

Table 14.2.1.5 Slit lamp examination (Full analysis set)

Investigational Medicinal Product: rhNGF 20 µg/mL - Overall Dry Eye Severity Level

Parameter	Visit	Statistics	Full Analysis Set N=20			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Eyelid - Meibomian glands	Screening - Day -15/-1	N	20		20	
		Mean	1.2		1.2	
		SD	0.8		0.7	
		CV%	70.7		58.3	
		Min	0		0	
		Median	1.0		1.0	
		Max	3		3	
Eyelid - Meibomian glands	Visit 2 - Day 1	N	20	20	20	20
		Mean	1.3	0.1	1.1	-0.1
		SD	0.8	0.6	0.7	0.4
		CV%	62.9	552.5	65.3	-788.1
		Min	0	-1	0	-1
		Median	1.0	0.0	1.0	0.0
		Max	3	1	3	1
Eyelid - Meibomian glands	Visit 3 - Day 8±1	N	20	20	20	20
		Mean	1.1	-0.1	1.0	-0.2

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Parameter	Visit	Statistics	Full Analysis Set N=20			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Eyelid - Meibomian glands	Visit 6 - Day 29±1	SD	0.7	0.6	0.7	0.6
		CV%	65.4	-640.7	72.2	-307.8
		Min	0	-1	0	-1
		Median	1.0	0.0	1.0	0.0
		Max	3	1	3	1
		N	20	20	20	20
		Mean	0.6	-0.6	0.7	-0.5
		SD	0.8	0.8	0.7	0.6
		CV%	125.7	-150.1	104.7	-134.4
		Min	0	-2	0	-1
		Median	0.5	-1.0	1.0	-0.5
Eyelid - Meibomian glands	Final Visit - Day 56±4/ETV	Max	3	1	3	1
		N	20	20	20	20
		Mean	0.8	-0.4	0.7	-0.5
		SD	0.6	0.9	0.7	0.7
		CV%	76.9	-250.0	93.8	-152.5
		Min	0	-2	0	-2

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Parameter	Visit	Statistics	Full Analysis Set N=20			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Eyelid - Erythema	Screening - Day -15/-1	Median	1.0	0.0	1.0	0.0
		Max	2	1	2	1
		N	20		20	
		Mean	0.9		0.9	
		SD	0.7		0.7	
		CV%	79.8		79.8	
		Min	0		0	
		Median	1.0		1.0	
		Max	2		2	
Eyelid - Erythema	Visit 2 - Day 1	N	20	20	20	20
		Mean	0.8	-0.1	0.8	-0.2
		SD	0.8	0.6	0.7	0.5
		CV%	96.0	-552.5	95.5	-326.2
		Min	0	-2	0	-2
		Median	1.0	0.0	1.0	0.0
		Max	2	1	2	0

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			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Eyelid - Erythema	Visit 3 - Day 8±1	N	20	20	20	20
		Mean	0.6	-0.3	0.6	-0.3
		SD	0.6	0.7	0.6	0.7
		CV%	99.7	-219.0	99.7	-219.0
		Min	0	-2	0	-2
		Median	1.0	0.0	1.0	0.0
		Max	2	1	2	1
Eyelid - Erythema	Visit 6 - Day 29±1	N	20	20	20	20
		Mean	0.2	-0.8	0.2	-0.8
		SD	0.4	0.6	0.4	0.6
		CV%	244.2	-85.2	244.2	-85.2
		Min	0	-2	0	-2
		Median	0.0	-1.0	0.0	-1.0
		Max	1	0	1	0
Eyelid - Erythema	Final Visit - Day 56±4/ETV	N	20	20	20	20
		Mean	0.2	-0.8	0.2	-0.8
		SD	0.4	0.7	0.4	0.7

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Investigational Medicinal Product: rhNGF 20 µg/mL - Overall Dry Eye Severity Level

Parameter	Visit	Statistics	Full Analysis Set N=20			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Eyelid - Oedema	Screening - Day -15/-1	CV%	244.2	-95.5	244.2	-95.5
		Min	0	-2	0	-2
		Median	0.0	-1.0	0.0	-1.0
		Max	1	1	1	1
		N	20		20	
		Mean	0.4		0.4	
		SD	0.5		0.5	
		CV%	125.7		125.7	
Eyelid - Oedema	Visit 2 - Day 1	Min	0		0	
		Median	0.0		0.0	
		Max	1		1	
		N	20	20	20	20
		Mean	0.6	0.2	0.5	0.1
		SD	0.6	0.5	0.5	0.4
		CV%	110.0	326.2	102.6	447.2
		Min	0	-1	0	-1
		Median	0.5	0.0	0.5	0.0

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Parameter	Visit	Statistics	Full Analysis Set N=20			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
		Max	2	1	1	1
Eyelid - Oedema	Visit 3 - Day 8±1	N	20	20	20	20
		Mean	0.2	-0.2	0.2	-0.3
		SD	0.4	0.5	0.4	0.6
		CV%	205.2	-261.6	244.2	-220.0
		Min	0	-1	0	-1
		Median	0.0	0.0	0.0	0.0
		Max	1	1	1	1
Eyelid - Oedema	Visit 6 - Day 29±1	N	20	20	20	20
		Mean	0.1	-0.4	0.1	-0.4
		SD	0.2	0.5	0.2	0.5
		CV%	447.2	-139.8	447.2	-139.8
		Min	0	-1	0	-1
		Median	0.0	0.0	0.0	0.0
		Max	1	0	1	0
Eyelid - Oedema	Final Visit - Day 56±4/ETV	N	20	20	20	20

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Parameter	Visit	Statistics	Full Analysis Set N=20			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Lashes	Screening - Day -15/-1	Mean	0.1	-0.4	0.1	-0.4
		SD	0.2	0.5	0.2	0.5
		CV%	447.2	-139.8	447.2	-139.8
		Min	0	-1	0	-1
		Median	0.0	0.0	0.0	0.0
		Max	1	0	1	0
	Visit 2 - Day 1	N	20		20	
		Mean	0.0		0.0	
		SD	0.0		0.0	
		CV%	NC		NC	
		Min	0		0	
		Median	0.0		0.0	
		Max	0		0	

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Investigational Medicinal Product: rhNGF 20 µg/mL - Overall Dry Eye Severity Level

Parameter	Visit	Statistics	Full Analysis Set N=20			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Lashes	Visit 3 - Day 8±1	Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
		Max	0	0	0	0
		N	20	20	20	20
		Mean	0.0	0.0	0.0	0.0
		SD	0.0	0.0	0.0	0.0
		CV%	NC	NC	NC	NC
		Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
		Max	0	0	0	0
		N	20	20	20	20
		Mean	0.0	0.0	0.0	0.0
		SD	0.0	0.0	0.0	0.0
		CV%	NC	NC	NC	NC
		Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
		Max	0	0	0	0

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Parameter	Visit	Statistics	Full Analysis Set N=20			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Lashes	Final Visit - Day 56±4/ETV	N	20	20	20	20
		Mean	0.0	0.0	0.0	0.0
		SD	0.0	0.0	0.0	0.0
		CV%	NC	NC	NC	NC
		Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
		Max	0	0	0	0
Conjunctiva - Erythema	Screening - Day -15/-1	N	20		20	
		Mean	1.6		1.5	
		SD	0.7		0.6	
		CV%	44.3		41.7	
		Min	0		0	
		Median	2.0		1.5	
		Max	3		2	
Conjunctiva - Erythema	Visit 2 - Day 1	N	20	20	20	20
		Mean	1.4	-0.2	1.4	-0.1

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Investigational Medicinal Product: rhNGF 20 µg/mL - Overall Dry Eye Severity Level

Parameter	Visit	Statistics	Full Analysis Set N=20			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Conjunctiva - Erythema	Visit 3 - Day 8±1	SD	0.5	0.5	0.5	0.5
		CV%	36.2	-261.6	35.9	-1020.8
		Min	1	-1	1	-1
		Median	1.0	0.0	1.0	0.0
		Max	2	1	2	1
		N	20	20	20	20
		Mean	1.2	-0.4	1.1	-0.4
		SD	0.6	0.7	0.6	0.7
		CV%	51.3	-212.9	50.2	-191.7
		Min	0	-2	0	-2
Conjunctiva - Erythema	Visit 6 - Day 29±1	Median	1.0	0.0	1.0	0.0
		Max	2	1	2	1
		N	20	20	20	20
		Mean	1.1	-0.5	1.0	-0.5
		SD	0.5	0.7	0.5	0.7
		CV%	48.6	-137.6	45.9	-152.5
		Min	0	-2	0	-2

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Parameter	Visit	Statistics	Full Analysis Set N=20			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Conjunctiva - Erythema	Final Visit - Day 56±4/ETV	Median	1.0	-0.5	1.0	0.0
		Max	2	1	2	1
		N	20	20	20	20
		Mean	1.1	-0.5	0.9	-0.6
		SD	0.6	0.9	0.6	0.9
		CV%	57.6	-177.7	61.4	-161.3
		Min	0	-2	0	-2
		Median	1.0	0.0	1.0	0.0
		Max	2	1	2	1
Conjunctiva - Oedema	Screening - Day -15/-1	N	20		20	
		Mean	1.1		1.3	
		SD	0.6		0.8	
		CV%	58.2		62.9	
		Min	0		0	
		Median	1.0		1.0	
		Max	2		3	

