

**Table 14.2.1.4Ocular tolerability (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	
			Value	Change from Baseline	Value	Change from Baseline
Foreign Body Sensation (mm)	Screening - Day -15/-1	N	20		20	
		Mean	48.0		39.5	
		SD	27.6		25.3	
		CV%	57.5		64.1	
		Min	0		0	
		Median	46.5		33.5	
		Max	98		85	
Foreign Body Sensation (mm)	Visit 2 - Day 1	N	20	20	20	20
		Mean	29.6	-18.4	23.0	-16.5
		SD	26.5	18.6	23.3	20.3
		CV%	89.4	-101.1	101.3	-123.2
		Min	0	-72	0	-63
		Median	19.0	-14.5	17.0	-19.0
		Max	87	14	85	18
Foreign Body Sensation (mm)	Visit 3 - Day 8±1	N	20	20	20	20

**Table 14.2.1.4 Ocular tolerability (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	
			Value	Change from Baseline	Value	Change from Baseline
		Mean	22.8	-25.2	19.5	-20.0
		SD	25.3	19.4	23.4	29.8
		CV%	110.8	-77.1	120.2	-148.9
		Min	0	-66	0	-65
		Median	11.0	-21.5	11.0	-20.5
		Max	83	3	83	71
Foreign Body Sensation (mm)	Visit 6 - Day 29±1	N	20	20	20	20
		Mean	16.6	-31.4	14.8	-24.7
		SD	24.7	24.3	21.1	28.2
		CV%	148.8	-77.4	142.7	-114.3
		Min	0	-72	0	-74
		Median	5.5	-27.0	5.5	-22.5
		Max	86	7	77	48
Foreign Body Sensation (mm)	Final Visit - Day 56±4/ETV	N	20	20	20	20
		Mean	17.4	-30.7	14.5	-25.0
		SD	25.8	20.5	21.4	27.5
		CV%	148.5	-66.8	147.5	-110.3

**Table 14.2.1.4Ocular tolerability (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	
			Value	Change from Baseline	Value	Change from Baseline
Burning/Stinging (mm)	Screening - Day -15/-1	Min	0	-69	0	-71
		Median	4.0	-26.5	6.0	-25.5
		Max	84	6	77	55
		N	20		20	
		Mean	48.2		40.7	
		SD	23.6		22.3	
		CV%	49.1		54.9	
		Min	7		4	
	Visit 2 - Day 1	Median	49.0		41.5	
		Max	96		84	
		N	20	20	20	20
		Mean	26.9	-21.3	23.5	-17.2
		SD	24.8	21.1	21.6	19.9
		CV%	92.1	-99.0	91.8	-116.2
		Min	0	-68	0	-57
		Median	19.5	-11.0	18.5	-9.5
		Max	89	2	80	4

**Table 14.2.1.4 Ocular tolerability (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	
			Value	Change from Baseline	Value	Change from Baseline
Burning/Stinging (mm)	Visit 3 - Day 8±1	N	20	20	20	20
		Mean	22.4	-25.9	20.0	-20.7
		SD	24.2	21.1	22.9	27.4
		CV%	108.5	-81.5	114.4	-132.5
		Min	1	-61	0	-64
		Median	15.5	-20.5	10.5	-15.0
		Max	85	1	85	51
Burning/Stinging (mm)	Visit 6 - Day 29±1	N	20	20	20	20
		Mean	15.5	-32.7	12.4	-28.3
		SD	24.7	21.8	19.1	25.4
		CV%	159.5	-66.8	154.3	-89.7
		Min	0	-70	0	-74
		Median	7.0	-32.5	5.5	-26.5
		Max	85	6	66	38
Burning/Stinging (mm)	Final Visit - Day 56±4/ETV	N	20	20	20	20
		Mean	18.0	-30.2	15.2	-25.5

**Table 14.2.1.4Ocular tolerability (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	
			Value	Change from Baseline	Value	Change from Baseline
Itching (mm)	Screening - Day -15/-1	SD	25.7	19.6	21.4	25.1
		CV%	142.7	-65.0	140.9	-98.7
		Min	0	-66	0	-69
		Median	4.5	-27.0	4.5	-24.0
		Max	85	-1	77	34
		N	20		20	
		Mean	43.3		39.4	
		SD	23.5		19.4	
		CV%	54.2		49.1	
		Min	3		3	
		Median	44.0		39.5	
		Max	97		83	
		N	20	20	20	20
		Mean	28.7	-14.6	20.5	-19.0
		SD	26.2	20.4	17.9	18.3
		CV%	91.2	-139.8	87.7	-96.3
		Min	0	-52	0	-55
		Max				

**Table 14.2.1.4 Ocular tolerability (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	
			Value	Change from Baseline	Value	Change from Baseline
Itching (mm)	Visit 3 - Day 8±1	Median	24.5	-18.5	18.0	-20.0
		Max	90	23	57	12
		N	20	20	20	20
		Mean	19.6	-23.8	21.1	-18.4
		SD	18.1	18.2	22.1	21.4
		CV%	92.8	-76.4	105.2	-116.7
		Min	0	-57	0	-61
		Median	16.0	-23.0	14.0	-21.5
		Max	72	7	80	24
Itching (mm)	Visit 6 - Day 29±1	N	20	20	20	20
		Mean	12.7	-30.7	9.5	-29.9
		SD	21.0	20.3	13.4	21.0
		CV%	166.1	-66.1	141.4	-70.4
		Min	0	-75	0	-82
		Median	5.0	-26.0	3.5	-30.0
		Max	83	2	45	6

**Table 14.2.1.4Ocular tolerability (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	
			Value	Change from Baseline	Value	Change from Baseline
Itching (mm)	Final Visit - Day 56±4/ETV	N	20	20	20	20
		Mean	17.4	-26.0	14.7	-24.7
		SD	26.4	25.8	23.1	23.8
		CV%	152.3	-99.5	156.8	-96.3
		Min	0	-72	0	-80
		Median	3.5	-26.0	3.0	-26.0
		Max	83	24	78	13
Pain (mm)	Screening - Day -15/-1	N	20		20	
		Mean	40.7		36.8	
		SD	29.5		25.4	
		CV%	72.6		69.1	
		Min	0		0	
		Median	37.5		36.5	
		Max	100		92	
Pain (mm)	Visit 2 - Day 1	N	20	20	20	20
		Mean	21.5	-19.2	13.3	-23.5
		SD	24.6	21.6	14.5	27.1

**Table 14.2.1.4Ocular tolerability (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	
			Value	Change from Baseline	Value	Change from Baseline
Pain (mm)	Visit 3 - Day 8±1	CV%	114.5	-112.9	109.8	-115.3
		Min	0	-74	0	-86
		Median	13.0	-16.0	10.0	-18.5
		Max	89	13	57	11
		N	20	20	20	20
		Mean	25.3	-15.4	21.1	-15.7
		SD	34.2	30.0	30.4	29.0
		CV%	135.2	-195.3	143.9	-185.2
		Min	0	-73	0	-69
		Median	7.5	-10.5	6.5	-13.0
Pain (mm)	Visit 6 - Day 29±1	Max	94	47	94	34
		N	20	20	20	20
		Mean	16.3	-24.4	9.6	-27.2
		SD	28.2	21.7	17.4	21.7
		CV%	173.6	-89.0	181.6	-79.9
		Min	0	-73	0	-70
		Median	2.5	-18.5	3.5	-25.0



