

Table 14.2.1.15 Conjunctival impression cytology for goblet cells' count (Full analysis set)

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

Parameter	Visit	Statistics	Full Analysis Set N=20	
			Counts/Optic Field	Change from Baseline
Temporal Bulbar Conjunctiva - Mean of 3 Optic Fields	Screening - Day -15/-1	N	17	
		Mean	5.92	
		SD	7.09	
		CV%	119.65	
		Min	0.0	
		Median	3.00	
		Max	23.0	
Temporal Bulbar Conjunctiva - Mean of 3 Optic Fields	Visit 2 - Day 1	N	18	15
		Mean	5.04	-2.04
		SD	5.63	7.66
		CV%	111.84	-374.69
		Min	0.0	-20.3
		Median	2.67	-0.33
		Max	18.3	12.7
Temporal Bulbar Conjunctiva - Mean of 3 Optic Fields	Visit 3 - Day 8±1	N	20	17
		Mean	4.17	-2.25
		SD	4.59	6.73

Table 14.2.1.15 Conjunctival impression cytology for goblet cells' count (Full analysis set)

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

Parameter	Visit	Statistics	Full Analysis Set N=20	
			Counts/Optic Field	Change from Baseline
Temporal Bulbar Conjunctiva - Mean of 3 Optic Fields	Visit 6 - Day 29±1	CV%	110.26	-298.34
		Min	0.0	-22.3
		Median	3.00	-2.00
		Max	15.3	11.3
		N	18	15
		Mean	6.35	0.03
		SD	10.57	11.18
		CV%	166.41	33542.19
		Min	0.0	-20.3
		Median	2.00	-1.67
Temporal Bulbar Conjunctiva - Mean of 3 Optic Fields	Final Visit - Day 56±4/ETV	Max	38.3	29.0
		N	17	15
		Mean	3.90	-2.47
		SD	4.95	7.86
		CV%	126.95	-318.72
		Min	0.0	-19.7
		Median	1.00	0.00
		Max	14.3	10.7

Table 14.2.1.15 Conjunctival impression cytology for goblet cells' count (Full analysis set)

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

Parameter	Visit	Statistics	Full Analysis Set N=20	
			Counts/Optic Field	Change from Baseline
Nasal Bulbar Conjunctiva - Mean of 3 Optic Fields	Screening - Day -15/-1	N	18	
		Mean	4.65	
		SD	7.26	
		CV%	156.29	
		Min	0.3	
		Median	2.00	
		Max	29.0	
Nasal Bulbar Conjunctiva - Mean of 3 Optic Fields	Visit 2 - Day 1	N	17	15
		Mean	3.92	-0.84
		SD	3.44	8.55
		CV%	87.80	-1012.65
		Min	0.7	-28.3
		Median	2.00	1.00
		Max	10.0	8.7
Nasal Bulbar Conjunctiva - Mean of 3 Optic Fields	Visit 3 - Day 8±1	N	17	16
		Mean	5.82	0.98
		SD	11.04	14.02

Table 14.2.1.15 Conjunctival impression cytology for goblet cells' count (Full analysis set)

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

Parameter	Visit	Statistics	Full Analysis Set N=20	
			Counts/Optic Field	Change from Baseline
		CV%	189.50	1431.92
		Min	0.0	-26.7
		Median	2.33	-0.50
		Max	41.7	41.3
Nasal Bulbar Conjunctiva - Mean of 3 Optic Fields	Visit 6 - Day 29±1	N	17	16
		Mean	5.18	0.96
		SD	4.84	9.14
		CV%	93.54	953.23
		Min	0.0	-27.0
		Median	2.67	0.67
		Max	12.3	11.7
Nasal Bulbar Conjunctiva - Mean of 3 Optic Fields	Final Visit - Day 56±4/ETV	N	18	17
		Mean	5.97	0.99
		SD	9.49	12.81
		CV%	158.83	1294.02
		Min	0.0	-22.0
		Median	1.67	-0.33
		Max	31.7	31.3

Table 14.2.1.15 Conjunctival impression cytology for goblet cells' count (Full analysis set)