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Parameter	Visit	Statistics	Full Analysis Set N=20			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Conjunctiva - Oedema	Visit 2 - Day 1	N	20	20	20	20
		Mean	1.1	0.0	1.1	-0.2
		SD	0.9	0.6	0.8	0.5
		CV%	77.5	NC	72.3	-261.6
		Min	0	-1	0	-1
		Median	1.0	0.0	1.0	0.0
		Max	3	2	3	1
Conjunctiva - Oedema	Visit 3 - Day 8±1	N	20	20	20	20
		Mean	0.8	-0.4	0.8	-0.5
		SD	0.6	0.8	0.4	0.9
		CV%	73.3	-232.2	59.2	-189.2
		Min	0	-2	0	-2
		Median	1.0	0.0	1.0	-0.5
		Max	2	1	1	1
Conjunctiva - Oedema	Visit 6 - Day 29±1	N	20	20	20	20
		Mean	0.5	-0.7	0.4	-0.9
		SD	0.5	0.9	0.5	1.0

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Parameter	Visit	Statistics	Full Analysis Set N=20			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Conjunctiva - Oedema	Final Visit - Day 56±4/ETV	CV%	113.4	-143.6	125.7	-122.4
		Min	0	-2	0	-3
		Median	0.0	-1.0	0.0	-1.0
		Max	1	1	1	1
		N	20	20	20	20
		Mean	0.9	-0.3	0.7	-0.6
		SD	0.6	1.0	0.6	1.0
		CV%	69.1	-386.6	81.6	-181.6
		Min	0	-2	0	-2
		Median	1.0	0.0	1.0	0.0
		Max	2	1	2	1
Lens	Screening - Day -15/-1	N	19		19	
		Mean	0.4		0.4	
		SD	0.5		0.5	
		CV%	134.5		134.5	
		Min	0		0	
		Median	0.0		0.0	

Table 14.2.1.5 Slit lamp examination (Full analysis set)

Investigational Medicinal Product: rhNGF 20 µg/mL - Overall Dry Eye Severity Level

Parameter	Visit	Statistics	Full Analysis Set N=20			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Lens	Visit 2 - Day 1	Max	1		1	
		N	19	19	19	19
		Mean	0.4	0.1	0.4	0.1
		SD	0.5	0.2	0.5	0.2
		CV%	120.5	435.9	120.5	435.9
		Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
		Max	1	1	1	1
Lens	Visit 3 - Day 8±1	N	19	19	19	19
		Mean	0.4	0.0	0.4	0.0
		SD	0.5	0.3	0.5	0.3
		CV%	134.5	NC	134.5	NC
		Min	0	-1	0	-1
		Median	0.0	0.0	0.0	0.0
		Max	1	1	1	1
Lens	Visit 6 - Day 29±1	N	19	19	19	19

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Parameter	Visit	Statistics	Full Analysis Set N=20			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Lens	Final Visit - Day 56±4/ETV	Mean	0.3	-0.1	0.3	-0.1
		SD	0.5	0.5	0.5	0.5
		CV%	171.9	-435.9	171.9	-435.9
		Min	0	-1	0	-1
		Median	0.0	0.0	0.0	0.0
		Max	1	1	1	1
		N	19	19	19	19
		Mean	0.3	-0.1	0.3	-0.1
		SD	0.5	0.5	0.5	0.5
		CV%	171.9	-435.9	171.9	-435.9
		Min	0	-1	0	-1
		Median	0.0	0.0	0.0	0.0
		Max	1	1	1	1
Iris	Screening - Day -15/-1	N	20		20	
		Mean	0.0		0.0	
		SD	0.0		0.0	
		CV%	NC		NC	

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Parameter	Visit	Statistics	Full Analysis Set N=20			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Iris	Visit 2 - Day 1	Min	0		0	
		Median	0.0		0.0	
		Max	0		0	
		N	20	20	20	20
		Mean	0.0	0.0	0.0	0.0
		SD	0.0	0.0	0.0	0.0
		CV%	NC	NC	NC	NC
		Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
		Max	0	0	0	0
		N	20	20	20	20
		Mean	0.0	0.0	0.0	0.0
		SD	0.0	0.0	0.0	0.0
		CV%	NC	NC	NC	NC
		Min	0	0	0	0
Iris	Visit 3 - Day 8±1	Median	0.0	0.0	0.0	0.0
		Max	0	0	0	0
		N	20	20	20	20
		Mean	0.0	0.0	0.0	0.0
		SD	0.0	0.0	0.0	0.0
		CV%	NC	NC	NC	NC

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Parameter	Visit	Statistics	Full Analysis Set N=20			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Iris	Visit 6 - Day 29±1	N	20	20	20	20
		Mean	0.0	0.0	0.0	0.0
		SD	0.0	0.0	0.0	0.0
		CV%	NC	NC	NC	NC
		Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
		Max	0	0	0	0
Iris	Final Visit - Day 56±4/ETV	N	20	20	20	20
		Mean	0.0	0.0	0.0	0.0
		SD	0.0	0.0	0.0	0.0
		CV%	NC	NC	NC	NC
		Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
		Max	0	0	0	0
Anterior Chamber Inflammation	Screening - Day -15/-1	N	20		20	
		Mean	0.0		0.0	

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Parameter	Visit	Statistics	Full Analysis Set N=20			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Anterior Chamber Inflammation	Visit 2 - Day 1	SD	0.0		0.0	
		CV%	NC		NC	
		Min	0		0	
		Median	0.0		0.0	
		Max	0		0	
		N	20	20	20	20
		Mean	0.0	0.0	0.0	0.0
		SD	0.0	0.0	0.0	0.0
		CV%	NC	NC	NC	NC
		Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
Anterior Chamber Inflammation	Visit 3 - Day 8±1	Max	0	0	0	0
		N	20	20	20	20
		Mean	0.0	0.0	0.0	0.0
		SD	0.0	0.0	0.0	0.0
		CV%	NC	NC	NC	NC
		Min	0	0	0	0

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Investigational Medicinal Product: rhNGF 20 µg/mL - Overall Dry Eye Severity Level

Parameter	Visit	Statistics	Full Analysis Set N=20			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Anterior Chamber Inflammation	Visit 6 - Day 29±1	Median	0.0	0.0	0.0	0.0
		Max	0	0	0	0
		N	20	20	20	20
		Mean	0.0	0.0	0.0	0.0
		SD	0.0	0.0	0.0	0.0
		CV%	NC	NC	NC	NC
		Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
		Max	0	0	0	0
		N	20	20	20	20
		Mean	0.0	0.0	0.0	0.0
		SD	0.0	0.0	0.0	0.0
		CV%	NC	NC	NC	NC
		Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
		Max	0	0	0	0

Table 14.2.1.5 Slit lamp examination (Full analysis set)

Investigational Medicinal Product: rhNGF 20 µg/mL - Overall Dry Eye Severity Level

Parameter	Visit	Statistics	Full Analysis Set N=20			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline

Note: Patients are summarised according to the Investigational Medicinal Product they actually received

Baseline: Screening visit assessment

Source: [Listing 16.2.6.5](#) - Slit lamp examination

Program: Tables\c116-qs-01-tbl.sas

Table 14.2.1.5 Slit lamp examination (Full analysis set)

Investigational Medicinal Product: rhNGF 4 µg/mL - Dry Eye Severity Level ≤ 2

Parameter	Visit	Statistics	Full Analysis Set N=13			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline

Eyelid - Meibomian glands	Screening - Day -15/-1	N	13		13	
		Mean	0.4		0.5	
		SD	0.7		0.7	
		CV%	169.1		143.0	

Table 14.2.1.5 Slit lamp examination (Full analysis set)

Investigational Medicinal Product: rhNGF 4 µg/mL - Dry Eye Severity Level > 2

Parameter	Visit	Statistics	Full Analysis Set N=7			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline

Note: Patients are summarised according to the Investigational Medicinal Product they actually received

Baseline: Screening visit assessment

Source: [Listing 16.2.6.5](#) - Slit lamp examination

Program: Tables\c116-qs-01-tbl.sas

Table 14.2.1.5 Slit lamp examination (Full analysis set)

Investigational Medicinal Product: rhNGF 4 µg/mL - Overall Dry Eye Severity Level

Parameter	Visit	Statistics	Full Analysis Set N=20			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline

Eyelid - Meibomian glands	Screening - Day -15/-1	N	20		20	
		Mean	0.6		0.6	
		SD	0.8		0.7	
		CV%	125.7		113.4	

Table 14.2.1.5 Slit lamp examination (Full analysis set)

Investigational Medicinal Product: rhNGF 4 µg/mL - Overall Dry Eye Severity Level

Parameter	Visit	Statistics	Full Analysis Set N=20			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Eyelid - Meibomian glands	Visit 2 - Day 1	Min	0		0	
		Median	0.0		0.5	
		Max	2		2	
		N	20	20	20	20
		Mean	0.5	-0.2	0.5	-0.1
		SD	0.6	0.4	0.7	0.3
		CV%	134.4	-244.2	137.6	-307.8
		Min	0	-1	0	-1
		Median	0.0	0.0	0.0	0.0
		Max	2	0	2	0
		N	20	20	20	20
		Mean	0.3	-0.3	0.5	-0.1
		SD	0.6	0.6	0.7	0.7
		CV%	190.4	-190.4	137.6	-718.2
		Min	0	-2	0	-1
		Median	0.0	0.0	0.0	0.0
		Max	2	0	2	2