**Table 14.2.1.4Ocular tolerability (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	
			Value	Change from Baseline	Value	Change from Baseline
		Max	92	9	65	5
Pain (mm)	Final Visit - Day 56±4/ETV	N	20	20	20	20
		Mean	15.8	-24.9	12.7	-24.1
		SD	27.0	20.1	22.3	20.8
		CV%	171.6	-80.9	175.9	-86.4
		Min	0	-62	0	-62
		Median	2.5	-22.5	2.0	-25.0
		Max	84	18	78	13
Sticky Feeling (mm)	Screening - Day -15/-1	N	20		20	
		Mean	30.2		26.1	
		SD	25.6		20.7	
		CV%	84.7		79.6	
		Min	0		0	
		Median	21.0		18.5	
		Max	94		68	
Sticky Feeling (mm)	Visit 2 - Day 1	N	20	20	20	20

**Table 14.2.1.4 Ocular tolerability (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	
			Value	Change from Baseline	Value	Change from Baseline
		Mean	21.0	-9.2	19.5	-6.6
		SD	22.0	15.1	21.7	9.9
		CV%	104.6	-164.2	111.8	-150.6
		Min	0	-41	1	-30
		Median	11.5	-7.0	10.0	-6.0
		Max	88	17	69	7
Sticky Feeling (mm)	Visit 3 - Day 8±1	N	20	20	20	20
		Mean	18.5	-11.7	16.5	-9.6
		SD	21.9	20.0	19.9	16.3
		CV%	118.6	-170.7	121.0	-170.2
		Min	0	-63	0	-60
		Median	11.5	-7.0	9.0	-9.0
		Max	87	20	70	17
Sticky Feeling (mm)	Visit 6 - Day 29±1	N	20	20	20	20
		Mean	17.5	-12.7	12.4	-13.7
		SD	28.9	22.1	23.0	19.3
		CV%	164.9	-174.2	186.3	-140.5

**Table 14.2.1.4 Ocular tolerability (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	
			Value	Change from Baseline	Value	Change from Baseline
Sticky Feeling (mm)	Final Visit - Day 56±4/ETV	Min	0	-68	0	-64
		Median	5.5	-10.5	5.0	-11.0
		Max	97	37	97	35
		N	20	20	20	20
		Mean	17.1	-13.2	15.8	-10.3
		SD	30.1	22.0	27.6	23.7
		CV%	176.6	-167.6	175.0	-231.3
		Min	0	-68	0	-64
		Median	3.0	-10.5	2.0	-10.0
		Max	89	31	91	43
Blurred Vision (mm)	Screening - Day -15/-1	N	20		20	
		Mean	58.7		53.9	
		SD	22.8		21.4	
		CV%	38.9		39.8	
		Min	10		10	
		Median	59.5		58.0	
		Max	96		92	

**Table 14.2.1.4 Ocular tolerability (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	
			Value	Change from Baseline	Value	Change from Baseline
Blurred Vision (mm)	Visit 2 - Day 1	N	20	20	20	20
		Mean	34.7	-24.0	30.3	-23.6
		SD	25.6	21.1	21.5	20.5
		CV%	73.9	-87.8	70.9	-86.9
		Min	0	-78	0	-76
		Median	30.5	-21.5	30.5	-19.0
		Max	87	6	71	-1
Blurred Vision (mm)	Visit 3 - Day 8±1	N	20	20	20	20
		Mean	28.8	-29.9	25.9	-28.0
		SD	28.5	30.7	25.9	29.7
		CV%	99.0	-102.8	100.1	-106.1
		Min	1	-82	1	-83
		Median	17.5	-31.5	18.5	-27.5
		Max	86	42	84	52
Blurred Vision (mm)	Visit 6 - Day 29±1	N	20	20	20	20
		Mean	17.7	-41.0	16.0	-37.9

**Table 14.2.1.4 Ocular tolerability (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	
			Value	Change from Baseline	Value	Change from Baseline
Blurred Vision (mm)	Final Visit - Day 56±4/ETV	SD	26.5	28.4	20.7	24.8
		CV%	149.6	-69.3	129.7	-65.4
		Min	0	-83	0	-82
		Median	7.0	-50.5	6.0	-43.5
		Max	91	6	74	5
		N	20	20	20	20
		Mean	19.3	-39.4	17.0	-36.9
		SD	27.6	27.4	24.9	26.1
		CV%	143.1	-69.6	146.5	-70.9
		Min	0	-79	0	-76
		Median	5.5	-51.0	3.0	-44.0
		Max	85	8	77	17
Photophobia (mm)	Screening - Day -15/-1	N	20		20	
		Mean	59.9		59.1	
		SD	20.8		21.7	
		CV%	34.7		36.7	
		Min	23		21	

**Table 14.2.1.4Ocular tolerability (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	
			Value	Change from Baseline	Value	Change from Baseline
Photophobia (mm)	Visit 2 - Day 1	Median	59.0		59.0	
		Max	97		100	
		N	20	20	20	20
		Mean	38.9	-21.0	37.0	-22.1
		SD	30.6	23.1	28.2	23.9
		CV%	78.7	-109.9	76.3	-108.3
		Min	0	-77	0	-75
		Median	32.5	-16.5	27.0	-18.0
		Max	99	13	100	14
Photophobia (mm)	Visit 3 - Day 8±1	N	20	20	20	20
		Mean	32.9	-27.1	30.3	-28.8
		SD	30.5	22.8	28.0	22.6
		CV%	92.8	-84.3	92.3	-78.5
		Min	0	-75	0	-67
		Median	20.5	-24.5	23.5	-29.0
		Max	93	11	95	13

**Table 14.2.1.4 Ocular tolerability (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	
			Value	Change from Baseline	Value	Change from Baseline
Photophobia (mm)	Visit 6 - Day 29±1	N	20	20	20	20
		Mean	28.4	-31.5	21.9	-37.2
		SD	31.2	22.6	27.8	22.6
		CV%	109.8	-71.9	126.8	-60.9
		Min	1	-63	1	-77
		Median	13.5	-24.5	7.5	-35.0
		Max	95	6	92	5
Photophobia (mm)	Final Visit - Day 56±4/ETV	N	20	20	20	20
		Mean	27.7	-32.3	24.2	-34.9
		SD	32.3	21.9	29.1	22.0
		CV%	116.9	-67.9	120.4	-63.1
		Min	0	-66	1	-80
		Median	11.5	-25.5	10.0	-29.0
		Max	96	3	95	0