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

Parameter	Visit	Statistics	Full Analysis Set N=20	
			Counts/Optic Field	Change from Baseline
Inferior Bulbar Conjunctiva - Mean of 3 Optic Fields	Screening - Day -15/-1	N	20	
		Mean	6.65	
		SD	6.59	
		CV%	99.02	
		Min	0.0	
		Median	5.17	
		Max	25.3	
Inferior Bulbar Conjunctiva - Mean of 3 Optic Fields	Visit 2 - Day 1	N	19	19
		Mean	3.61	-2.77
		SD	3.89	7.49
		CV%	107.66	-270.39
		Min	0.0	-25.3
		Median	2.33	-1.33
		Max	12.0	6.3
Inferior Bulbar Conjunctiva - Mean of 3 Optic Fields	Visit 3 - Day 8±1	N	19	19
		Mean	5.63	-1.11
		SD	8.38	11.30

Table 14.2.1.15 Conjunctival impression cytology for goblet cells' count (Full analysis set)

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

Parameter	Visit	Statistics	Full Analysis Set N=20	
			Counts/Optic Field	Change from Baseline
		CV%	148.79	-1022.24
		Min	0.0	-25.3
		Median	1.67	-0.67
		Max	31.3	30.7
Inferior Bulbar Conjunctiva - Mean of 3 Optic Fields	Visit 6 - Day 29±1	N	19	19
		Mean	2.88	-3.79
		SD	3.46	7.30
		CV%	120.35	-192.72
		Min	0.0	-25.0
		Median	2.00	-2.33
		Max	13.7	8.0
Inferior Bulbar Conjunctiva - Mean of 3 Optic Fields	Final Visit - Day 56±4/ETV	N	19	19
		Mean	5.26	-1.60
		SD	5.88	8.94
		CV%	111.74	-559.97
		Min	0.0	-25.3
		Median	2.67	-0.33
		Max	22.0	21.3

Table 14.2.1.15 Conjunctival impression cytology for goblet cells' count (Full analysis set)

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

Parameter	Visit	Statistics	Full Analysis Set N=20	
			Counts/Optic Field	Change from Baseline
Superior Bulbar Conjunctiva - Mean of 3 Optic Fields	Screening - Day -15/-1	N	20	
		Mean	8.23	
		SD	10.69	
		CV%	129.87	
		Min	0.3	
		Median	3.67	
		Max	37.0	
Superior Bulbar Conjunctiva - Mean of 3 Optic Fields	Visit 2 - Day 1	N	19	19
		Mean	5.77	-2.28
		SD	9.97	9.87
		CV%	172.81	-432.64
		Min	0.0	-26.0
		Median	2.33	-0.67
		Max	42.3	15.0
Superior Bulbar Conjunctiva - Mean of 3 Optic Fields	Visit 3 - Day 8±1	N	18	18
		Mean	5.70	-2.48
		SD	7.62	12.53

Table 14.2.1.15 Conjunctival impression cytology for goblet cells' count (Full analysis set)

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

Parameter	Visit	Statistics	Full Analysis Set N=20	
			Counts/Optic Field	Change from Baseline
		CV%	133.54	-504.98
		Min	0.0	-36.3
		Median	2.33	-0.83
		Max	25.3	25.0
Superior Bulbar Conjunctiva - Mean of 3 Optic Fields	Visit 6 - Day 29±1	N	19	19
		Mean	3.96	-4.44
		SD	4.87	10.16
		CV%	122.82	-228.83
		Min	0.0	-34.7
		Median	1.67	-1.67
		Max	16.3	7.7
Superior Bulbar Conjunctiva - Mean of 3 Optic Fields	Final Visit - Day 56±4/ETV	N	18	18
		Mean	5.98	-1.09
		SD	9.67	10.45
		CV%	161.67	-956.83
		Min	0.0	-29.3
		Median	1.83	-1.17

Table 14.2.1.15 Conjunctival impression cytology for goblet cells' count (Full analysis set)

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

Parameter	Visit	Statistics	Counts/Optic Field	Full Analysis Set N=20	Change from Baseline
		Max	37.3		23.7

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

Baseline: Screening visit assessment

Source: [Listing 16.2.6.15](#) - Conjunctival impression cytology for goblet cells' count

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

Table 14.2.1.15 Conjunctival impression cytology for goblet cells' count (Full analysis set)

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

Parameter	Visit	Statistics	Counts/Optic Field	Full Analysis Set N=13	Change from Baseline
Temporal Bulbar Conjunctiva - Mean of 3 Optic Fields	Screening - Day -15/-1	N	13		
		Mean	1.92		
		SD	3.13		
		CV%	162.78		
		Min	0.0		