Table 14.2.1.5 Slit lamp examination (Full analysis set)

Investigational Medicinal Product: rhNGF 4 µg/mL - Overall Dry Eye Severity Level

Parameter	Visit	Statistics	Full Analysis Set N=20			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Eyelid - Meibomian glands	Visit 6 - Day 29±1	N	19	19	19	19
		Mean	0.4	-0.3	0.3	-0.3
		SD	0.5	0.7	0.5	0.6
		CV%	134.5	-248.3	151.2	-184.4
		Min	0	-1	0	-1
		Median	0.0	0.0	0.0	0.0
		Max	1	1	1	1
Eyelid - Meibomian glands	Final Visit - Day 56±4/ETV	N	20	20	20	20
		Mean	0.4	-0.3	0.4	-0.3
		SD	0.5	0.7	0.5	0.6
		CV%	139.8	-286.5	139.8	-220.0
		Min	0	-2	0	-1
		Median	0.0	0.0	0.0	0.0
		Max	1	1	1	1
Eyelid - Erythema	Screening - Day -15/-1	N	20		20	
		Mean	0.4		0.4	

Table 14.2.1.5 Slit lamp examination (Full analysis set)

Investigational Medicinal Product: rhNGF 4 µg/mL - Overall Dry Eye Severity Level

Parameter	Visit	Statistics	Full Analysis Set N=20			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Eyelid - Erythema	Visit 2 - Day 1	SD	0.7		0.8	
		CV%	191.7		205.2	
		Min	0		0	
		Median	0.0		0.0	
		Max	2		3	
		N	20	20	20	20
		Mean	0.3	-0.1	0.4	-0.1
		SD	0.7	0.2	0.8	0.2
		CV%	219.0	-447.2	232.2	-447.2
		Min	0	-1	0	-1
Eyelid - Erythema	Visit 3 - Day 8±1	Median	0.0	0.0	0.0	0.0
		Max	2	0	3	0
		N	20	20	20	20
		Mean	0.4	0.0	0.4	-0.1
		SD	0.7	0.6	0.8	0.4
		CV%	212.9	NC	232.2	-788.1
		Min	0	-1	0	-1

Table 14.2.1.5 Slit lamp examination (Full analysis set)

Investigational Medicinal Product: rhNGF 4 µg/mL - Overall Dry Eye Severity Level

Parameter	Visit	Statistics	Full Analysis Set N=20			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Eyelid - Erythema	Visit 6 - Day 29±1	Median	0.0	0.0	0.0	0.0
		Max	2	2	3	1
		N	19	19	19	19
		Mean	0.4	0.1	0.3	-0.1
		SD	0.7	0.7	0.6	0.7
		CV%	164.5	1339.6	184.4	-624.9
		Min	0	-1	0	-2
		Median	0.0	0.0	0.0	0.0
		Max	2	2	2	1
		N	20	20	20	20
		Mean	0.3	-0.1	0.2	-0.2
		SD	0.4	0.6	0.4	0.6
		CV%	177.7	-552.5	205.2	-307.8
		Min	0	-1	0	-2
		Median	0.0	0.0	0.0	0.0
		Max	1	1	1	1

Table 14.2.1.5 Slit lamp examination (Full analysis set)

Investigational Medicinal Product: rhNGF 4 µg/mL - Overall Dry Eye Severity Level

Parameter	Visit	Statistics	Full Analysis Set N=20			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Eyelid - Oedema	Screening - Day -15/-1	N	20		20	
		Mean	0.3		0.3	
		SD	0.6		0.6	
		CV%	220.0		220.0	
		Min	0		0	
		Median	0.0		0.0	
		Max	2		2	
Eyelid - Oedema	Visit 2 - Day 1	N	20	20	20	20
		Mean	0.3	0.0	0.3	0.0
		SD	0.6	0.3	0.6	0.3
		CV%	220.0	NC	220.0	NC
		Min	0	-1	0	-1
		Median	0.0	0.0	0.0	0.0
		Max	2	1	2	1
Eyelid - Oedema	Visit 3 - Day 8±1	N	20	20	20	20
		Mean	0.4	0.2	0.4	0.2
		SD	0.7	0.5	0.8	0.6

Table 14.2.1.5 Slit lamp examination (Full analysis set)

Investigational Medicinal Product: rhNGF 4 µg/mL - Overall Dry Eye Severity Level

Parameter	Visit	Statistics	Full Analysis Set N=20			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Eyelid - Oedema	Visit 6 - Day 29±1	CV%	170.1	326.2	205.2	391.4
		Min	0	-1	0	-1
		Median	0.0	0.0	0.0	0.0
		Max	2	1	3	2
		N	19	19	19	19
		Mean	0.4	0.2	0.4	0.1
		SD	0.7	0.6	0.7	0.6
		CV%	164.5	381.4	185.7	538.8
Eyelid - Oedema	Final Visit - Day 56±4/ETV	Min	0	-1	0	-1
		Median	0.0	0.0	0.0	0.0
		Max	2	1	2	1
		N	20	20	20	20
		Mean	0.3	0.0	0.2	-0.1
		SD	0.6	0.6	0.5	0.5
		CV%	220.0	NC	261.6	-1020.8
		Min	0	-1	0	-1
		Median	0.0	0.0	0.0	0.0

Table 14.2.1.5 Slit lamp examination (Full analysis set)

Investigational Medicinal Product: rhNGF 4 µg/mL - Overall Dry Eye Severity Level

Parameter	Visit	Statistics	Full Analysis Set N=20			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
		Max	2	1	2	1
Lashes	Screening - Day -15/-1	N	20		20	
		Mean	0.0		0.0	
		SD	0.0		0.0	
		CV%	NC		NC	
		Min	0		0	
		Median	0.0		0.0	
		Max	0		0	
Lashes	Visit 2 - Day 1	N	20	20	20	20
		Mean	0.0	0.0	0.0	0.0
		SD	0.0	0.0	0.0	0.0
		CV%	NC	NC	NC	NC
		Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
		Max	0	0	0	0
Lashes	Visit 3 - Day 8±1	N	20	20	20	20

Table 14.2.1.5 Slit lamp examination (Full analysis set)

Investigational Medicinal Product: rhNGF 4 µg/mL - Overall Dry Eye Severity Level

Parameter	Visit	Statistics	Full Analysis Set N=20			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Lashes	Visit 6 - Day 29±1	Mean	0.0	0.0	0.0	0.0
		SD	0.0	0.0	0.0	0.0
		CV%	NC	NC	NC	NC
		Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
		Max	0	0	0	0
		N	19	19	19	19
		Mean	0.0	0.0	0.0	0.0
		SD	0.0	0.0	0.0	0.0
		CV%	NC	NC	NC	NC
		Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
		Max	0	0	0	0
Lashes	Final Visit - Day 56±4/ETV	N	20	20	20	20
		Mean	0.0	0.0	0.0	0.0
		SD	0.0	0.0	0.0	0.0
		CV%	NC	NC	NC	NC

Table 14.2.1.5 Slit lamp examination (Full analysis set)

Investigational Medicinal Product: rhNGF 4 µg/mL - Overall Dry Eye Severity Level

Parameter	Visit	Statistics	Full Analysis Set N=20			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Conjunctiva - Erythema	Screening - Day -15/-1	Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
		Max	0	0	0	0
		N	20		20	
		Mean	1.3		1.2	
		SD	0.7		0.6	
		CV%	57.3		51.1	
		Min	0		0	
		Median	1.0		1.0	
		Max	3		2	
		N	20	20	20	20
		Mean	1.3	0.0	1.2	0.1
		SD	0.6	0.3	0.5	0.2
		CV%	44.0	NC	43.6	447.2
		Min	0	-1	0	0
		Median	1.0	0.0	1.0	0.0
		Max	2	1	2	1

Table 14.2.1.5 Slit lamp examination (Full analysis set)

Investigational Medicinal Product: rhNGF 4 µg/mL - Overall Dry Eye Severity Level

Parameter	Visit	Statistics	Full Analysis Set N=20			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Conjunctiva - Erythema	Visit 3 - Day 8±1	N	20	20	20	20
		Mean	1.0	-0.3	1.1	-0.1
		SD	0.3	0.6	0.4	0.6
		CV%	32.4	-255.5	40.7	-1209.6
		Min	0	-2	0	-1
		Median	1.0	0.0	1.0	0.0
		Max	2	1	2	1
Conjunctiva - Erythema	Visit 6 - Day 29±1	N	19	19	19	19
		Mean	1.0	-0.3	0.9	-0.3
		SD	0.6	0.7	0.6	0.7
		CV%	57.7	-278.7	63.4	-248.3
		Min	0	-2	0	-1
		Median	1.0	0.0	1.0	0.0
		Max	2	1	2	1
Conjunctiva - Erythema	Final Visit - Day 56±4/ETV	N	20	20	20	20
		Mean	1.0	-0.3	1.0	-0.2

