Infections and infestations	2	(4.5)	2	1	(2.2)	2
Cellulitis	0	(0.0)	0	1	(2.2)	1
Endocarditis	1	(2.3)	1	0	(0.0)	0
Pneumonia	1	(2.3)	1	0	(0.0)	0
Pneumonia Escherichia	0	(0.0)	0	1	(2.2)	1
Nervous system disorders	0	(0.0)	0	3	(6.7)	3
Cerebrovascular accident	0	(0.0)	0	1	(2.2)	1
Subarachnoid haemorrhage	0	(0.0)	0	1	(2.2)	1
Transient ischaemic attack	0	(0.0)	0	1	(2.2)	1
Respiratory, thoracic and mediastinal disorders	2	(4.5)	3	1	(2.2)	1
Dyspnoea	1	(2.3)	1	1	(2.2)	1
Chronic obstructive pulmonary disease	1	(2.3)	2	0	(0.0)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	(2.3)	1	1	(2.2)	1
Pancreatic carcinoma	1	(2.3)	1	0	(0.0)	0
Thyroid cancer	0	(0.0)	0	1	(2.2)	1
Gastrointestinal disorders	1	(2.3)	1	0	(0.0)	0
Colitis	1	(2.3)	1	0	(0.0)	0
General disorders and administration site conditions	0	(0.0)	0	1	(2.2)	1
Chest pain	0	(0.0)	0	1	(2.2)	1
Investigations	0	(0.0)	0	1	(2.2)	1
Heart rate irregular	0	(0.0)	0	1	(2.2)	1
Vascular disorders	1	(2.3)	1	0	(0.0)	0
Aortic aneurysm	1	(2.3)	1	0	(0.0)	0

ESBA 1008 = ESBA 1008 6 mg/50µL
EYLEA = EYLEA 2 mg/50µL
N = Total number of subjects in each treatment group; n = Number of subjects with the events
E = Number of events
If a subject has multiple occurrences of an AE, the subject is presented only once in the respective subject count column (n) for the corresponding AE. Events are counted each time in the event (E) column.
Adverse events are coded using MedDRA version 15.0

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C-12-006, Safety Set Incidence of Nonocular Serious Treatment Emergent Adverse Events (TEAE) by System Organ Class and Preferred Term

	ESBA 1008 (N=44)			EYLEA (N=45)		
	n	(%)	E	n	(%)	E
Any Event	2	(4.5)	2	1	(2.2)	1
Study eye	2	(4.5)	2	1	(2.2)	1
Nonstudy eye	0	(0.0)	0	0	(0.0)	0
Eye disorders						
Overall	1	(2.3)	1	1	(2.2)	1
Study eye	1	(2.3)	1	1	(2.2)	1
Nonstudy eye	0	(0.0)	0	0	(0.0)	0
Retinal detachment	0	(0.0)	0	1	(2.2)	1
Study eye	0	(0.0)	0	1	(2.2)	1
Nonstudy eye	0	(0.0)	0	0	(0.0)	0
Retinal tear	1	(2.3)	1	0	(0.0)	0
Study eye	1	(2.3)	1	0	(0.0)	0
Nonstudy eye	0	(0.0)	0	0	(0.0)	0
Investigations						
Overall	1	(2.3)	1	0	(0.0)	0
Study eye	1	(2.3)	1	0	(0.0)	0
Nonstudy eye	0	(0.0)	0	0	(0.0)	0
Intraocular pressure increased	1	(2.3)	1	0	(0.0)	0
Study eye	1	(2.3)	1	0	(0.0)	0
Nonstudy eye	0	(0.0)	0	0	(0.0)	0

ESBA 1008 = ESBA 1008 6 mg/50µL
EYLEA = EYLEA 2 mg/50µL
N = Total number of subjects in each treatment group; n = Number of subjects with the events
E = Number of events
If a subject has multiple occurrences of an AE, the subject is presented only once in the respective subject count column (n) for the corresponding AE. Events are counted each time in the event (E) column.
Adverse events are coded using MedDRA version 15.0