Table 14.2.1.15 Conjunctival impression cytology for goblet cells' count (Full analysis set)

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

Parameter	Visit	Statistics	Counts/Optic Field	Full Analysis Set N=7	Change from Baseline
		Max	6.0		5.7

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

Baseline: Screening visit assessment

Source: [Listing 16.2.6.15](#) - Conjunctival impression cytology for goblet cells' count

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

Table 14.2.1.15 Conjunctival impression cytology for goblet cells' count (Full analysis set)

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

Parameter	Visit	Statistics	Counts/Optic Field	Full Analysis Set N=20	Change from Baseline
Temporal Bulbar Conjunctiva - Mean of 3 Optic Fields	Screening - Day -15/-1	N	20		
		Mean	1.83		
		SD	2.81		
		CV%	153.54		
		Min	0.0		

Table 14.2.1.15 Conjunctival impression cytology for goblet cells' count (Full analysis set)

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

Parameter	Visit	Statistics	Full Analysis Set N=20	
			Counts/Optic Field	Change from Baseline
Temporal Bulbar Conjunctiva - Mean of 3 Optic Fields	Visit 2 - Day 1	Median	1.00	
		Max	12.0	
		N	20	20
		Mean	1.62	-0.19
		SD	1.64	3.40
		CV%	101.29	-1773.86
		Min	0.0	-11.3
		Median	1.17	-0.33
Temporal Bulbar Conjunctiva - Mean of 3 Optic Fields	Visit 3 - Day 8±1	Max	6.0	4.5
		N	19	19
		Mean	1.47	0.16
		SD	1.86	2.19
		CV%	126.23	1389.91
		Min	0.0	-4.3
		Median	1.00	0.00
		Max	7.0	4.7
Temporal Bulbar Conjunctiva - Mean of 3 Optic Fields	Visit 6 - Day 29±1	N	18	18

Table 14.2.1.15 Conjunctival impression cytology for goblet cells' count (Full analysis set)

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

Parameter	Visit	Statistics	Full Analysis Set N=20	
			Counts/Optic Field	Change from Baseline
		Mean	2.15	0.83
		SD	3.05	2.72
		CV%	141.84	326.55
		Min	0.0	-3.7
		Median	0.83	0.17
		Max	9.3	6.7
Temporal Bulbar Conjunctiva - Mean of 3 Optic Fields	Final Visit - Day 56±4/ETV	N	20	20
		Mean	1.82	0.00
		SD	2.42	2.76
		CV%	133.05	NC
		Min	0.0	-6.3
		Median	1.00	-0.17
		Max	9.3	8.3
Nasal Bulbar Conjunctiva - Mean of 3 Optic Fields	Screening - Day -15/-1	N	19	
		Mean	1.81	
		SD	2.47	
		CV%	136.57	
		Min	0.0	

Table 14.2.1.15 Conjunctival impression cytology for goblet cells' count (Full analysis set)

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

Parameter	Visit	Statistics	Full Analysis Set N=20	
			Counts/Optic Field	Change from Baseline
Nasal Bulbar Conjunctiva - Mean of 3 Optic Fields	Visit 2 - Day 1	Median	0.67	
		Max	8.0	
		N	20	19
		Mean	1.50	-0.52
		SD	2.10	2.50
		CV%	139.90	-482.32
		Min	0.0	-6.0
		Median	0.33	0.00
		Max	6.7	4.7
Nasal Bulbar Conjunctiva - Mean of 3 Optic Fields	Visit 3 - Day 8±1	N	18	17
		Mean	2.93	1.24
		SD	4.36	4.06
		CV%	149.18	328.80
		Min	0.0	-3.3
		Median	1.50	0.00
		Max	16.3	12.7
Nasal Bulbar Conjunctiva - Mean of 3 Optic Fields	Visit 6 - Day 29±1	N	17	16

Table 14.2.1.15 Conjunctival impression cytology for goblet cells' count (Full analysis set)

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

Parameter	Visit	Statistics	Full Analysis Set N=20	
			Counts/Optic Field	Change from Baseline
		Mean	1.53	-0.06
		SD	1.81	2.98
		CV%	118.64	-4771.15
		Min	0.0	-10.0
		Median	0.33	0.00
		Max	4.7	3.3
Nasal Bulbar Conjunctiva - Mean of 3 Optic Fields	Final Visit - Day 56±4/ETV	N	17	16
		Mean	2.82	1.19
		SD	3.17	3.89
		CV%	112.39	327.19
		Min	0.0	-5.3
		Median	1.33	0.33
		Max	10.7	10.7
Inferior Bulbar Conjunctiva - Mean of 3 Optic Fields	Screening - Day -15/-1	N	20	
		Mean	3.40	
		SD	4.21	
		CV%	123.87	
		Min	0.0	

