

Table 14.2.1.1 Symptom assessment in dry eye (SANDE, Full analysis set)

Investigational Medicinal Product: rhNGF 20 µg/mL - Dry Eye Severity Level > 2

Parameter	Visit	Statistics	Value	Full Analysis Set N=9	Change from Baseline
		Max	80		-3

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

Baseline: Screening visit assessment (all assessments were performed using a 100 mm Visual Analogue Scale)

Source: [Listing 16.2.6.1](#) - Symptom assessment in dry eye (SANDE)

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

Table 14.2.1.1 Symptom assessment in dry eye (SANDE, Full analysis set)

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

Parameter	Visit	Statistics	Value	Full Analysis Set N=20	Change from Baseline
Frequency of Symptoms (mm)	Screening - Day -15/-1	N	20		
		Mean	55.3		
		SD	27.3		
		CV%	49.5		
		Min	11		

Table 14.2.1.1 Symptom assessment in dry eye (SANDE, Full analysis set)

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

Parameter	Visit	Statistics	Full Analysis Set N=20	
			Value	Change from Baseline
Frequency of Symptoms (mm)	Visit 2 - Day 1	Median	48.0	
		Max	100	
		N	20	20
		Mean	47.3	-8.0
		SD	24.2	15.9
		CV%	51.1	-200.0
		Min	4	-49
		Median	45.5	-1.0
Frequency of Symptoms (mm)	Visit 3 - Day 8±1	Max	97	25
		N	20	20
		Mean	40.3	-15.0
		SD	23.1	20.1
		CV%	57.4	-134.8
		Min	5	-82
		Median	33.5	-9.5
		Max	97	14
Frequency of Symptoms (mm)	Visit 6 - Day 29±1	N	20	20

Table 14.2.1.1 Symptom assessment in dry eye (SANDE, Full analysis set)

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

Parameter	Visit	Statistics	Full Analysis Set N=20	
			Value	Change from Baseline
Frequency of Symptoms (mm)	Final Visit - Day 56±4/ETV	Mean	28.4	-26.9
		SD	26.2	24.5
		CV%	92.2	-91.3
		Min	1	-88
		Median	19.0	-21.0
		Max	89	9
Severity of Symptoms (mm)	Screening - Day -15/-1	N	20	
		Mean	52.8	
		SD	23.2	
		CV%	44.0	
		Min	7	

Table 14.2.1.1 Symptom assessment in dry eye (SANDE, Full analysis set)

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

Parameter	Visit	Statistics	Full Analysis Set N=20	
			Value	Change from Baseline
Severity of Symptoms (mm)	Visit 2 - Day 1	Median	53.0	
		Max	98	
		N	20	20
		Mean	45.3	-7.6
		SD	23.7	20.1
		CV%	52.5	-265.8
		Min	7	-68
		Median	40.5	0.0
Severity of Symptoms (mm)	Visit 3 - Day 8±1	Max	99	27
		N	20	20
		Mean	41.1	-11.7
		SD	23.1	19.9
		CV%	56.3	-170.1
		Min	8	-56
		Median	36.0	-8.0
		Max	99	23
Severity of Symptoms (mm)	Visit 6 - Day 29±1	N	20	20

Table 14.2.1.1 Symptom assessment in dry eye (SANDE, Full analysis set)

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

Parameter	Visit	Statistics	Full Analysis Set N=20	
			Value	Change from Baseline
Severity of Symptoms (mm)	Final Visit - Day 56±4/ETV	Mean	25.9	-27.0
		SD	26.9	28.4
		CV%	104.2	-105.3
		Min	0	-79
		Median	16.0	-21.0
		Max	89	23
	Final Visit - Day 56±4/ETV	N	20	20
		Mean	23.9	-29.0
		SD	28.1	23.9
		CV%	117.6	-82.6
		Min	0	-78
		Median	11.5	-28.5
		Max	89	34

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

Baseline: Screening visit assessment (all assessments were performed using a 100 mm Visual Analogue Scale)

Source: [Listing 16.2.6.1](#) - Symptom assessment in dry eye (SANDE)

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

Table 14.2.1.1 Symptom assessment in dry eye (SANDE, Full analysis set)

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

Parameter	Visit	Statistics	Full Analysis Set N=20	
			Value	Change from Baseline
Frequency of Symptoms (mm)	Screening - Day -15/-1	N	20	
		Mean	59.7	
		SD	29.2	
		CV%	48.9	
		Min	7	
		Median	54.0	
		Max	100	
Frequency of Symptoms (mm)	Visit 2 - Day 1	N	20	20
		Mean	49.7	-10.0
		SD	22.4	24.8
		CV%	45.0	-248.3
		Min	9	-52
		Median	47.5	-2.0
		Max	100	40
Frequency of Symptoms (mm)	Visit 3 - Day 8±1	N	20	20
		Mean	36.4	-23.4
		SD	23.8	26.0