NOVARTIS

	ESBA 1008 (N=44)			EYLEA (N=45)		
	n	(%)	E	n	(%)	E
Any Event	10	(22.7)	11	8	(17.8)	14
Injury, poisoning and procedural complications	2	(4.5)	2	2	(4.4)	3
Arthropod bite	1	(2.3)	1	0	(0.0)	0
Humerus fracture	0	(0.0)	0	1	(2.2)	1
Incisional hernia	0	(0.0)	0	1	(2.2)	1
Lower limb fracture	1	(2.3)	1	0	(0.0)	0
Subdural haematoma	0	(0.0)	0	1	(2.2)	1
Cardiac disorders	1	(2.3)	1	2	(4.4)	2
Atrial fibrillation	0	(0.0)	0	2	(4.4)	2
Myocardial ischaemia	1	(2.3)	1	0	(0.0)	0
Infections and infestations	2	(4.5)	2	1	(2.2)	2
Cellulitis	0	(0.0)	0	1	(2.2)	1
Endocarditis	1	(2.3)	1	0	(0.0)	0
Pneumonia	1	(2.3)	1	0	(0.0)	0
Pneumonia Escherichia	0	(0.0)	0	1	(2.2)	1
Nervous system disorders	0	(0.0)	0	3	(6.7)	3
Cerebrovascular accident	0	(0.0)	0	1	(2.2)	1
Subarachnoid haemorrhage	0	(0.0)	0	1	(2.2)	1
Transient ischaemic attack	0	(0.0)	0	1	(2.2)	1
Respiratory, thoracic and mediastinal disorders	2	(4.5)	3	1	(2.2)	1
Dyspnoea	1	(2.3)	1	1	(2.2)	1
Chronic obstructive pulmonary disease	1	(2.3)	2	0	(0.0)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1	(2.3)	1	1	(2.2)	1
Pancreatic carcinoma	1	(2.3)	1	0	(0.0)	0
Thyroid cancer	0	(0.0)	0	1	(2.2)	1
Gastrointestinal disorders	1	(2.3)	1	0	(0.0)	0
Colitis	1	(2.3)	1	0	(0.0)	0
General disorders and administration site conditions	0	(0.0)	0	1	(2.2)	1
Chest pain	0	(0.0)	0	1	(2.2)	1
Investigations	0	(0.0)	0	1	(2.2)	1
Heart rate irregular	0	(0.0)	0	1	(2.2)	1
Vascular disorders	1	(2.3)	1	0	(0.0)	0
Aortic aneurysm	1	(2.3)	1	0	(0.0)	0

ESBA 1008 = ESBA 1008 6 mg/50µL
EYLEA = EYLEA 2 mg/50µL
N = Total number of subjects in each treatment group; n = Number of subjects with the events
E = Number of events
If a subject has multiple occurrences of an AE, the subject is presented only once in the respective subject count column (n) for the corresponding AE. Events are counted each time in the event (E) column.
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Conclusion:
Overall, this study demonstrated the noninferiority of ESBA1008 to EYLEA for the improvement of BCVA from baseline at Weeks 12 and 16. Superiority of ESBA1008 to EYLEA for the change from baseline in BCVA at these time points was not demonstrated. The stability of treatment effect on BCVA in the ESBA1008 group was observed at later weeks relative to Week 12; there were no clinically or statistically meaningful treatment group differences in regard to changes in BCVA during the period of 8-week treatment cycles (ie, Weeks 12 up to 40). Based upon a review of AEs, ocular parameters, and clinical laboratory results, ESBA1008 was generally well-tolerated when administered via intravitreal injection at 4, 8, and 12 week intervals for up to 56 weeks in adult subjects with an untreated and active CNV lesion due to AMD.

Date of Clinical Trial Report
06 November 2015