Table 14.2.1.15 Conjunctival impression cytology for goblet cells' count (Full analysis set)

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

Parameter	Visit	Statistics	Full Analysis Set N=20	
			Counts/Optic Field	Change from Baseline
Inferior Bulbar Conjunctiva - Mean of 3 Optic Fields	Visit 2 - Day 1	Median	2.50	
		Max	17.7	
		N	20	20
		Mean	1.23	-2.17
		SD	1.49	4.65
		CV%	120.90	-214.72
		Min	0.0	-17.7
		Median	0.83	-0.67
Inferior Bulbar Conjunctiva - Mean of 3 Optic Fields	Visit 3 - Day 8±1	Max	4.7	3.0
		N	19	19
		Mean	1.32	-1.33
		SD	2.34	3.41
		CV%	177.83	-255.63
		Min	0.0	-10.0
		Median	0.33	-1.00
		Max	8.7	5.3
Inferior Bulbar Conjunctiva - Mean of 3 Optic Fields	Visit 6 - Day 29±1	N	19	19

Table 14.2.1.15 Conjunctival impression cytology for goblet cells' count (Full analysis set)

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

Parameter	Visit	Statistics	Full Analysis Set N=20	
			Counts/Optic Field	Change from Baseline
Inferior Bulbar Conjunctiva - Mean of 3 Optic Fields	Final Visit - Day 56±4/ETV	Mean	1.05	-1.60
		SD	1.48	3.11
		CV%	140.54	-194.94
		Min	0.0	-10.0
		Median	0.33	-1.67
		Max	5.3	3.3
		N	20	20
Inferior Bulbar Conjunctiva - Mean of 3 Optic Fields	Final Visit - Day 56±4/ETV	Mean	2.33	-1.07
		SD	2.45	4.46
		CV%	104.88	-418.48
		Min	0.0	-16.3
		Median	1.67	0.17
		Max	8.0	4.0
		N	19	
Superior Bulbar Conjunctiva - Mean of 3 Optic Fields	Screening - Day -15/-1	Mean	1.26	
		SD	1.52	
		CV%	120.47	
		Min	0.0	
		N		

Table 14.2.1.15 Conjunctival impression cytology for goblet cells' count (Full analysis set)

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

Parameter	Visit	Statistics	Full Analysis Set N=20	
			Counts/Optic Field	Change from Baseline
Superior Bulbar Conjunctiva - Mean of 3 Optic Fields	Visit 2 - Day 1	Median	0.67	
		Max	4.3	
		N	20	19
		Mean	1.88	0.73
		SD	2.58	2.23
		CV%	137.13	305.91
		Min	0.0	-2.3
		Median	1.00	0.33
Superior Bulbar Conjunctiva - Mean of 3 Optic Fields	Visit 3 - Day 8±1	Max	9.3	5.7
		N	19	18
		Mean	1.58	0.33
		SD	2.17	2.35
		CV%	137.69	703.77
		Min	0.0	-2.7
		Median	0.33	0.00
		Max	7.0	7.0
Superior Bulbar Conjunctiva - Mean of 3 Optic Fields	Visit 6 - Day 29±1	N	17	16

Table 14.2.1.15 Conjunctival impression cytology for goblet cells' count (Full analysis set)

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

Parameter	Visit	Statistics	Full Analysis Set N=20	
			Counts/Optic Field	Change from Baseline
		Mean	1.57	0.44
		SD	1.87	1.93
		CV%	119.21	441.40
		Min	0.0	-2.7
		Median	1.00	0.00
		Max	6.0	4.3
Superior Bulbar Conjunctiva - Mean of 3 Optic Fields	Final Visit - Day 56±4/ETV	N	18	18
		Mean	2.20	1.07
		SD	1.95	1.99
		CV%	88.53	185.16
		Min	0.0	-1.7
		Median	2.33	0.33
		Max	6.0	5.7

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

Baseline: Screening visit assessment

Source: [Listing 16.2.6.15](#) - Conjunctival impression cytology for goblet cells' count