Table 14.2.1.5 Slit lamp examination (Full analysis set)

Investigational Medicinal Product: rhNGF 4 µg/mL - Overall Dry Eye Severity Level

Parameter	Visit	Statistics	Full Analysis Set N=20			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Conjunctiva - Oedema	Screening - Day -15/-1	SD	0.5	0.8	0.5	0.7
		CV%	45.9	-314.6	45.9	-447.2
		Min	0	-2	0	-1
		Median	1.0	0.0	1.0	0.0
		Max	2	1	2	1
		N	20		20	
		Mean	0.9		0.9	
		SD	0.7		0.7	
		CV%	78.9		78.9	
		Min	0		0	
Conjunctiva - Oedema	Visit 2 - Day 1	Median	1.0		1.0	
		Max	2		2	
		N	20	20	20	20
		Mean	0.6	-0.3	0.7	-0.2
		SD	0.7	0.6	0.7	0.6
		CV%	113.4	-255.5	103.2	-307.8
		Min	0	-2	0	-2

Table 14.2.1.5 Slit lamp examination (Full analysis set)

Investigational Medicinal Product: rhNGF 4 µg/mL - Overall Dry Eye Severity Level

Parameter	Visit	Statistics	Full Analysis Set N=20			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Conjunctiva - Oedema	Visit 3 - Day 8±1	Median	0.5	0.0	1.0	0.0
		Max	2	1	2	1
		N	20	20	20	20
		Mean	0.5	-0.4	0.6	-0.3
		SD	0.5	0.7	0.6	0.8
		CV%	102.6	-212.9	110.0	-267.1
		Min	0	-2	0	-2
		Median	0.5	0.0	0.5	0.0
		Max	1	1	2	1
Conjunctiva - Oedema	Visit 6 - Day 29±1	N	19	19	19	19
		Mean	0.5	-0.4	0.5	-0.4
		SD	0.7	0.9	0.7	0.9
		CV%	147.1	-214.1	147.1	-214.1
		Min	0	-2	0	-2
		Median	0.0	-1.0	0.0	-1.0
		Max	2	2	2	2

Table 14.2.1.5 Slit lamp examination (Full analysis set)

Investigational Medicinal Product: rhNGF 4 µg/mL - Overall Dry Eye Severity Level

Parameter	Visit	Statistics	Full Analysis Set N=20			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Conjunctiva - Oedema	Final Visit - Day 56±4/ETV	N	20	20	20	20
		Mean	0.3	-0.6	0.3	-0.6
		SD	0.7	1.0	0.7	1.0
		CV%	219.0	-181.6	219.0	-181.6
		Min	0	-2	0	-2
		Median	0.0	-1.0	0.0	-1.0
		Max	2	2	2	2
Lens	Screening - Day -15/-1	N	16		16	
		Mean	0.4		0.3	
		SD	0.6		0.5	
		CV%	165.1		153.2	
		Min	0		0	
		Median	0.0		0.0	
		Max	2		1	
Lens	Visit 2 - Day 1	N	16	16	16	16
		Mean	0.4	0.0	0.3	0.0
		SD	0.6	0.0	0.5	0.0

Table 14.2.1.5 Slit lamp examination (Full analysis set)

Investigational Medicinal Product: rhNGF 4 µg/mL - Overall Dry Eye Severity Level

Parameter	Visit	Statistics	Full Analysis Set N=20			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Lens	Visit 3 - Day 8±1	CV%	165.1	NC	153.2	NC
		Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
		Max	2	0	1	0
		N	16	16	16	16
		Mean	0.4	0.0	0.3	0.0
		SD	0.6	0.0	0.5	0.0
		CV%	165.1	NC	153.2	NC
		Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
Lens	Visit 6 - Day 29±1	Max	2	0	1	0
		N	15	15	15	15
		Mean	0.3	-0.1	0.3	0.0
		SD	0.5	0.3	0.5	0.0
		CV%	146.4	-387.3	146.4	NC
		Min	0	-1	0	0
		Median	0.0	0.0	0.0	0.0

Table 14.2.1.5 Slit lamp examination (Full analysis set)

Investigational Medicinal Product: rhNGF 4 µg/mL - Overall Dry Eye Severity Level

Parameter	Visit	Statistics	Full Analysis Set N=20			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
		Max	1	0	1	0
Lens	Final Visit - Day 56±4/ETV	N	16	16	16	16
		Mean	0.3	-0.1	0.3	0.0
		SD	0.5	0.3	0.5	0.0
		CV%	153.2	-400.0	153.2	NC
		Min	0	-1	0	0
		Median	0.0	0.0	0.0	0.0
		Max	1	0	1	0
Iris	Screening - Day -15/-1	N	20		20	
		Mean	0.0		0.0	
		SD	0.0		0.0	
		CV%	NC		NC	
		Min	0		0	
		Median	0.0		0.0	
		Max	0		0	
Iris	Visit 2 - Day 1	N	20	20	20	20

Table 14.2.1.5 Slit lamp examination (Full analysis set)

Investigational Medicinal Product: rhNGF 4 µg/mL - Overall Dry Eye Severity Level

Parameter	Visit	Statistics	Full Analysis Set N=20			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Iris	Visit 3 - Day 8±1	Mean	0.0	0.0	0.0	0.0
		SD	0.0	0.0	0.0	0.0
		CV%	NC	NC	NC	NC
		Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
		Max	0	0	0	0
		N	20	20	20	20
	Visit 6 - Day 29±1	Mean	0.0	0.0	0.0	0.0
		SD	0.0	0.0	0.0	0.0
		CV%	NC	NC	NC	NC
		Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
		Max	0	0	0	0

Table 14.2.1.5 Slit lamp examination (Full analysis set)

Investigational Medicinal Product: rhNGF 4 µg/mL - Overall Dry Eye Severity Level

Parameter	Visit	Statistics	Full Analysis Set N=20			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Iris	Final Visit - Day 56±4/ETV	Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
		Max	0	0	0	0
		N	20	20	20	20
		Mean	0.0	0.0	0.0	0.0
		SD	0.0	0.0	0.0	0.0
		CV%	NC	NC	NC	NC
		Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
		Max	0	0	0	0
Anterior Chamber Inflammation	Screening - Day -15/-1	N	20		20	
		Mean	0.0		0.0	
		SD	0.0		0.0	
		CV%	NC		NC	
		Min	0		0	
		Median	0.0		0.0	
		Max	0		0	

Table 14.2.1.5 Slit lamp examination (Full analysis set)

Investigational Medicinal Product: rhNGF 4 µg/mL - Overall Dry Eye Severity Level

Parameter	Visit	Statistics	Full Analysis Set N=20			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Anterior Chamber Inflammation	Visit 2 - Day 1	N	20	20	20	20
		Mean	0.0	0.0	0.0	0.0
		SD	0.0	0.0	0.0	0.0
		CV%	NC	NC	NC	NC
		Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
		Max	0	0	0	0
Anterior Chamber Inflammation	Visit 3 - Day 8±1	N	20	20	20	20
		Mean	0.0	0.0	0.0	0.0
		SD	0.0	0.0	0.0	0.0
		CV%	NC	NC	NC	NC
		Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
		Max	0	0	0	0
Anterior Chamber Inflammation	Visit 6 - Day 29±1	N	19	19	19	19
		Mean	0.0	0.0	0.0	0.0

Table 14.2.1.5 Slit lamp examination (Full analysis set)

Investigational Medicinal Product: rhNGF 4 µg/mL - Overall Dry Eye Severity Level

Parameter	Visit	Statistics	Full Analysis Set N=20			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Anterior Chamber Inflammation	Final Visit - Day 56±4/ETV	SD	0.0	0.0	0.0	0.0
		CV%	NC	NC	NC	NC
		Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
		Max	0	0	0	0
		N	20	20	20	20
		Mean	0.0	0.0	0.0	0.0
		SD	0.0	0.0	0.0	0.0
		CV%	NC	NC	NC	NC
		Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
		Max	0	0	0	0

Note: Patients are summarised according to the Investigational Medicinal Product they actually received

Baseline: Screening visit assessment

Source: [Listing 16.2.6.5](#) - Slit lamp examination

Program: Tables\c116-qs-01-tbl.sas

Table 14.2.1.20 Slit lamp examination (Per protocol set)

Investigational Medicinal Product: rhNGF 20 µg/mL - Overall Dry Eye Severity Level

Parameter	Visit	Statistics	Per Protocol Set N=14			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Eyelid - Meibomian glands	Screening - Day -15/-1	N	14		14	
		Mean	0.9		0.9	
		SD	0.7		0.5	
		CV%	78.6		51.1	
		Min	0		0	
		Median	1.0		1.0	
		Max	2		2	
Eyelid - Meibomian glands	Visit 2 - Day 1	N	14	14	14	14
		Mean	1.1	0.2	0.9	0.0
		SD	0.8	0.4	0.6	0.4
		CV%	67.4	198.7	66.3	NC
		Min	0	0	0	-1
		Median	1.0	0.0	1.0	0.0
		Max	2	1	2	1
Eyelid - Meibomian glands	Visit 3 - Day 8±1	N	14	14	14	14
		Mean	0.9	-0.1	0.8	-0.1