**Table 14.2.1.4 Ocular tolerability (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	
			Value	Change from Baseline	Value	Change from Baseline
Foreign Body Sensation (mm)	Screening - Day -15/-1	N	20		20	
		Mean	48.3		44.8	
		SD	26.2		27.0	
		CV%	54.3		60.3	
		Min	7		6	
		Median	43.5		38.0	
		Max	100		100	
Foreign Body Sensation (mm)	Visit 2 - Day 1	N	20	20	20	20
		Mean	47.1	-1.2	43.4	-1.4
		SD	28.6	22.8	28.7	16.6
		CV%	60.8	-1901.6	66.2	-1185.8
		Min	0	-38	0	-31
		Median	47.5	-0.5	42.0	-3.5
		Max	100	44	100	36
Foreign Body Sensation (mm)	Visit 3 - Day 8±1	N	20	20	20	20



**Table 14.2.1.4 Ocular tolerability (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	
			Value	Change from Baseline	Value	Change from Baseline
		Mean	28.4	-19.9	34.5	-10.3
		SD	27.4	24.0	31.2	16.6
		CV%	96.6	-120.8	90.5	-162.1
		Min	0	-62	0	-32
		Median	19.0	-16.5	28.5	-18.0
		Max	100	19	100	30
Foreign Body Sensation (mm)	Visit 6 - Day 29±1	N	19	19	19	19
		Mean	18.7	-30.4	20.0	-25.7
		SD	19.5	33.5	23.1	29.4
		CV%	104.3	-110.3	115.5	-114.4
		Min	0	-100	0	-100
		Median	18.0	-30.0	14.0	-24.0
		Max	70	41	76	52
Foreign Body Sensation (mm)	Final Visit - Day 56±4/ETV	N	20	20	20	20
		Mean	18.4	-29.9	20.4	-24.4
		SD	25.9	28.2	26.5	30.4
		CV%	140.5	-94.5	130.0	-124.4

**Table 14.2.1.4 Ocular tolerability (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	
			Value	Change from Baseline	Value	Change from Baseline
Burning/Stinging (mm)	Screening - Day -15/-1	Min	0	-100	0	-100
		Median	9.0	-28.0	7.5	-26.0
		Max	86	31	78	41
		N	20		20	
		Mean	46.8		48.5	
		SD	28.6		27.6	
		CV%	61.2		56.9	
		Min	0		0	
	Visit 2 - Day 1	Median	43.0		37.0	
		Max	100		100	
		N	20	20	20	20
		Mean	39.4	-7.4	41.4	-7.1
		SD	28.6	17.3	29.7	20.3
		CV%	72.8	-233.6	71.7	-286.2
		Min	9	-39	3	-61
		Median	30.0	-5.0	35.0	-2.0
		Max	100	25	100	32

**Table 14.2.1.4 Ocular tolerability (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	
			Value	Change from Baseline	Value	Change from Baseline
Burning/Stinging (mm)	Visit 3 - Day 8±1	N	20	20	20	20
		Mean	33.1	-13.7	27.5	-21.0
		SD	28.6	30.9	27.7	21.0
		CV%	86.5	-226.7	100.8	-99.8
		Min	0	-68	0	-72
		Median	23.0	-17.5	22.0	-21.0
		Max	100	52	100	16
Burning/Stinging (mm)	Visit 6 - Day 29±1	N	19	19	19	19
		Mean	21.2	-24.1	22.6	-24.1
		SD	23.4	30.9	24.3	22.6
		CV%	110.4	-128.5	107.2	-93.8
		Min	0	-77	0	-81
		Median	14.0	-27.0	19.0	-27.0
		Max	76	46	79	16
Burning/Stinging (mm)	Final Visit - Day 56±4/ETV	N	20	20	20	20
		Mean	16.9	-29.9	20.7	-27.8

**Table 14.2.1.4 Ocular tolerability (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	
			Value	Change from Baseline	Value	Change from Baseline
Itching (mm)	Screening - Day -15/-1	SD	23.6	28.1	26.7	26.8
		CV%	139.4	-94.3	129.2	-96.4
		Min	0	-96	0	-89
		Median	7.5	-28.0	12.0	-27.0
		Max	85	13	85	35
		N	20		20	
		Mean	54.0		54.1	
		SD	26.9		25.4	
		CV%	49.8		47.1	
		Min	10		16	
		Median	53.0		54.0	
		Max	100		100	
		N	20	20	20	20
Itching (mm)	Visit 2 - Day 1	Mean	40.0	-14.0	39.0	-15.1
		SD	30.0	22.3	30.9	23.6
		CV%	75.1	-159.2	79.3	-156.8
		Min	0	-72	0	-74
		Max				

**Table 14.2.1.4 Ocular tolerability (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	
			Value	Change from Baseline	Value	Change from Baseline
Itching (mm)	Visit 3 - Day 8±1	Median	37.5	-6.0	40.0	-12.5
		Max	100	10	100	17
		N	20	20	20	20
		Mean	29.9	-24.1	29.8	-24.3
		SD	29.9	29.6	29.8	27.1
		CV%	100.0	-122.9	100.0	-111.6
		Min	0	-72	0	-59
		Median	18.0	-27.5	22.0	-29.0
		Max	100	48	100	63
Itching (mm)	Visit 6 - Day 29±1	N	19	19	19	19
		Mean	19.1	-33.9	18.2	-34.8
		SD	22.4	32.8	22.1	30.2
		CV%	117.3	-96.6	121.4	-86.7
		Min	0	-99	0	-100
		Median	10.0	-38.0	9.0	-34.0
		Max	76	42	68	21

**Table 14.2.1.4 Ocular tolerability (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	
			Value	Change from Baseline	Value	Change from Baseline
Itching (mm)	Final Visit - Day 56±4/ETV	N	20	20	20	20
		Mean	18.8	-35.2	19.4	-34.7
		SD	21.9	33.0	23.4	29.5
		CV%	116.5	-93.7	120.8	-85.2
		Min	0	-99	0	-100
		Median	9.5	-39.0	9.5	-34.0
		Max	72	21	74	25
Pain (mm)	Screening - Day -15/-1	N	20		20	
		Mean	29.5		27.1	
		SD	26.2		23.0	
		CV%	89.0		85.0	
		Min	0		0	
		Median	21.0		22.0	
		Max	100		100	
Pain (mm)	Visit 2 - Day 1	N	20	20	20	20
		Mean	27.0	-2.5	27.3	0.2
		SD	25.0	14.9	24.3	15.1