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

Error! Bookmark not defined. **Table 14.2.1.30 Conjunctival impression cytology for goblet cells' count (Per protocol set)**

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

Parameter	Visit	Statistics	Counts/Optic Field	Per Protocol Set N=14	Change from Baseline
Temporal Bulbar Conjunctiva - Mean of 3 Optic Fields	Screening - Day -15/-1	N	12		
		Mean	6.67		
		SD	8.16		
		CV%	122.44		
		Min	0.0		
		Median	2.83		
		Max	23.0		
Temporal Bulbar Conjunctiva - Mean of 3 Optic Fields	Visit 2 - Day 1	N	14		12
		Mean	5.43		-2.28
		SD	5.99		8.54
		CV%	110.38		-374.91
		Min	0.0		-20.3
		Median	3.33		-0.67
		Max	18.3		12.7
Temporal Bulbar Conjunctiva - Mean of 3 Optic Fields	Visit 3 - Day 8±1	N	14		12
		Mean	4.05		-3.00
		SD	5.10		7.85

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

Parameter	Visit	Statistics	Per Protocol Set N=14	
			Counts/Optic Field	Change from Baseline
Temporal Bulbar Conjunctiva - Mean of 3 Optic Fields	Visit 6 - Day 29±1	CV%	125.93	-261.82
		Min	0.0	-22.3
		Median	2.33	-2.17
		Max	15.3	11.3
		N	12	10
		Mean	4.94	-1.93
		SD	7.71	9.62
		CV%	155.86	-497.64
Temporal Bulbar Conjunctiva - Mean of 3 Optic Fields	Final Visit - Day 56±4/ETV	Min	0.0	-20.3
		Median	2.00	-2.00
		Max	21.3	18.7
		N	12	11
		Mean	2.75	-3.64
		SD	4.03	8.81
		CV%	146.47	-242.27
		Min	0.0	-19.7
		Median	0.83	-1.67
		Max	13.3	10.7

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

Parameter	Visit	Statistics	Per Protocol Set N=14	
			Counts/Optic Field	Change from Baseline
Nasal Bulbar Conjunctiva - Mean of 3 Optic Fields	Screening - Day -15/-1	N	12	
		Mean	5.50	
		SD	8.40	
		CV%	152.79	
		Min	0.3	
		Median	2.50	
		Max	29.0	
Nasal Bulbar Conjunctiva - Mean of 3 Optic Fields	Visit 2 - Day 1	N	12	10
		Mean	3.39	-3.17
		SD	3.44	9.55
		CV%	101.60	-301.68
		Min	0.7	-28.3
		Median	1.33	-0.17
		Max	10.0	5.0
Nasal Bulbar Conjunctiva - Mean of 3 Optic Fields	Visit 3 - Day 8±1	N	11	10
		Mean	2.33	-4.00
		SD	3.67	10.00

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

Parameter	Visit	Statistics	Per Protocol Set N=14	
			Counts/Optic Field	Change from Baseline
Nasal Bulbar Conjunctiva - Mean of 3 Optic Fields	Visit 6 - Day 29±1	CV%	157.40	-250.12
		Min	0.0	-26.7
		Median	1.67	-1.83
		Max	13.0	12.7
		N	11	10
		Mean	5.09	0.07
		SD	5.08	10.70
		CV%	99.86	16049.92
Nasal Bulbar Conjunctiva - Mean of 3 Optic Fields	Final Visit - Day 56±4/ETV	Min	0.0	-27.0
		Median	2.00	0.33
		Max	12.3	11.7
		N	12	11
		Mean	4.90	-1.29
		SD	8.18	12.19
		CV%	166.81	-946.14
		Min	0.0	-22.0
		Median	1.17	-0.67
		Max	26.0	25.7

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

Parameter	Visit	Statistics	Per Protocol Set N=14	
			Counts/Optic Field	Change from Baseline
Inferior Bulbar Conjunctiva - Mean of 3 Optic Fields	Screening - Day -15/-1	N	14	
		Mean	7.76	
		SD	6.74	
		CV%	86.80	
		Min	0.0	
		Median	5.83	
		Max	25.3	
Inferior Bulbar Conjunctiva - Mean of 3 Optic Fields	Visit 2 - Day 1	N	13	13
		Mean	4.44	-3.03
		SD	4.37	8.33
		CV%	98.47	-275.22
		Min	0.0	-25.3
		Median	3.00	-1.67
		Max	12.0	6.3
Inferior Bulbar Conjunctiva - Mean of 3 Optic Fields	Visit 3 - Day 8±1	N	13	13
		Mean	2.33	-5.64
		SD	3.41	8.32