Table 14.2.1.20 Slit lamp examination (Per protocol set)

Investigational Medicinal Product: rhNGF 20 µg/mL - Overall Dry Eye Severity Level

Parameter	Visit	Statistics	Per Protocol Set N=14			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Eyelid - Meibomian glands	Visit 6 - Day 29±1	SD	0.5	0.6	0.6	0.7
		CV%	62.4	-862.0	73.7	-464.1
		Min	0	-1	0	-1
		Median	1.0	0.0	1.0	0.0
		Max	2	1	2	1
		N	14	14	14	14
		Mean	0.4	-0.5	0.6	-0.4
		SD	0.5	0.9	0.5	0.6
		CV%	119.8	-171.0	89.9	-177.3
		Min	0	-2	0	-1
		Median	0.0	-1.0	1.0	0.0
Eyelid - Meibomian glands	Final Visit - Day 56±4/ETV	Max	1	1	1	1
		N	14	14	14	14
		Mean	0.8	-0.1	0.6	-0.4
		SD	0.6	0.9	0.6	0.7
		CV%	73.7	-605.1	113.1	-208.6
		Min	0	-2	0	-2

Table 14.2.1.20 Slit lamp examination (Per protocol set)

Investigational Medicinal Product: rhNGF 20 µg/mL - Overall Dry Eye Severity Level

Parameter	Visit	Statistics	Per Protocol Set N=14			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Eyelid - Erythema	Screening - Day -15/-1	Median	1.0	0.0	0.5	0.0
		Max	2	1	2	1
		N	14		14	
		Mean	0.7		0.7	
		SD	0.6		0.6	
		CV%	85.6		85.6	
		Min	0		0	
		Median	1.0		1.0	
		Max	2		2	
		N	14	14	14	14
		Mean	0.8	0.1	0.7	0.0
		SD	0.7	0.3	0.6	0.0
		CV%	89.0	374.2	85.6	NC
		Min	0	0	0	0
		Median	1.0	0.0	1.0	0.0
		Max	2	1	2	0

Table 14.2.1.20 Slit lamp examination (Per protocol set)

Investigational Medicinal Product: rhNGF 20 µg/mL - Overall Dry Eye Severity Level

Parameter	Visit	Statistics	Per Protocol Set N=14			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Eyelid - Erythema	Visit 3 - Day 8±1	N	14	14	14	14
		Mean	0.5	-0.2	0.5	-0.2
		SD	0.5	0.4	0.5	0.4
		CV%	103.8	-198.7	103.8	-198.7
		Min	0	-1	0	-1
		Median	0.5	0.0	0.5	0.0
		Max	1	0	1	0
Eyelid - Erythema	Visit 6 - Day 29±1	N	14	14	14	14
		Mean	0.1	-0.6	0.1	-0.6
		SD	0.3	0.6	0.3	0.6
		CV%	374.2	-98.5	374.2	-98.5
		Min	0	-2	0	-2
		Median	0.0	-1.0	0.0	-1.0
		Max	1	0	1	0
Eyelid - Erythema	Final Visit - Day 56±4/ETV	N	14	14	14	14
		Mean	0.1	-0.6	0.1	-0.6
		SD	0.3	0.7	0.3	0.7

Table 14.2.1.20 Slit lamp examination (Per protocol set)

Investigational Medicinal Product: rhNGF 20 µg/mL - Overall Dry Eye Severity Level

Parameter	Visit	Statistics	Per Protocol Set N=14			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Eyelid - Oedema	Screening - Day -15/-1	CV%	374.2	-115.9	374.2	-115.9
		Min	0	-2	0	-2
		Median	0.0	-1.0	0.0	-1.0
		Max	1	1	1	1
		N	14		14	
		Mean	0.5		0.5	
		SD	0.5		0.5	
		CV%	103.8		103.8	
		Min	0		0	
		Median	0.5		0.5	
Eyelid - Oedema	Visit 2 - Day 1	Max	1		1	
		N	14	14	14	14
		Mean	0.6	0.1	0.5	0.0
		SD	0.6	0.5	0.5	0.4
		CV%	113.1	664.5	103.8	NC
		Min	0	-1	0	-1
		Median	0.5	0.0	0.5	0.0

Table 14.2.1.20 Slit lamp examination (Per protocol set)

Investigational Medicinal Product: rhNGF 20 µg/mL - Overall Dry Eye Severity Level

Parameter	Visit	Statistics	Per Protocol Set N=14			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
		Max	2	1	1	1
Eyelid - Oedema	Visit 3 - Day 8±1	N	14	14	14	14
		Mean	0.2	-0.3	0.1	-0.4
		SD	0.4	0.5	0.4	0.5
		CV%	198.7	-164.1	254.2	-139.2
		Min	0	-1	0	-1
		Median	0.0	0.0	0.0	0.0
		Max	1	0	1	0
Eyelid - Oedema	Visit 6 - Day 29±1	N	14	14	14	14
		Mean	0.1	-0.4	0.1	-0.4
		SD	0.3	0.5	0.3	0.5
		CV%	374.2	-119.8	374.2	-119.8
		Min	0	-1	0	-1
		Median	0.0	0.0	0.0	0.0
		Max	1	0	1	0
Eyelid - Oedema	Final Visit - Day 56±4/ETV	N	14	14	14	14

Table 14.2.1.20 Slit lamp examination (Per protocol set)

Investigational Medicinal Product: rhNGF 20 µg/mL - Overall Dry Eye Severity Level

Parameter	Visit	Statistics	Per Protocol Set N=14			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Lashes	Screening - Day -15/-1	Mean	0.1	-0.4	0.1	-0.4
		SD	0.3	0.5	0.3	0.5
		CV%	374.2	-119.8	374.2	-119.8
		Min	0	-1	0	-1
		Median	0.0	0.0	0.0	0.0
		Max	1	0	1	0
	Visit 2 - Day 1	N	14		14	
		Mean	0.0		0.0	
		SD	0.0		0.0	
		CV%	NC		NC	
		Min	0		0	
		Median	0.0		0.0	
		Max	0		0	
Lashes	Visit 2 - Day 1	N	14	14	14	14
		Mean	0.0	0.0	0.0	0.0
		SD	0.0	0.0	0.0	0.0
		CV%	NC	NC	NC	NC

Table 14.2.1.20 Slit lamp examination (Per protocol set)

Investigational Medicinal Product: rhNGF 20 µg/mL - Overall Dry Eye Severity Level

Parameter	Visit	Statistics	Per Protocol Set N=14			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Lashes	Visit 3 - Day 8±1	Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
		Max	0	0	0	0
		N	14	14	14	14
		Mean	0.0	0.0	0.0	0.0
		SD	0.0	0.0	0.0	0.0
		CV%	NC	NC	NC	NC
		Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
		Max	0	0	0	0
		N	14	14	14	14
		Mean	0.0	0.0	0.0	0.0
		SD	0.0	0.0	0.0	0.0
		CV%	NC	NC	NC	NC

Table 14.2.1.20 Slit lamp examination (Per protocol set)

Investigational Medicinal Product: rhNGF 20 µg/mL - Overall Dry Eye Severity Level

Parameter	Visit	Statistics	Per Protocol Set N=14			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Lashes	Final Visit - Day 56±4/ETV	N	14	14	14	14
		Mean	0.0	0.0	0.0	0.0
		SD	0.0	0.0	0.0	0.0
		CV%	NC	NC	NC	NC
		Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
		Max	0	0	0	0
Conjunctiva - Erythema	Screening - Day -15/-1	N	14		14	
		Mean	1.3		1.2	
		SD	0.6		0.6	
		CV%	47.5		47.7	
		Min	0		0	
		Median	1.0		1.0	
		Max	2		2	
Conjunctiva - Erythema	Visit 2 - Day 1	N	14	14	14	14
		Mean	1.1	-0.1	1.2	0.0

Table 14.2.1.20 Slit lamp examination (Per protocol set)

Investigational Medicinal Product: rhNGF 20 µg/mL - Overall Dry Eye Severity Level

Parameter	Visit	Statistics	Per Protocol Set N=14			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
		SD	0.4	0.5	0.4	0.6
		CV%	31.8	-374.2	35.1	NC
		Min	1	-1	1	-1
		Median	1.0	0.0	1.0	0.0
		Max	2	1	2	1
Conjunctiva - Erythema	Visit 3 - Day 8±1	N	14	14	14	14
		Mean	1.1	-0.1	1.0	-0.2
		SD	0.7	0.8	0.6	0.7
		CV%	58.0	-539.2	55.5	-326.3
		Min	0	-2	0	-2
		Median	1.0	0.0	1.0	0.0
		Max	2	1	2	1
Conjunctiva - Erythema	Visit 6 - Day 29±1	N	14	14	14	14
		Mean	1.0	-0.3	1.0	-0.2
		SD	0.4	0.6	0.4	0.6
		CV%	39.2	-213.9	39.2	-270.2
		Min	0	-1	0	-1

Table 14.2.1.20 Slit lamp examination (Per protocol set)

Investigational Medicinal Product: rhNGF 20 µg/mL - Overall Dry Eye Severity Level