**Table 14.2.1.4 Ocular tolerability (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	
			Value	Change from Baseline	Value	Change from Baseline
Pain (mm)	Visit 3 - Day 8±1	CV%	92.4	-607.4	89.2	7559.6
		Min	0	-35	0	-29
		Median	21.0	1.0	25.0	1.0
		Max	100	24	100	34
		N	20	20	20	20
		Mean	25.4	-4.1	29.9	2.8
		SD	27.8	29.8	28.2	26.4
		CV%	109.5	-736.4	94.6	943.6
	Visit 6 - Day 29±1	Min	0	-55	0	-39
		Median	13.5	-11.0	23.0	-8.5
		Max	91	55	86	68
		N	19	19	19	19
		Mean	16.1	-14.9	17.9	-10.5
		SD	24.9	28.9	24.1	21.3
		CV%	154.6	-194.3	134.4	-202.1
		Min	0	-55	0	-50
		Median	6.0	-18.0	6.0	-13.0

**Table 14.2.1.4 Ocular tolerability (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	
			Value	Change from Baseline	Value	Change from Baseline
Pain (mm)	Final Visit - Day 56±4/ETV	Max	89	81	76	43
		N	20	20	20	20
		Mean	12.6	-16.9	14.4	-12.7
		SD	20.3	22.6	23.5	19.9
		CV%	160.9	-134.4	163.9	-156.8
		Min	0	-59	0	-52
		Median	1.0	-14.5	2.5	-16.5
		Max	67	34	76	35
Sticky Feeling (mm)	Screening - Day -15/-1	N	20		20	
		Mean	38.8		43.8	
		SD	26.7		29.9	
		CV%	69.0		68.3	
		Min	4		5	
		Median	30.5		37.5	
		Max	100		100	
Sticky Feeling (mm)	Visit 2 - Day 1	N	20	20	20	20



**Table 14.2.1.4 Ocular tolerability (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	
			Value	Change from Baseline	Value	Change from Baseline
		Mean	37.4	-1.4	31.5	-12.3
		SD	30.9	26.0	30.5	20.7
		CV%	82.6	-1859.9	96.8	-168.4
		Min	0	-49	0	-63
		Median	25.0	-2.0	25.5	-8.5
		Max	100	53	100	23
Sticky Feeling (mm)	Visit 3 - Day 8±1	N	20	20	20	20
		Mean	21.9	-16.9	22.0	-21.8
		SD	27.3	27.1	27.6	19.5
		CV%	124.8	-160.7	125.3	-89.5
		Min	0	-62	0	-59
		Median	14.5	-25.0	14.0	-22.5
		Max	99	51	100	11
Sticky Feeling (mm)	Visit 6 - Day 29±1	N	19	19	19	19
		Mean	16.6	-22.7	17.7	-26.8
		SD	26.4	23.8	26.9	27.9
		CV%	158.6	-104.8	151.9	-104.0

**Table 14.2.1.4 Ocular tolerability (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	
			Value	Change from Baseline	Value	Change from Baseline
Sticky Feeling (mm)	Final Visit - Day 56±4/ETV	Min	0	-64	0	-100
		Median	5.0	-23.0	7.0	-25.0
		Max	82	21	87	14
		N	20	20	20	20
		Mean	16.2	-22.6	16.4	-27.5
		SD	23.6	22.5	24.1	29.7
		CV%	145.5	-99.9	147.3	-108.1
		Min	0	-62	0	-100
		Median	7.0	-15.5	4.0	-25.0
		Max	72	14	76	31
Blurred Vision (mm)	Screening - Day -15/-1	N	20		20	
		Mean	54.5		54.2	
		SD	31.8		32.2	
		CV%	58.3		59.5	
		Min	0		0	
		Median	56.0		53.5	
		Max	100		100	

**Table 14.2.1.4 Ocular tolerability (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	
			Value	Change from Baseline	Value	Change from Baseline
Blurred Vision (mm)	Visit 2 - Day 1	N	20	20	20	20
		Mean	47.5	-7.0	43.5	-10.7
		SD	31.7	17.6	33.5	15.1
		CV%	66.7	-253.1	77.0	-140.7
		Min	0	-48	0	-37
		Median	50.0	-2.5	37.5	-6.0
		Max	100	23	100	15
Blurred Vision (mm)	Visit 3 - Day 8±1	N	20	20	20	20
		Mean	37.3	-17.2	34.5	-19.7
		SD	32.5	25.9	32.7	24.2
		CV%	87.2	-150.8	94.8	-123.0
		Min	0	-66	0	-53
		Median	30.5	-20.5	22.0	-26.5
		Max	100	46	100	49
Blurred Vision (mm)	Visit 6 - Day 29±1	N	19	19	19	19
		Mean	25.7	-31.6	27.3	-29.7

**Table 14.2.1.4 Ocular tolerability (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	
			Value	Change from Baseline	Value	Change from Baseline
Blurred Vision (mm)	Final Visit - Day 56±4/ETV	SD	28.0	28.3	28.8	27.9
		CV%	108.8	-89.5	105.5	-94.0
		Min	0	-100	0	-100
		Median	20.0	-38.0	19.0	-34.0
		Max	93	19	94	15
		N	20	20	20	20
		Mean	26.1	-28.4	24.0	-30.2
		SD	27.9	27.2	28.1	26.9
		CV%	106.8	-96.1	117.0	-89.3
		Min	0	-74	0	-77
		Median	18.5	-27.5	14.5	-31.5
		Max	100	9	100	12
Photophobia (mm)	Screening - Day -15/-1	N	20		20	
		Mean	48.1		52.1	
		SD	31.6		33.9	
		CV%	65.6		65.1	
		Min	0		0	

**Table 14.2.1.4 Ocular tolerability (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	
			Value	Change from Baseline	Value	Change from Baseline
Photophobia (mm)	Visit 2 - Day 1	Median	52.0		64.0	
		Max	100		100	
		N	20	20	20	20
		Mean	53.1	5.0	50.1	-2.1
		SD	32.5	23.9	30.2	17.5
		CV%	61.2	478.2	60.3	-853.7
		Min	0	-22	0	-22
		Median	55.5	-0.5	48.0	-4.0
		Max	100	66	100	55
Photophobia (mm)	Visit 3 - Day 8±1	N	20	20	20	20
		Mean	37.3	-10.8	32.2	-20.0
		SD	31.7	35.9	29.7	31.6
		CV%	85.0	-332.8	92.5	-158.4
		Min	0	-69	0	-60
		Median	31.5	-11.5	27.5	-25.5
		Max	100	59	100	57

**Table 14.2.1.4 Ocular tolerability (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	
			Value	Change from Baseline	Value	Change from Baseline
Photophobia (mm)	Visit 6 - Day 29±1	N	19	19	19	19
		Mean	29.8	-20.8	31.0	-23.8
		SD	34.8	42.8	35.5	46.8
		CV%	117.0	-205.3	114.6	-196.2
		Min	0	-70	0	-98
		Median	14.0	-30.0	13.0	-32.0
		Max	94	94	96	96
Photophobia (mm)	Final Visit - Day 56±4/ETV	N	20	20	20	20
		Mean	25.1	-23.1	24.1	-28.1
		SD	26.8	29.8	24.4	30.0
		CV%	107.1	-129.1	101.3	-107.0
		Min	0	-69	0	-72
		Median	15.0	-28.0	16.0	-33.5
		Max	85	34	68	45