Error! Bookmark not defined. **Table 14.2.1.30 Conjunctival impression cytology for goblet cells' count (Per protocol set)**

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

Parameter	Visit	Statistics	Per Protocol Set N=14	
			Counts/Optic Field	Change from Baseline
Inferior Bulbar Conjunctiva - Mean of 3 Optic Fields	Visit 6 - Day 29±1	CV%	146.27	-147.54
		Min	0.0	-25.3
		Median	0.67	-5.00
		Max	10.0	8.0
		N	13	13
		Mean	2.15	-5.72
		SD	1.64	7.80
Inferior Bulbar Conjunctiva - Mean of 3 Optic Fields	Final Visit - Day 56±4/ETV	CV%	75.98	-136.42
		Min	0.3	-25.0
		Median	2.00	-4.33
		Max	5.0	5.0
		N	13	13
		Mean	4.72	-3.44
		SD	4.61	8.29
Inferior Bulbar Conjunctiva - Mean of 3 Optic Fields	Final Visit - Day 56±4/ETV	CV%	97.72	-241.42
		Min	0.0	-25.3
		Median	2.67	0.33
		Max	14.0	5.0
		N	13	13
		Mean	4.72	-3.44
		SD	4.61	8.29

Error! Bookmark not defined. **Table 14.2.1.30 Conjunctival impression cytology for goblet cells' count (Per protocol set)**

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

Parameter	Visit	Statistics	Counts/Optic Field	Per Protocol Set N=14	Change from Baseline
Superior Bulbar Conjunctiva - Mean of 3 Optic Fields	Screening - Day -15/-1	N	14		
		Mean	7.86		
		SD	11.60		
		CV%	147.61		
		Min	0.3		
		Median	3.17		
		Max	37.0		
Superior Bulbar Conjunctiva - Mean of 3 Optic Fields	Visit 2 - Day 1	N	14		14
		Mean	7.52		-0.33
		SD	11.17		9.18
		CV%	148.45		-2752.62
		Min	0.0		-25.0
		Median	4.50		0.17
		Max	42.3		15.0
Superior Bulbar Conjunctiva - Mean of 3 Optic Fields	Visit 3 - Day 8±1	N	12		12
		Mean	4.19		-3.53
		SD	7.15		14.89

Error! Bookmark not defined. **Table 14.2.1.30 Conjunctival impression cytology for goblet cells' count (Per protocol set)**

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

Parameter	Visit	Statistics	Per Protocol Set N=14	
			Counts/Optic Field	Change from Baseline
Superior Bulbar Conjunctiva - Mean of 3 Optic Fields	Visit 6 - Day 29±1	CV%	170.46	-421.98
		Min	0.0	-36.3
		Median	1.33	-1.33
		Max	25.3	25.0
		N	13	13
		Mean	2.77	-5.31
		SD	3.83	11.28
Superior Bulbar Conjunctiva - Mean of 3 Optic Fields	Final Visit - Day 56±4/ETV	CV%	138.15	-212.59
		Min	0.0	-34.7
		Median	1.00	-1.67
		Max	11.7	7.0
		N	12	12
		Mean	4.81	-1.25
		SD	6.75	12.20
		CV%	140.53	-976.10
		Min	0.3	-29.3
		Median	1.67	-0.33

Error! Bookmark not defined. **Table 14.2.1.30 Conjunctival impression cytology for goblet cells' count (Per protocol set)**

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

Parameter	Visit	Statistics	Counts/Optic Field	Per Protocol Set N=14	Change from Baseline
		Max	24.0		23.7

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

Baseline: Screening visit assessment

Source: [Listing 16.2.6.15](#) - Conjunctival impression cytology for goblet cells' count

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Table 14.2.1.30 Conjunctival impression cytology for goblet cells' count (Per protocol set)

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

Parameter	Visit	Statistics	Counts/Optic Field	Per Protocol Set N=5	Change from Baseline
Temporal Bulbar Conjunctiva - Mean of 3 Optic Fields	Screening - Day -15/-1	N	5		
		Mean	2.20		
		SD	2.63		
		CV%	119.59		
		Min	0.0		

Table 14.2.1.30 Conjunctival impression cytology for goblet cells' count (Per protocol set)