Parameter	Visit	Statistics	Per Protocol Set N=14			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Conjunctiva - Erythema	Final Visit - Day 56±4/ETV	Median	1.0	0.0	1.0	0.0
		Max	2	1	2	1
		N	14	14	14	14
		Mean	1.1	-0.2	1.0	-0.2
		SD	0.5	0.8	0.4	0.7
		CV%	44.3	-374.2	39.2	-326.3
		Min	0	-2	0	-2
		Median	1.0	0.0	1.0	0.0
		Max	2	1	2	1
		N	14		14	
		Mean	0.9		0.9	
		SD	0.5		0.6	
		CV%	62.4		66.3	
		Min	0		0	
		Median	1.0		1.0	
		Max	2		2	

Table 14.2.1.20 Slit lamp examination (Per protocol set)

Investigational Medicinal Product: rhNGF 20 µg/mL - Overall Dry Eye Severity Level

Parameter	Visit	Statistics	Per Protocol Set N=14			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Conjunctiva - Oedema	Visit 2 - Day 1	N	14	14	14	14
		Mean	0.7	-0.1	0.7	-0.2
		SD	0.5	0.4	0.5	0.4
		CV%	65.6	-254.2	65.6	-198.7
		Min	0	-1	0	-1
		Median	1.0	0.0	1.0	0.0
		Max	1	0	1	0
Conjunctiva - Oedema	Visit 3 - Day 8±1	N	14	14	14	14
		Mean	0.8	-0.1	0.8	-0.1
		SD	0.6	0.6	0.4	0.8
		CV%	73.7	-862.0	54.2	-539.2
		Min	0	-1	0	-1
		Median	1.0	0.0	1.0	0.0
		Max	2	1	1	1
Conjunctiva - Oedema	Visit 6 - Day 29±1	N	14	14	14	14
		Mean	0.5	-0.4	0.4	-0.5
		SD	0.5	0.8	0.5	0.9

Table 14.2.1.20 Slit lamp examination (Per protocol set)

Investigational Medicinal Product: rhNGF 20 µg/mL - Overall Dry Eye Severity Level

Parameter	Visit	Statistics	Per Protocol Set N=14			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Conjunctiva - Oedema	Final Visit - Day 56±4/ETV	CV%	103.8	-235.7	119.8	-171.0
		Min	0	-2	0	-2
		Median	0.5	0.0	0.0	0.0
		Max	1	1	1	1
		N	14	14	14	14
		Mean	0.7	-0.1	0.6	-0.3
		SD	0.5	0.9	0.5	0.9
		CV%	65.6	-605.1	77.3	-319.9
		Min	0	-2	0	-2
		Median	1.0	0.0	1.0	0.0
Lens	Screening - Day -15/-1	Max	1	1	1	1
		N	13		13	
		Mean	0.3		0.3	
		SD	0.5		0.5	
		CV%	156.1		156.1	
		Min	0		0	
		Median	0.0		0.0	

Table 14.2.1.20 Slit lamp examination (Per protocol set)

Investigational Medicinal Product: rhNGF 20 µg/mL - Overall Dry Eye Severity Level

Parameter	Visit	Statistics	Per Protocol Set N=14			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Lens	Visit 2 - Day 1	Max	1		1	
		N	13	13	13	13
		Mean	0.3	0.0	0.3	0.0
		SD	0.5	0.0	0.5	0.0
		CV%	156.1	NC	156.1	NC
		Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
		Max	1	0	1	0
Lens	Visit 3 - Day 8±1	N	13	13	13	13
		Mean	0.2	-0.1	0.2	-0.1
		SD	0.4	0.3	0.4	0.3
		CV%	190.0	-360.6	190.0	-360.6
		Min	0	-1	0	-1
		Median	0.0	0.0	0.0	0.0
		Max	1	0	1	0
Lens	Visit 6 - Day 29±1	N	13	13	13	13

Table 14.2.1.20 Slit lamp examination (Per protocol set)

Investigational Medicinal Product: rhNGF 20 µg/mL - Overall Dry Eye Severity Level

Parameter	Visit	Statistics	Per Protocol Set N=14			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Lens	Final Visit - Day 56±4/ETV	Mean	0.2	-0.2	0.2	-0.2
		SD	0.4	0.4	0.4	0.4
		CV%	244.1	-244.1	244.1	-244.1
		Min	0	-1	0	-1
		Median	0.0	0.0	0.0	0.0
		Max	1	0	1	0
		N	13	13	13	13
		Mean	0.2	-0.2	0.2	-0.2
		SD	0.4	0.4	0.4	0.4
		CV%	244.1	-244.1	244.1	-244.1
		Min	0	-1	0	-1
		Median	0.0	0.0	0.0	0.0
		Max	1	0	1	0
Iris	Screening - Day -15/-1	N	14		14	
		Mean	0.0		0.0	
		SD	0.0		0.0	
		CV%	NC		NC	

Table 14.2.1.20 Slit lamp examination (Per protocol set)

Investigational Medicinal Product: rhNGF 20 µg/mL - Overall Dry Eye Severity Level

Parameter	Visit	Statistics	Per Protocol Set N=14			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Iris	Visit 2 - Day 1	Min	0		0	
		Median	0.0		0.0	
		Max	0		0	
		N	14	14	14	14
		Mean	0.0	0.0	0.0	0.0
		SD	0.0	0.0	0.0	0.0
		CV%	NC	NC	NC	NC
		Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
		Max	0	0	0	0
	Visit 3 - Day 8±1	N	14	14	14	14
		Mean	0.0	0.0	0.0	0.0
		SD	0.0	0.0	0.0	0.0
		CV%	NC	NC	NC	NC
		Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
		Max	0	0	0	0

Table 14.2.1.20 Slit lamp examination (Per protocol set)

Investigational Medicinal Product: rhNGF 20 µg/mL - Overall Dry Eye Severity Level

Parameter	Visit	Statistics	Per Protocol Set N=14			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Iris	Visit 6 - Day 29±1	N	14	14	14	14
		Mean	0.0	0.0	0.0	0.0
		SD	0.0	0.0	0.0	0.0
		CV%	NC	NC	NC	NC
		Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
		Max	0	0	0	0
Iris	Final Visit - Day 56±4/ETV	N	14	14	14	14
		Mean	0.0	0.0	0.0	0.0
		SD	0.0	0.0	0.0	0.0
		CV%	NC	NC	NC	NC
		Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
		Max	0	0	0	0
Anterior Chamber Inflammation	Screening - Day -15/-1	N	14		14	
		Mean	0.0		0.0	

Table 14.2.1.20 Slit lamp examination (Per protocol set)

Investigational Medicinal Product: rhNGF 20 µg/mL - Overall Dry Eye Severity Level

Parameter	Visit	Statistics	Per Protocol Set N=14			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Anterior Chamber Inflammation	Visit 2 - Day 1	SD	0.0		0.0	
		CV%	NC		NC	
		Min	0		0	
		Median	0.0		0.0	
		Max	0		0	
		N	14	14	14	14
		Mean	0.0	0.0	0.0	0.0
		SD	0.0	0.0	0.0	0.0
		CV%	NC	NC	NC	NC
		Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
Anterior Chamber Inflammation	Visit 3 - Day 8±1	Max	0	0	0	0
		N	14	14	14	14
		Mean	0.0	0.0	0.0	0.0
		SD	0.0	0.0	0.0	0.0
		CV%	NC	NC	NC	NC
		Min	0	0	0	0

Table 14.2.1.20 Slit lamp examination (Per protocol set)

Investigational Medicinal Product: rhNGF 20 µg/mL - Overall Dry Eye Severity Level

Parameter	Visit	Statistics	Per Protocol Set N=14			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Anterior Chamber Inflammation	Visit 6 - Day 29±1	Median	0.0	0.0	0.0	0.0
		Max	0	0	0	0
		N	14	14	14	14
		Mean	0.0	0.0	0.0	0.0
		SD	0.0	0.0	0.0	0.0
		CV%	NC	NC	NC	NC
		Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
		Max	0	0	0	0
		N	14	14	14	14
		Mean	0.0	0.0	0.0	0.0
		SD	0.0	0.0	0.0	0.0
		CV%	NC	NC	NC	NC
		Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
		Max	0	0	0	0

Table 14.2.1.20 Slit lamp examination (Per protocol set)

Investigational Medicinal Product: rhNGF 20 µg/mL - Overall Dry Eye Severity Level

Parameter	Visit	Statistics	Per Protocol Set N=14			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline

Note: Patients are summarised according to the Investigational Medicinal Product they actually received

Baseline: Screening visit assessment

Source: [Listing 16.2.6.5](#) - Slit lamp examination

Program: Tables\c116-qs-01-tbl.sas

Table 14.2.1.20 Slit lamp examination (Per protocol set)

Investigational Medicinal Product: rhNGF 4 µg/mL - Dry Eye Severity Level <= 2

Parameter	Visit	Statistics	Per Protocol Set N=11			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline

Eyelid - Meibomian glands	Screening - Day -15/-1	N	11		11	
		Mean	0.4		0.5	
		SD	0.7		0.7	
		CV%	185.4		151.3	

Table 14.2.1.20 Slit lamp examination (Per protocol set)

Investigational Medicinal Product: rhNGF 4 µg/mL - Dry Eye Severity Level > 2

Parameter	Visit	Statistics	Per Protocol Set N=5			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline

Note: Patients are summarised according to the Investigational Medicinal Product they actually received

Baseline: Screening visit assessment

Source: [Listing 16.2.6.5](#) - Slit lamp examination

Program: Tables\c116-qs-01-tbl.sas

Table 14.2.1.20 Slit lamp examination (Per protocol set)

Investigational Medicinal Product: rhNGF 4 µg/mL - Overall Dry Eye Severity Level

Parameter	Visit	Statistics	Per Protocol Set N=16			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline

Eyelid - Meibomian glands	Screening - Day -15/-1	N	16		16	
		Mean	0.6		0.6	
		SD	0.7		0.6	
		CV%	129.3		111.8	

Table 14.2.1.20 Slit lamp examination (Per protocol set)

Investigational Medicinal Product: rhNGF 4 µg/mL - Overall Dry Eye Severity Level

Parameter	Visit	Statistics	Per Protocol Set N=16			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Eyelid - Meibomian glands	Visit 2 - Day 1	Min	0		0	
		Median	0.0		0.5	
		Max	2		2	
		N	16	16	16	16
		Mean	0.4	-0.1	0.5	-0.1
		SD	0.5	0.3	0.6	0.3
		CV%	117.1	-273.3	126.5	-400.0
		Min	0	-1	0	-1
		Median	0.0	0.0	0.0	0.0
		Max	1	0	2	0
		N	16	16	16	16
		Mean	0.3	-0.3	0.5	-0.1
		SD	0.4	0.6	0.6	0.8
		CV%	178.9	-192.7	126.5	-1235.0
		Min	0	-2	0	-1
		Median	0.0	0.0	0.0	0.0
		Max	1	0	2	2

Table 14.2.1.20 Slit lamp examination (Per protocol set)

Investigational Medicinal Product: rhNGF 4 µg/mL - Overall Dry Eye Severity Level

Parameter	Visit	Statistics	Per Protocol Set N=16			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Eyelid - Meibomian glands	Visit 6 - Day 29±1	N	16	16	16	16
		Mean	0.4	-0.2	0.3	-0.3
		SD	0.5	0.7	0.5	0.6
		CV%	133.3	-349.4	153.2	-230.9
		Min	0	-1	0	-1
		Median	0.0	0.0	0.0	0.0
		Max	1	1	1	1
Eyelid - Meibomian glands	Final Visit - Day 56±4/ETV	N	16	16	16	16
		Mean	0.4	-0.2	0.4	-0.2
		SD	0.5	0.8	0.5	0.5
		CV%	133.3	-400.0	133.3	-290.1
		Min	0	-2	0	-1
		Median	0.0	0.0	0.0	0.0
		Max	1	1	1	1
Eyelid - Erythema	Screening - Day -15/-1	N	16		16	
		Mean	0.3		0.3	

Table 14.2.1.20 Slit lamp examination (Per protocol set)

Investigational Medicinal Product: rhNGF 4 µg/mL - Overall Dry Eye Severity Level

Parameter	Visit	Statistics	Per Protocol Set N=16			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Eyelid - Erythema	Visit 2 - Day 1	SD	0.6		0.8	
		CV%	230.9		253.8	
		Min	0		0	
		Median	0.0		0.0	
		Max	2		3	
		N	16	16	16	16
		Mean	0.3	0.0	0.3	0.0
		SD	0.6	0.0	0.8	0.0
		CV%	230.9	NC	253.8	NC
		Min	0	0	0	0
Eyelid - Erythema	Visit 3 - Day 8±1	Median	0.0	0.0	0.0	0.0
		Max	2	0	3	0
		N	16	16	16	16
		Mean	0.3	0.1	0.3	0.0
		SD	0.7	0.6	0.8	0.4
		CV%	225.3	918.0	253.8	NC
		Min	0	-1	0	-1

Table 14.2.1.20 Slit lamp examination (Per protocol set)

Investigational Medicinal Product: rhNGF 4 µg/mL - Overall Dry Eye Severity Level

Parameter	Visit	Statistics	Per Protocol Set N=16			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Eyelid - Erythema	Visit 6 - Day 29±1	Median	0.0	0.0	0.0	0.0
		Max	2	2	3	1
		N	16	16	16	16
		Mean	0.4	0.1	0.3	-0.1
		SD	0.6	0.7	0.4	0.7
		CV%	165.1	575.0	178.9	-1088.1
		Min	0	-1	0	-2
		Median	0.0	0.0	0.0	0.0
		Max	2	2	1	1
		N	16	16	16	16
		Mean	0.3	0.0	0.2	-0.1
		SD	0.4	0.5	0.4	0.6
		CV%	178.9	NC	215.0	-495.3
		Min	0	-1	0	-2
		Median	0.0	0.0	0.0	0.0
		Max	1	1	1	1

Table 14.2.1.20 Slit lamp examination (Per protocol set)

Investigational Medicinal Product: rhNGF 4 µg/mL - Overall Dry Eye Severity Level

Parameter	Visit	Statistics	Per Protocol Set N=16			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Eyelid - Oedema	Screening - Day -15/-1	N	16		16	
		Mean	0.2		0.2	
		SD	0.4		0.4	
		CV%	215.0		215.0	
		Min	0		0	
		Median	0.0		0.0	
		Max	1		1	
Eyelid - Oedema	Visit 2 - Day 1	N	16	16	16	16
		Mean	0.3	0.1	0.3	0.1
		SD	0.6	0.3	0.6	0.3
		CV%	230.9	400.0	230.9	400.0
		Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
		Max	2	1	2	1
Eyelid - Oedema	Visit 3 - Day 8±1	N	16	16	16	16
		Mean	0.4	0.3	0.4	0.3
		SD	0.7	0.4	0.9	0.6

Table 14.2.1.20 Slit lamp examination (Per protocol set)

Investigational Medicinal Product: rhNGF 4 µg/mL - Overall Dry Eye Severity Level

Parameter	Visit	Statistics	Per Protocol Set N=16			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Eyelid - Oedema	Visit 6 - Day 29±1	CV%	166.3	178.9	203.9	230.9
		Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
		Max	2	1	3	2
		N	16	16	16	16
		Mean	0.4	0.2	0.3	0.1
		SD	0.6	0.7	0.6	0.6
		CV%	165.1	349.4	192.7	495.3
Eyelid - Oedema	Final Visit - Day 56±4/ETV	Min	0	-1	0	-1
		Median	0.0	0.0	0.0	0.0
		Max	2	1	2	1
		N	16	16	16	16
		Mean	0.3	0.1	0.2	0.0
		SD	0.6	0.6	0.5	0.5
		CV%	230.9	918.0	290.1	NC
		Min	0	-1	0	-1
		Median	0.0	0.0	0.0	0.0

Table 14.2.1.20 Slit lamp examination (Per protocol set)

Investigational Medicinal Product: rhNGF 4 µg/mL - Overall Dry Eye Severity Level

Parameter	Visit	Statistics	Per Protocol Set N=16			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
		Max	2	1	2	1
Lashes	Screening - Day -15/-1	N	16		16	
		Mean	0.0		0.0	
		SD	0.0		0.0	
		CV%	NC		NC	
		Min	0		0	
		Median	0.0		0.0	
		Max	0		0	
Lashes	Visit 2 - Day 1	N	16	16	16	16
		Mean	0.0	0.0	0.0	0.0
		SD	0.0	0.0	0.0	0.0
		CV%	NC	NC	NC	NC
		Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
		Max	0	0	0	0
Lashes	Visit 3 - Day 8±1	N	16	16	16	16

Table 14.2.1.20 Slit lamp examination (Per protocol set)

Investigational Medicinal Product: rhNGF 4 µg/mL - Overall Dry Eye Severity Level

Parameter	Visit	Statistics	Per Protocol Set N=16			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Lashes	Visit 6 - Day 29±1	Mean	0.0	0.0	0.0	0.0
		SD	0.0	0.0	0.0	0.0
		CV%	NC	NC	NC	NC
		Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
		Max	0	0	0	0
		N	16	16	16	16
	Final Visit - Day 56±4/ETV	Mean	0.0	0.0	0.0	0.0
		SD	0.0	0.0	0.0	0.0
		CV%	NC	NC	NC	NC
		Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
		Max	0	0	0	0

Table 14.2.1.20 Slit lamp examination (Per protocol set)

Investigational Medicinal Product: rhNGF 4 µg/mL - Overall Dry Eye Severity Level

Parameter	Visit	Statistics	Per Protocol Set N=16			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Conjunctiva - Erythema	Screening - Day -15/-1	Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
		Max	0	0	0	0
		N	16		16	
		Mean	1.3		1.1	
		SD	0.8		0.6	
		CV%	62.0		55.0	
		Min	0		0	
		Median	1.0		1.0	
		Max	3		2	
	Visit 2 - Day 1	N	16	16	16	16
		Mean	1.3	0.0	1.2	0.1
		SD	0.6	0.4	0.5	0.3
		CV%	46.2	NC	45.8	400.0
		Min	0	-1	0	0
		Median	1.0	0.0	1.0	0.0
		Max	2	1	2	1

Table 14.2.1.20 Slit lamp examination (Per protocol set)

Investigational Medicinal Product: rhNGF 4 µg/mL - Overall Dry Eye Severity Level