**Table 14.2.1.19 Ocular tolerability (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	
			Value	Change from Baseline	Value	Change from Baseline
Foreign Body Sensation (mm)	Screening - Day -15/-1	N	14		14	
		Mean	46.7		36.8	
		SD	28.4		26.2	
		CV%	60.8		71.1	
		Min	0		0	
		Median	50.5		32.0	
		Max	98		78	
Foreign Body Sensation (mm)	Visit 2 - Day 1	N	14	14	14	14
		Mean	27.8	-18.9	20.2	-16.6
		SD	27.1	18.9	21.5	21.9
		CV%	97.4	-99.7	106.2	-132.1
		Min	0	-72	0	-63
		Median	17.5	-15.5	14.0	-19.0
		Max	87	14	71	18
Foreign Body Sensation (mm)	Visit 3 - Day 8±1	N	14	14	14	14

**Table 14.2.1.19 Ocular tolerability (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	
			Value	Change from Baseline	Value	Change from Baseline
		Mean	18.5	-28.2	13.7	-23.1
		SD	25.3	20.9	20.9	34.8
		CV%	136.9	-74.2	152.5	-150.8
		Min	0	-66	0	-65
		Median	6.5	-24.5	5.5	-24.0
		Max	83	3	71	71
Foreign Body Sensation (mm)	Visit 6 - Day 29±1	N	14	14	14	14
		Mean	15.5	-31.2	12.2	-24.6
		SD	24.8	26.9	17.4	32.2
		CV%	159.9	-86.3	142.5	-131.2
		Min	0	-72	0	-74
		Median	4.5	-23.0	4.0	-24.5
		Max	86	7	51	48
Foreign Body Sensation (mm)	Final Visit - Day 56±4/ETV	N	14	14	14	14
		Mean	16.1	-30.6	12.7	-24.1
		SD	25.4	21.5	18.2	30.9
		CV%	157.9	-70.3	143.0	-128.5



**Table 14.2.1.19 Ocular tolerability (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	
			Value	Change from Baseline	Value	Change from Baseline
Burning/Stinging (mm)	Screening - Day -15/-1	Min	0	-69	0	-71
		Median	2.5	-27.5	5.5	-28.0
		Max	84	6	55	55
		N	14		14	
		Mean	49.9		40.1	
		SD	23.8		22.1	
		CV%	47.7		55.1	
		Min	7		4	
	Visit 2 - Day 1	Median	54.0		38.5	
		Max	96		74	
		N	14	14	14	14
		Mean	22.9	-26.9	17.7	-22.4
		SD	25.0	22.3	18.6	21.7
		CV%	108.9	-82.6	104.8	-96.9
		Min	0	-68	0	-57
		Median	18.0	-26.5	13.5	-16.0
		Max	89	-1	55	4

**Table 14.2.1.19 Ocular tolerability (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	
			Value	Change from Baseline	Value	Change from Baseline
Burning/Stinging (mm)	Visit 3 - Day 8±1	N	14	14	14	14
		Mean	17.9	-32.0	13.5	-26.6
		SD	23.7	22.1	18.2	30.2
		CV%	133.0	-69.0	135.1	-113.6
		Min	1	-61	0	-64
		Median	9.0	-35.0	8.0	-25.5
		Max	85	-2	64	51
Burning/Stinging (mm)	Visit 6 - Day 29±1	N	14	14	14	14
		Mean	15.1	-34.7	10.6	-29.4
		SD	24.3	25.1	16.7	29.9
		CV%	160.6	-72.2	156.8	-101.6
		Min	0	-70	0	-74
		Median	6.0	-33.0	4.0	-27.5
		Max	85	6	51	38
Burning/Stinging (mm)	Final Visit - Day 56±4/ETV	N	14	14	14	14
		Mean	17.2	-32.6	14.1	-26.0

**Table 14.2.1.19 Ocular tolerability (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	
			Value	Change from Baseline	Value	Change from Baseline
Itching (mm)	Screening - Day -15/-1	SD	25.2	22.4	18.3	28.9
		CV%	146.3	-68.7	130.2	-111.1
		Min	0	-66	0	-69
		Median	4.0	-27.5	4.0	-24.0
		Max	85	-1	47	34
		N	14		14	
		Mean	43.6		37.6	
		SD	26.1		19.7	
		CV%	59.8		52.6	
		Min	3		3	
		Median	44.0		38.0	
		Max	97		83	
		N	14	14	14	14
		Mean	23.0	-20.6	16.3	-21.3
		SD	27.1	18.5	18.6	15.5
		CV%	117.8	-90.1	114.3	-72.9
		Min	0	-52	0	-51

**Table 14.2.1.19 Ocular tolerability (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	
			Value	Change from Baseline	Value	Change from Baseline
Itching (mm)	Visit 3 - Day 8±1	Median	12.5	-19.5	11.0	-21.0
		Max	90	8	57	5
		N	14	14	14	14
		Mean	15.6	-28.0	13.9	-23.6
		SD	20.4	17.7	19.0	21.5
		CV%	131.2	-63.1	136.6	-91.0
		Min	0	-57	0	-61
		Median	7.5	-28.5	6.0	-22.5
		Max	72	5	63	24
		N	14	14	14	14
		Mean	14.4	-29.2	10.6	-26.9
		SD	23.7	21.4	15.8	22.2
		CV%	165.2	-73.3	148.3	-82.5
		Min	0	-75	0	-82
		Median	5.0	-26.0	2.5	-26.0
		Max	83	2	45	6

**Table 14.2.1.19 Ocular tolerability (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	
			Value	Change from Baseline	Value	Change from Baseline
Itching (mm)	Final Visit - Day 56±4/ETV	N	14	14	14	14
		Mean	17.5	-26.1	14.5	-23.1
		SD	25.7	25.2	20.2	23.7
		CV%	146.6	-96.5	139.6	-102.8
		Min	0	-72	0	-80
		Median	3.0	-27.0	3.0	-25.5
		Max	83	18	57	7
Pain (mm)	Screening - Day -15/-1	N	14		14	
		Mean	40.1		34.6	
		SD	29.8		25.2	
		CV%	74.3		72.9	
		Min	0		0	
		Median	40.0		40.0	
		Max	95		74	
Pain (mm)	Visit 2 - Day 1	N	14	14	14	14
		Mean	20.3	-19.8	11.1	-23.4
		SD	25.6	23.8	16.2	25.4