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

Parameter	Visit	Statistics	Per Protocol Set N=16	
			Counts/Optic Field	Change from Baseline
Temporal Bulbar Conjunctiva - Mean of 3 Optic Fields	Screening - Day -15/-1	N	16	
		Mean	1.40	
		SD	1.62	
		CV%	116.41	
		Min	0.0	
		Median	1.00	
		Max	5.7	
Temporal Bulbar Conjunctiva - Mean of 3 Optic Fields	Visit 2 - Day 1	N	16	16
		Mean	1.69	0.32
		SD	1.76	2.39
		CV%	104.14	740.18
		Min	0.0	-3.7
		Median	1.17	-0.33
		Max	6.0	4.5
Temporal Bulbar Conjunctiva - Mean of 3 Optic Fields	Visit 3 - Day 8±1	N	16	16
		Mean	1.71	0.29
		SD	1.94	2.37

Table 14.2.1.30 Conjunctival impression cytology for goblet cells' count (Per protocol set)

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

Parameter	Visit	Statistics	Per Protocol Set N=16	
			Counts/Optic Field	Change from Baseline
Temporal Bulbar Conjunctiva - Mean of 3 Optic Fields	Visit 6 - Day 29±1	CV%	113.52	814.16
		Min	0.0	-4.3
		Median	1.33	0.17
		Max	7.0	4.7
		N	15	15
		Mean	2.51	1.09
		SD	3.22	2.93
Temporal Bulbar Conjunctiva - Mean of 3 Optic Fields	Final Visit - Day 56±4/ETV	CV%	128.29	268.80
		Min	0.0	-3.7
		Median	1.00	0.67
		Max	9.3	6.7
		N	16	16
		Mean	1.90	0.52
		SD	2.41	2.56
Temporal Bulbar Conjunctiva - Mean of 3 Optic Fields	Final Visit - Day 56±4/ETV	CV%	127.23	492.27
		Min	0.0	-2.7
		Median	1.17	0.17
		Max	9.3	8.3
		N	16	16

Table 14.2.1.30 Conjunctival impression cytology for goblet cells' count (Per protocol set)

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

Parameter	Visit	Statistics	Per Protocol Set N=16	
			Counts/Optic Field	Change from Baseline
Nasal Bulbar Conjunctiva - Mean of 3 Optic Fields	Screening - Day -15/-1	N	15	
		Mean	1.91	
		SD	2.51	
		CV%	131.43	
		Min	0.0	
		Median	1.00	
		Max	8.0	
Nasal Bulbar Conjunctiva - Mean of 3 Optic Fields	Visit 2 - Day 1	N	16	15
		Mean	1.81	-0.33
		SD	2.24	2.46
		CV%	123.82	-738.72
		Min	0.0	-6.0
		Median	0.67	-0.33
		Max	6.7	4.7
Nasal Bulbar Conjunctiva - Mean of 3 Optic Fields	Visit 3 - Day 8±1	N	15	14
		Mean	3.47	1.48
		SD	4.61	4.47

Table 14.2.1.30 Conjunctival impression cytology for goblet cells' count (Per protocol set)

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

Parameter	Visit	Statistics	Per Protocol Set N=16	
			Counts/Optic Field	Change from Baseline
Nasal Bulbar Conjunctiva - Mean of 3 Optic Fields	Visit 6 - Day 29±1	CV%	132.93	302.53
		Min	0.0	-3.3
		Median	2.33	0.00
		Max	16.3	12.7
		N	14	13
		Mean	1.67	-0.26
		SD	1.89	3.26
		CV%	113.41	-1269.47
Nasal Bulbar Conjunctiva - Mean of 3 Optic Fields	Final Visit - Day 56±4/ETV	Min	0.0	-10.0
		Median	1.00	0.00
		Max	4.7	3.3
		N	14	13
		Mean	3.33	1.38
		SD	3.27	4.30
		CV%	98.21	310.77
		Min	0.0	-5.3
Nasal Bulbar Conjunctiva - Mean of 3 Optic Fields	Final Visit - Day 56±4/ETV	Median	1.67	0.67
		Max	10.7	10.7

Table 14.2.1.30 Conjunctival impression cytology for goblet cells' count (Per protocol set)