Parameter	Visit	Statistics	Per Protocol Set N=16			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Conjunctiva - Erythema	Visit 3 - Day 8±1	N	16	16	16	16
		Mean	1.0	-0.3	1.1	0.0
		SD	0.4	0.7	0.5	0.6
		CV%	36.5	-273.3	44.4	NC
		Min	0	-2	0	-1
		Median	1.0	0.0	1.0	0.0
		Max	2	1	2	1
Conjunctiva - Erythema	Visit 6 - Day 29±1	N	16	16	16	16
		Mean	1.0	-0.3	0.9	-0.3
		SD	0.5	0.8	0.5	0.7
		CV%	51.6	-309.8	57.1	-273.3
		Min	0	-2	0	-1
		Median	1.0	0.0	1.0	0.0
		Max	2	1	2	1
Conjunctiva - Erythema	Final Visit - Day 56±4/ETV	N	16	16	16	16
		Mean	0.9	-0.3	0.9	-0.2

Table 14.2.1.20 Slit lamp examination (Per protocol set)

Investigational Medicinal Product: rhNGF 4 µg/mL - Overall Dry Eye Severity Level

Parameter	Visit	Statistics	Per Protocol Set N=16			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
		SD	0.4	0.8	0.4	0.7
		CV%	47.2	-253.8	47.2	-349.4
		Min	0	-2	0	-1
		Median	1.0	0.0	1.0	0.0
		Max	2	1	2	1
Conjunctiva - Oedema	Screening - Day -15/-1	N	16		16	
		Mean	0.8		0.8	
		SD	0.5		0.5	
		CV%	66.9		66.9	
		Min	0		0	
		Median	1.0		1.0	
		Max	2		2	
Conjunctiva - Oedema	Visit 2 - Day 1	N	16	16	16	16
		Mean	0.6	-0.2	0.7	-0.1
		SD	0.6	0.5	0.6	0.5
		CV%	99.1	-290.1	87.6	-400.0
		Min	0	-1	0	-1

Table 14.2.1.20 Slit lamp examination (Per protocol set)

Investigational Medicinal Product: rhNGF 4 µg/mL - Overall Dry Eye Severity Level

Parameter	Visit	Statistics	Per Protocol Set N=16			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Conjunctiva - Oedema	Visit 3 - Day 8±1	Median	1.0	0.0	1.0	0.0
		Max	2	1	2	1
		N	16	16	16	16
		Mean	0.6	-0.3	0.6	-0.2
		SD	0.5	0.7	0.6	0.8
		CV%	91.1	-273.3	99.1	-400.0
		Min	0	-1	0	-1
		Median	1.0	0.0	1.0	0.0
		Max	1	1	2	1
		N	16	16	16	16
		Mean	0.5	-0.3	0.5	-0.3
		SD	0.7	0.9	0.7	0.9
		CV%	146.1	-279.4	146.1	-279.4
		Min	0	-1	0	-1
		Median	0.0	-0.5	0.0	-0.5
		Max	2	2	2	2

Table 14.2.1.20 Slit lamp examination (Per protocol set)

Investigational Medicinal Product: rhNGF 4 µg/mL - Overall Dry Eye Severity Level

Parameter	Visit	Statistics	Per Protocol Set N=16			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Conjunctiva - Oedema	Final Visit - Day 56±4/ETV	N	16	16	16	16
		Mean	0.3	-0.5	0.3	-0.5
		SD	0.7	1.0	0.7	1.0
		CV%	225.3	-206.6	225.3	-206.6
		Min	0	-1	0	-1
		Median	0.0	-1.0	0.0	-1.0
		Max	2	2	2	2
Lens	Screening - Day -15/-1	N	13		13	
		Mean	0.4		0.3	
		SD	0.7		0.5	
		CV%	169.1		156.1	
		Min	0		0	
		Median	0.0		0.0	
		Max	2		1	
Lens	Visit 2 - Day 1	N	13	13	13	13
		Mean	0.4	0.0	0.3	0.0
		SD	0.7	0.0	0.5	0.0

Table 14.2.1.20 Slit lamp examination (Per protocol set)

Investigational Medicinal Product: rhNGF 4 µg/mL - Overall Dry Eye Severity Level

Parameter	Visit	Statistics	Per Protocol Set N=16			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Lens	Visit 3 - Day 8±1	CV%	169.1	NC	156.1	NC
		Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
		Max	2	0	1	0
		N	13	13	13	13
		Mean	0.4	0.0	0.3	0.0
		SD	0.7	0.0	0.5	0.0
		CV%	169.1	NC	156.1	NC
		Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
Lens	Visit 6 - Day 29±1	Max	2	0	1	0
		N	13	13	13	13
		Mean	0.3	-0.1	0.3	0.0
		SD	0.5	0.3	0.5	0.0
		CV%	156.1	-360.6	156.1	NC
		Min	0	-1	0	0
		Median	0.0	0.0	0.0	0.0

Table 14.2.1.20 Slit lamp examination (Per protocol set)

Investigational Medicinal Product: rhNGF 4 µg/mL - Overall Dry Eye Severity Level

Parameter	Visit	Statistics	Per Protocol Set N=16			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
		Max	1	0	1	0
Lens	Final Visit - Day 56±4/ETV	N	13	13	13	13
		Mean	0.3	-0.1	0.3	0.0
		SD	0.5	0.3	0.5	0.0
		CV%	156.1	-360.6	156.1	NC
		Min	0	-1	0	0
		Median	0.0	0.0	0.0	0.0
		Max	1	0	1	0
Iris	Screening - Day -15/-1	N	16		16	
		Mean	0.0		0.0	
		SD	0.0		0.0	
		CV%	NC		NC	
		Min	0		0	
		Median	0.0		0.0	
		Max	0		0	
Iris	Visit 2 - Day 1	N	16	16	16	16

Table 14.2.1.20 Slit lamp examination (Per protocol set)

Investigational Medicinal Product: rhNGF 4 µg/mL - Overall Dry Eye Severity Level

Parameter	Visit	Statistics	Per Protocol Set N=16			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Iris	Visit 3 - Day 8±1	Mean	0.0	0.0	0.0	0.0
		SD	0.0	0.0	0.0	0.0
		CV%	NC	NC	NC	NC
		Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
		Max	0	0	0	0
		N	16	16	16	16
	Visit 6 - Day 29±1	Mean	0.0	0.0	0.0	0.0
		SD	0.0	0.0	0.0	0.0
		CV%	NC	NC	NC	NC
		Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
		Max	0	0	0	0

Table 14.2.1.20 Slit lamp examination (Per protocol set)

Investigational Medicinal Product: rhNGF 4 µg/mL - Overall Dry Eye Severity Level

Parameter	Visit	Statistics	Per Protocol Set N=16			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Iris	Final Visit - Day 56±4/ETV	Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
		Max	0	0	0	0
		N	16	16	16	16
		Mean	0.0	0.0	0.0	0.0
		SD	0.0	0.0	0.0	0.0
		CV%	NC	NC	NC	NC
		Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
		Max	0	0	0	0
Anterior Chamber Inflammation	Screening - Day -15/-1	N	16		16	
		Mean	0.0		0.0	
		SD	0.0		0.0	
		CV%	NC		NC	
		Min	0		0	
		Median	0.0		0.0	
		Max	0		0	

Table 14.2.1.20 Slit lamp examination (Per protocol set)

Investigational Medicinal Product: rhNGF 4 µg/mL - Overall Dry Eye Severity Level

Parameter	Visit	Statistics	Per Protocol Set N=16			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Anterior Chamber Inflammation	Visit 2 - Day 1	N	16	16	16	16
		Mean	0.0	0.0	0.0	0.0
		SD	0.0	0.0	0.0	0.0
		CV%	NC	NC	NC	NC
		Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
		Max	0	0	0	0
Anterior Chamber Inflammation	Visit 3 - Day 8±1	N	16	16	16	16
		Mean	0.0	0.0	0.0	0.0
		SD	0.0	0.0	0.0	0.0
		CV%	NC	NC	NC	NC
		Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
		Max	0	0	0	0
Anterior Chamber Inflammation	Visit 6 - Day 29±1	N	16	16	16	16
		Mean	0.0	0.0	0.0	0.0

Table 14.2.1.20 Slit lamp examination (Per protocol set)

Investigational Medicinal Product: rhNGF 4 µg/mL - Overall Dry Eye Severity Level

Parameter	Visit	Statistics	Per Protocol Set N=16			
			Study Eye		Non Study Eye	
			Score	Change from Baseline	Score	Change from Baseline
Anterior Chamber Inflammation	Final Visit - Day 56±4/ETV	SD	0.0	0.0	0.0	0.0
		CV%	NC	NC	NC	NC
		Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
		Max	0	0	0	0
		N	16	16	16	16
		Mean	0.0	0.0	0.0	0.0
		SD	0.0	0.0	0.0	0.0
		CV%	NC	NC	NC	NC
		Min	0	0	0	0
		Median	0.0	0.0	0.0	0.0
		Max	0	0	0	0

Note: Patients are summarised according to the Investigational Medicinal Product they actually received

Baseline: Screening visit assessment

Source: [Listing 16.2.6.5](#) - Slit lamp examination

Program: Tables\c116-qs-01-tbl.sas