**Table 14.2.1.19 Ocular tolerability (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	
			Value	Change from Baseline	Value	Change from Baseline
Pain (mm)	Visit 3 - Day 8±1	CV%	126.3	-120.4	145.6	-108.4
		Min	0	-74	0	-74
		Median	11.0	-16.0	4.5	-21.5
		Max	89	13	57	11
		N	14	14	14	14
		Mean	24.4	-15.7	18.7	-15.9
		SD	34.6	32.7	28.7	31.8
		CV%	142.2	-208.1	153.4	-200.6
		Min	0	-73	0	-69
		Median	6.0	-10.5	5.0	-12.0
Pain (mm)	Visit 6 - Day 29±1	Max	94	47	82	34
		N	14	14	14	14
		Mean	15.7	-24.4	7.6	-27.0
		SD	27.4	24.2	13.8	24.8
		CV%	174.4	-99.3	181.8	-91.9
		Min	0	-73	0	-70
		Median	1.5	-21.5	2.0	-23.5

**Table 14.2.1.19 Ocular tolerability (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	
			Value	Change from Baseline	Value	Change from Baseline
		Max	92	9	50	5
Pain (mm)	Final Visit - Day 56±4/ETV	N	14	14	14	14
		Mean	16.0	-24.1	11.9	-22.6
		SD	26.5	22.4	18.6	23.4
		CV%	165.6	-93.2	156.2	-103.2
		Min	0	-62	0	-62
		Median	1.5	-21.5	2.5	-24.5
		Max	84	18	49	13
Sticky Feeling (mm)	Screening - Day -15/-1	N	14		14	
		Mean	32.8		25.9	
		SD	27.1		20.6	
		CV%	82.7		79.8	
		Min	3		2	
		Median	28.0		22.5	
		Max	94		68	
Sticky Feeling (mm)	Visit 2 - Day 1	N	14	14	14	14

**Table 14.2.1.19 Ocular tolerability (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	
			Value	Change from Baseline	Value	Change from Baseline
		Mean	26.0	-6.8	20.2	-5.6
		SD	24.3	14.6	20.8	8.8
		CV%	93.3	-215.3	103.0	-155.2
		Min	2	-41	3	-20
		Median	18.5	-4.5	12.0	-5.0
		Max	88	17	69	6
Sticky Feeling (mm)	Visit 3 - Day 8±1	N	14	14	14	14
		Mean	19.3	-13.5	13.9	-12.0
		SD	25.1	21.2	16.9	17.9
		CV%	130.3	-157.1	121.6	-148.9
		Min	0	-63	0	-60
		Median	7.5	-7.0	9.0	-11.5
		Max	87	20	51	17
Sticky Feeling (mm)	Visit 6 - Day 29±1	N	14	14	14	14
		Mean	16.5	-16.3	9.2	-16.6
		SD	25.7	21.3	13.6	16.6
		CV%	155.7	-130.7	147.3	-100.0



**Table 14.2.1.19 Ocular tolerability (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	
			Value	Change from Baseline	Value	Change from Baseline
Sticky Feeling (mm)	Final Visit - Day 56±4/ETV	Min	0	-68	0	-64
		Median	5.5	-12.0	4.5	-11.5
		Max	90	17	48	-1
		N	14	14	14	14
		Mean	17.1	-15.7	14.9	-10.9
		SD	29.7	22.9	24.8	24.5
		CV%	174.2	-145.9	166.4	-223.9
		Min	0	-68	0	-64
		Median	2.0	-12.0	1.5	-10.0
		Max	89	31	77	43
Blurred Vision (mm)	Screening - Day -15/-1	N	14		14	
		Mean	58.0		53.3	
		SD	26.1		24.3	
		CV%	45.0		45.6	
		Min	10		10	
		Median	59.0		58.0	
		Max	96		92	

**Table 14.2.1.19 Ocular tolerability (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	
			Value	Change from Baseline	Value	Change from Baseline
Blurred Vision (mm)	Visit 2 - Day 1	N	14	14	14	14
		Mean	32.7	-25.3	26.9	-26.4
		SD	26.7	23.4	22.2	23.8
		CV%	81.7	-92.6	82.4	-90.1
		Min	0	-78	0	-76
		Median	26.0	-19.5	23.5	-23.0
		Max	87	2	71	-1
Blurred Vision (mm)	Visit 3 - Day 8±1	N	14	14	14	14
		Mean	24.3	-33.7	22.0	-31.3
		SD	29.3	34.4	25.5	33.9
		CV%	120.6	-102.1	116.1	-108.2
		Min	1	-82	1	-83
		Median	11.0	-33.5	8.0	-35.0
		Max	86	42	81	52
Blurred Vision (mm)	Visit 6 - Day 29±1	N	14	14	14	14
		Mean	16.4	-41.6	14.6	-38.6

**Table 14.2.1.19 Ocular tolerability (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	
			Value	Change from Baseline	Value	Change from Baseline
Blurred Vision (mm)	Final Visit - Day 56±4/ETV	SD	26.2	30.6	18.1	27.2
		CV%	159.4	-73.7	123.9	-70.4
		Min	0	-83	0	-82
		Median	6.0	-46.0	5.5	-40.0
		Max	91	-3	52	5
		N	14	14	14	14
		Mean	19.6	-38.4	16.9	-36.4
		SD	28.3	28.4	23.9	27.6
		CV%	144.5	-73.9	141.0	-75.9
		Min	0	-79	0	-76
		Median	4.0	-44.0	3.0	-39.0
Photophobia (mm)	Screening - Day -15/-1	Max	85	8	74	17
		N	14		14	
		Mean	62.1		60.4	
		SD	17.1		19.0	
		CV%	27.6		31.4	
		Min	33		21	

**Table 14.2.1.19 Ocular tolerability (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	
			Value	Change from Baseline	Value	Change from Baseline
Photophobia (mm)	Visit 2 - Day 1	Median	60.0		62.0	
		Max	92		91	
		N	14	14	14	14
		Mean	40.1	-21.9	35.1	-25.3
		SD	30.1	26.7	27.7	27.0
		CV%	74.9	-121.9	78.7	-106.8
		Min	0	-77	0	-75
		Median	41.0	-11.5	21.0	-22.0
		Max	90	13	88	14
		N	14	14	14	14
		Mean	31.9	-30.1	29.4	-31.0
		SD	30.6	25.8	27.0	26.1
		CV%	95.8	-85.6	91.7	-84.1
		Min	0	-75	0	-67
		Median	20.0	-37.5	23.5	-39.5
		Max	91	11	95	13

**Table 14.2.1.19 Ocular tolerability (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	
			Value	Change from Baseline	Value	Change from Baseline
Photophobia (mm)	Visit 6 - Day 29±1	N	14	14	14	14
		Mean	30.6	-31.4	21.9	-38.5
		SD	30.3	23.3	25.8	22.9
		CV%	98.7	-74.1	117.8	-59.5
		Min	1	-62	1	-72
		Median	21.0	-32.5	11.5	-46.0
		Max	89	6	87	5
Photophobia (mm)	Final Visit - Day 56±4/ETV	N	14	14	14	14
		Mean	29.9	-32.1	25.7	-34.7
		SD	31.5	21.4	26.6	21.2
		CV%	105.3	-66.6	103.5	-61.2
		Min	0	-64	1	-75
		Median	11.5	-30.5	12.0	-36.0
		Max	87	3	82	0