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

Parameter	Visit	Statistics	Per Protocol Set N=16	
			Counts/Optic Field	Change from Baseline
Inferior Bulbar Conjunctiva - Mean of 3 Optic Fields	Screening - Day -15/-1	N	16	
		Mean	2.88	
		SD	2.76	
		CV%	96.06	
		Min	0.0	
		Median	3.00	
		Max	10.3	
Inferior Bulbar Conjunctiva - Mean of 3 Optic Fields	Visit 2 - Day 1	N	16	16
		Mean	1.40	-1.48
		SD	1.61	3.22
		CV%	115.10	-217.86
		Min	0.0	-9.7
		Median	0.83	-0.50
		Max	4.7	3.0
Inferior Bulbar Conjunctiva - Mean of 3 Optic Fields	Visit 3 - Day 8±1	N	16	16
		Mean	1.54	-1.33
		SD	2.49	3.71

Table 14.2.1.30 Conjunctival impression cytology for goblet cells' count (Per protocol set)

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

Parameter	Visit	Statistics	Per Protocol Set N=16	
			Counts/Optic Field	Change from Baseline
Inferior Bulbar Conjunctiva - Mean of 3 Optic Fields	Visit 6 - Day 29±1	CV%	161.78	-278.09
		Min	0.0	-10.0
		Median	0.50	-0.83
		Max	8.7	5.3
		N	16	16
		Mean	1.23	-1.65
		SD	1.55	3.38
Inferior Bulbar Conjunctiva - Mean of 3 Optic Fields	Final Visit - Day 56±4/ETV	CV%	126.32	-205.28
		Min	0.0	-10.0
		Median	0.50	-1.33
		Max	5.3	3.3
		N	16	16
		Mean	2.60	-0.27
		SD	2.64	2.97
Inferior Bulbar Conjunctiva - Mean of 3 Optic Fields	Final Visit - Day 56±4/ETV	CV%	101.24	-1096.44
		Min	0.0	-6.7
		Median	1.83	0.33
		Max	8.0	4.0
		N	16	16
		Mean	2.60	-0.27
		SD	2.64	2.97

Table 14.2.1.30 Conjunctival impression cytology for goblet cells' count (Per protocol set)

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

Parameter	Visit	Statistics	Per Protocol Set N=16	
			Counts/Optic Field	Change from Baseline
Superior Bulbar Conjunctiva - Mean of 3 Optic Fields	Screening - Day -15/-1	N	15	
		Mean	1.22	
		SD	1.54	
		CV%	125.69	
		Min	0.0	
		Median	0.67	
		Max	4.3	
Superior Bulbar Conjunctiva - Mean of 3 Optic Fields	Visit 2 - Day 1	N	16	15
		Mean	2.13	1.04
		SD	2.81	2.35
		CV%	132.47	224.98
		Min	0.0	-2.3
		Median	1.17	0.33
		Max	9.3	5.7
Superior Bulbar Conjunctiva - Mean of 3 Optic Fields	Visit 3 - Day 8±1	N	15	14
		Mean	1.96	0.79
		SD	2.31	2.39

Table 14.2.1.30 Conjunctival impression cytology for goblet cells' count (Per protocol set)

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

Parameter	Visit	Statistics	Per Protocol Set N=16	
			Counts/Optic Field	Change from Baseline
Superior Bulbar Conjunctiva - Mean of 3 Optic Fields	Visit 6 - Day 29±1	CV%	118.07	304.39
		Min	0.0	-2.3
		Median	0.67	0.00
		Max	7.0	7.0
		N	14	13
		Mean	1.60	0.64
		SD	1.93	1.93
Superior Bulbar Conjunctiva - Mean of 3 Optic Fields	Final Visit - Day 56±4/ETV	CV%	120.78	301.32
		Min	0.0	-2.0
		Median	1.17	0.00
		Max	6.0	4.3
		N	15	15
		Mean	2.56	1.36
		SD	1.93	2.06
Superior Bulbar Conjunctiva - Mean of 3 Optic Fields	Final Visit - Day 56±4/ETV	CV%	75.68	152.00
		Min	0.0	-1.7
		Median	2.67	0.67

Table 14.2.1.30 Conjunctival impression cytology for goblet cells' count (Per protocol set)

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

Parameter	Visit	Statistics	Counts/Optic Field	Per Protocol Set N=16	Change from Baseline
		Max	6.0		5.7

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

Baseline: Screening visit assessment

Source: [Listing 16.2.6.15](#) - Conjunctival impression cytology for goblet cells' count

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