**Table 14.2.1.19 Ocular tolerability (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	
			Value	Change from Baseline	Value	Change from Baseline
Foreign Body Sensation (mm)	Screening - Day -15/-1	N	16		16	
		Mean	45.3		41.8	
		SD	25.7		26.1	
		CV%	56.9		62.5	
		Min	7		6	
		Median	37.5		37.0	
		Max	100		100	
Foreign Body Sensation (mm)	Visit 2 - Day 1	N	16	16	16	16
		Mean	43.3	-2.0	40.6	-1.2
		SD	24.1	22.8	25.0	16.5
		CV%	55.7	-1139.0	61.7	-1387.9
		Min	10	-38	3	-31
		Median	46.0	-2.0	42.0	-4.0
		Max	99	44	100	36
Foreign Body Sensation (mm)	Visit 3 - Day 8±1	N	16	16	16	16

**Table 14.2.1.19 Ocular tolerability (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	
			Value	Change from Baseline	Value	Change from Baseline
		Mean	27.7	-17.6	33.2	-8.6
		SD	26.3	24.4	31.5	17.3
		CV%	94.8	-138.8	94.9	-202.1
		Min	0	-62	0	-32
		Median	19.0	-11.5	19.5	-16.5
		Max	100	19	100	30
Foreign Body Sensation (mm)	Visit 6 - Day 29±1	N	16	16	16	16
		Mean	18.3	-27.0	18.0	-23.8
		SD	20.0	35.2	20.0	31.5
		CV%	109.7	-130.4	111.1	-132.8
		Min	0	-100	0	-100
		Median	14.0	-26.5	14.0	-20.0
		Max	70	41	59	52
Foreign Body Sensation (mm)	Final Visit - Day 56±4/ETV	N	16	16	16	16
		Mean	12.8	-32.5	15.9	-25.9
		SD	15.0	26.7	19.7	31.4
		CV%	118.0	-82.1	124.4	-121.4

**Table 14.2.1.19 Ocular tolerability (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	
			Value	Change from Baseline	Value	Change from Baseline
Burning/Stinging (mm)	Screening - Day -15/-1	Min	0	-100	0	-100
		Median	9.0	-28.0	7.5	-24.5
		Max	47	18	65	41
		N	16		16	
		Mean	43.0		44.6	
		SD	24.3		22.3	
		CV%	56.5		50.0	
		Min	17		20	
		Median	37.0		36.5	
		Max	99		100	
		N	16	16	16	16
		Mean	35.8	-7.2	37.3	-7.3
		SD	25.8	17.1	26.6	19.8
		CV%	71.9	-238.5	71.4	-270.2
		Min	10	-39	3	-61
		Median	23.0	-6.0	33.0	-3.5
		Max	100	25	100	32



**Table 14.2.1.19 Ocular tolerability (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	
			Value	Change from Baseline	Value	Change from Baseline
Burning/Stinging (mm)	Visit 3 - Day 8±1	N	16	16	16	16
		Mean	27.6	-15.4	24.9	-19.6
		SD	27.8	30.3	27.5	21.8
		CV%	100.8	-196.5	110.1	-111.0
		Min	0	-68	0	-72
		Median	16.0	-17.5	15.0	-19.0
		Max	100	52	100	16
Burning/Stinging (mm)	Visit 6 - Day 29±1	N	16	16	16	16
		Mean	19.6	-23.4	20.6	-23.9
		SD	22.0	32.5	22.3	23.2
		CV%	112.3	-139.1	108.1	-96.7
		Min	0	-77	1	-81
		Median	12.0	-26.0	17.5	-27.0
		Max	76	46	79	16
Burning/Stinging (mm)	Final Visit - Day 56±4/ETV	N	16	16	16	16
		Mean	10.6	-32.4	13.5	-31.1

**Table 14.2.1.19 Ocular tolerability (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	
			Value	Change from Baseline	Value	Change from Baseline
Itching (mm)	Screening - Day -15/-1	SD	11.6	27.3	17.6	26.9
		CV%	110.2	-84.1	130.6	-86.7
		Min	0	-96	0	-89
		Median	7.0	-28.0	8.5	-30.5
		Max	37	13	68	35
		N	16		16	
		Mean	50.9		50.3	
		SD	26.7		25.0	
		CV%	52.5		49.7	
		Min	10		16	
		Median	45.5		47.0	
		Max	99		100	
		N	16	16	16	16
Itching (mm)	Visit 2 - Day 1	Mean	36.6	-14.3	35.7	-14.6
		SD	26.9	17.7	28.2	20.3
		CV%	73.4	-124.5	79.1	-138.7
		Min	3	-64	1	-64
		N	16		16	

**Table 14.2.1.19 Ocular tolerability (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	
			Value	Change from Baseline	Value	Change from Baseline
Itching (mm)	Visit 3 - Day 8±1	Median	32.0	-6.5	36.5	-17.0
		Max	100	4	100	17
		N	16	16	16	16
		Mean	26.8	-24.1	25.5	-24.8
		SD	30.0	27.2	31.3	27.9
		CV%	112.2	-112.6	122.7	-112.3
		Min	0	-72	0	-59
		Median	14.5	-27.5	9.5	-29.0
		Max	100	48	100	63
Itching (mm)	Visit 6 - Day 29±1	N	16	16	16	16
		Mean	18.8	-32.1	15.9	-34.4
		SD	23.6	35.0	20.1	33.0
		CV%	125.4	-109.1	125.9	-95.9
		Min	0	-99	0	-100
		Median	8.5	-36.5	9.0	-30.5
		Max	76	42	64	21

**Table 14.2.1.19 Ocular tolerability (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	
			Value	Change from Baseline	Value	Change from Baseline
Itching (mm)	Final Visit - Day 56±4/ETV	N	16	16	16	16
		Mean	11.1	-39.8	13.0	-37.3
		SD	12.3	31.5	15.6	30.5
		CV%	110.7	-79.2	119.9	-81.8
		Min	0	-99	0	-100
		Median	5.0	-41.0	6.0	-34.0
		Max	36	21	53	25
Pain (mm)	Screening - Day -15/-1	N	16		16	
		Mean	28.7		25.2	
		SD	20.5		14.4	
		CV%	71.6		57.0	
		Min	3		3	
		Median	21.0		22.0	
		Max	73		56	
Pain (mm)	Visit 2 - Day 1	N	16	16	16	16
		Mean	23.4	-5.3	23.2	-2.0
		SD	17.5	14.6	15.9	15.5

**Table 14.2.1.19 Ocular tolerability (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	
			Value	Change from Baseline	Value	Change from Baseline
Pain (mm)	Visit 3 - Day 8±1	CV%	74.6	-277.7	68.4	-776.1
		Min	2	-35	2	-29
		Median	21.0	1.0	25.0	-3.5
		Max	72	12	52	34
		N	16	16	16	16
		Mean	22.9	-5.8	26.9	1.7
		SD	23.6	32.8	26.4	28.5
		CV%	103.2	-564.8	98.3	1686.0
	Visit 6 - Day 29±1	Min	0	-55	0	-39
		Median	13.5	-14.0	15.0	-9.0
		Max	72	55	77	68
		N	16	16	16	16
		Mean	14.3	-14.4	16.6	-8.6
		SD	23.3	31.1	22.7	21.7
		CV%	163.2	-215.5	136.6	-253.7
		Min	0	-55	0	-50
		Median	5.0	-18.0	5.5	-12.0

**Table 14.2.1.19 Ocular tolerability (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	
			Value	Change from Baseline	Value	Change from Baseline
		Max	89	81	76	43
Pain (mm)	Final Visit - Day 56±4/ETV	N	16	16	16	16
		Mean	7.6	-21.1	9.2	-16.0
		SD	9.9	20.1	15.1	19.0
		CV%	131.5	-95.0	163.9	-118.7
		Min	0	-59	0	-52
		Median	1.0	-18.0	2.5	-19.0
		Max	29	3	59	35
Sticky Feeling (mm)	Screening - Day -15/-1	N	16		16	
		Mean	33.9		41.0	
		SD	24.3		30.0	
		CV%	71.8		73.2	
		Min	4		5	
		Median	26.0		29.5	
		Max	76		100	
Sticky Feeling (mm)	Visit 2 - Day 1	N	16	16	16	16

**Table 14.2.1.19 Ocular tolerability (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	
			Value	Change from Baseline	Value	Change from Baseline
		Mean	34.3	0.4	27.9	-13.1
		SD	29.5	28.6	28.4	22.8
		CV%	86.0	6546.9	101.8	-174.5
		Min	0	-49	0	-63
		Median	21.0	-2.0	24.0	-8.5
		Max	99	53	100	23
Sticky Feeling (mm)	Visit 3 - Day 8±1	N	16	16	16	16
		Mean	22.3	-11.6	22.1	-18.9
		SD	27.5	27.7	27.1	20.7
		CV%	123.7	-238.1	123.0	-109.0
		Min	0	-62	0	-59
		Median	14.5	-8.5	15.0	-14.0
		Max	99	51	100	11
Sticky Feeling (mm)	Visit 6 - Day 29±1	N	16	16	16	16
		Mean	14.6	-19.3	15.6	-25.4
		SD	24.5	24.0	25.0	30.2
		CV%	167.4	-124.5	160.5	-118.8

**Table 14.2.1.19 Ocular tolerability (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	
			Value	Change from Baseline	Value	Change from Baseline
Sticky Feeling (mm)	Final Visit - Day 56±4/ETV	Min	0	-64	0	-100
		Median	4.0	-16.5	6.0	-16.0
		Max	82	21	87	14
		N	16	16	16	16
		Mean	11.2	-22.7	11.0	-30.0
		SD	17.8	22.1	18.1	28.9
		CV%	159.3	-97.3	164.6	-96.4
		Min	0	-62	0	-100
		Median	5.5	-15.0	4.0	-25.0
		Max	72	7	73	8
Blurred Vision (mm)	Screening - Day -15/-1	N	16		16	
		Mean	52.3		51.9	
		SD	28.2		28.8	
		CV%	54.0		55.5	
		Min	0		0	
		Median	53.5		52.5	
		Max	100		100	



**Table 14.2.1.19 Ocular tolerability (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	
			Value	Change from Baseline	Value	Change from Baseline
Blurred Vision (mm)	Visit 2 - Day 1	N	16	16	16	16
		Mean	45.1	-7.1	40.3	-11.7
		SD	28.4	19.5	30.6	16.4
		CV%	62.8	-273.8	75.9	-140.5
		Min	0	-48	0	-37
		Median	50.0	-2.5	37.0	-10.0
		Max	100	23	100	15
Blurred Vision (mm)	Visit 3 - Day 8±1	N	16	16	16	16
		Mean	34.8	-17.4	30.9	-21.1
		SD	30.4	27.9	29.5	26.0
		CV%	87.4	-159.7	95.4	-123.5
		Min	0	-66	0	-53
		Median	30.5	-20.5	19.0	-27.0
		Max	100	46	100	49
Blurred Vision (mm)	Visit 6 - Day 29±1	N	16	16	16	16
		Mean	19.9	-32.4	22.3	-29.6

**Table 14.2.1.19 Ocular tolerability (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	
			Value	Change from Baseline	Value	Change from Baseline
Blurred Vision (mm)	Final Visit - Day 56±4/ETV	SD	21.0	30.1	23.9	29.6
		CV%	105.9	-92.9	107.1	-99.9
		Min	0	-100	0	-100
		Median	16.0	-38.5	18.0	-31.0
		Max	80	19	88	15
		N	16	16	16	16
		Mean	20.5	-31.8	18.4	-33.5
		SD	21.3	28.5	21.7	27.8
		CV%	103.8	-89.7	117.5	-82.9
		Min	0	-74	0	-77
		Median	15.5	-32.0	10.5	-35.0
Photophobia (mm)	Screening - Day -15/-1	Max	78	9	79	12
		N	16		16	
		Mean	50.1		54.9	
		SD	27.6		30.4	
		CV%	55.0		55.4	
		Min	7		5	

**Table 14.2.1.19 Ocular tolerability (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	
			Value	Change from Baseline	Value	Change from Baseline
Photophobia (mm)	Visit 2 - Day 1	Median	52.0		66.0	
		Max	87		98	
		N	16	16	16	16
		Mean	56.4	6.3	52.8	-2.1
		SD	29.7	26.3	26.7	18.8
		CV%	52.8	420.2	50.6	-886.7
		Min	4	-22	4	-22
		Median	66.5	-2.5	50.5	-4.5
		Max	100	66	99	55
Photophobia (mm)	Visit 3 - Day 8±1	N	16	16	16	16
		Mean	37.4	-12.7	31.4	-23.6
		SD	33.4	36.6	30.8	29.9
		CV%	89.3	-288.6	98.1	-127.1
		Min	0	-69	0	-60
		Median	27.0	-11.5	23.5	-25.5
		Max	100	59	100	57

**Table 14.2.1.19 Ocular tolerability (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	
			Value	Change from Baseline	Value	Change from Baseline
Photophobia (mm)	Visit 6 - Day 29±1	N	16	16	16	16
		Mean	23.8	-26.4	25.8	-29.2
		SD	31.3	35.3	33.0	39.9
		CV%	131.8	-133.8	128.3	-136.6
		Min	0	-70	0	-98
		Median	8.0	-30.5	13.0	-30.5
		Max	89	78	88	75
Photophobia (mm)	Final Visit - Day 56±4/ETV	N	16	16	16	16
		Mean	23.7	-26.4	22.1	-32.8
		SD	27.9	28.9	24.7	26.2
		CV%	118.0	-109.1	111.5	-79.9
		Min	0	-69	0	-72
		Median	10.0	-28.0	10.0	-33.5
		Max	85	15	68	17