Table 14.2.1.1 Symptom assessment in dry eye (SANDE, Full analysis set)

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

Parameter	Visit	Statistics	Full Analysis Set N=20	
			Value	Change from Baseline
Frequency of Symptoms (mm)	Visit 6 - Day 29±1	CV%	65.4	-111.2
		Min	3	-59
		Median	33.0	-31.5
		Max	87	48
		N	19	19
		Mean	33.5	-24.5
		SD	26.4	22.2
Frequency of Symptoms (mm)	Final Visit - Day 56±4/ETV	CV%	78.8	-90.6
		Min	0	-75
		Median	31.0	-21.0
		Max	93	13
		N	20	20
		Mean	31.7	-28.0
		SD	26.8	23.6
Frequency of Symptoms (mm)	Final Visit - Day 56±4/ETV	CV%	84.6	-84.3
		Min	1	-84
		Median	25.0	-26.0
		Max	84	14

Table 14.2.1.1 Symptom assessment in dry eye (SANDE, Full analysis set)

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

Parameter	Visit	Statistics	Full Analysis Set N=20	
			Value	Change from Baseline
Severity of Symptoms (mm)	Screening - Day -15/-1	N	20	
		Mean	60.1	
		SD	29.6	
		CV%	49.2	
		Min	5	
		Median	64.0	
		Max	100	
Severity of Symptoms (mm)	Visit 2 - Day 1	N	20	20
		Mean	50.3	-9.9
		SD	21.6	21.9
		CV%	43.1	-222.0
		Min	13	-52
		Median	46.5	-6.0
		Max	91	41
Severity of Symptoms (mm)	Visit 3 - Day 8±1	N	20	20
		Mean	39.1	-21.1
		SD	27.0	29.6

Table 14.2.1.1 Symptom assessment in dry eye (SANDE, Full analysis set)

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

Parameter	Visit	Statistics	Full Analysis Set N=20	
			Value	Change from Baseline
Severity of Symptoms (mm)	Visit 6 - Day 29±1	CV%	69.1	-140.8
		Min	4	-94
		Median	35.0	-14.5
		Max	86	25
		N	19	19
		Mean	31.5	-28.9
		SD	25.5	28.4
		CV%	80.9	-98.4
		Min	1	-98
		Median	23.0	-22.0
Severity of Symptoms (mm)	Final Visit - Day 56±4/ETV	Max	95	15
		N	20	20
		Mean	31.9	-28.2
		SD	27.9	26.9
		CV%	87.5	-95.3
		Min	2	-79
		Median	21.5	-27.5

Table 14.2.1.1 Symptom assessment in dry eye (SANDE, Full analysis set)

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

Parameter	Visit	Statistics	Value	Full Analysis Set N=20	Change from Baseline
		Max	91		16

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

Baseline: Screening visit assessment (all assessments were performed using a 100 mm Visual Analogue Scale)

Source: [Listing 16.2.6.1](#) - Symptom assessment in dry eye (SANDE)

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

Table 14.2.1.1 Symptom assessment in dry eye (SANDE, Full analysis set)

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

Parameter	Visit	Statistics	Full Analysis Set N=20	
			Value	Change from Baseline
Frequency of Symptoms (mm)	Screening - Day -15/-1	N	20	
		Mean	59.7	
		SD	29.2	
		CV%	48.9	
		Min	7	
		Median	54.0	
		Max	100	
Frequency of Symptoms (mm)	Visit 2 - Day 1	N	20	20
		Mean	49.7	-10.0
		SD	22.4	24.8
		CV%	45.0	-248.3
		Min	9	-52
		Median	47.5	-2.0
		Max	100	40
Frequency of Symptoms (mm)	Visit 3 - Day 8±1	N	20	20
		Mean	36.4	-23.4
		SD	23.8	26.0

Table 14.2.1.1 Symptom assessment in dry eye (SANDE, Full analysis set)

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

Parameter	Visit	Statistics	Full Analysis Set N=20	
			Value	Change from Baseline
Frequency of Symptoms (mm)	Visit 6 - Day 29±1	CV%	65.4	-111.2
		Min	3	-59
		Median	33.0	-31.5
		Max	87	48
		N	19	19
		Mean	33.5	-24.5
		SD	26.4	22.2
Frequency of Symptoms (mm)	Final Visit - Day 56±4/ETV	CV%	78.8	-90.6
		Min	0	-75
		Median	31.0	-21.0
		Max	93	13
		N	20	20
		Mean	31.7	-28.0
		SD	26.8	23.6
Frequency of Symptoms (mm)	Final Visit - Day 56±4/ETV	CV%	84.6	-84.3
		Min	1	-84
		Median	25.0	-26.0
		Max	84	14

Table 14.2.1.1 Symptom assessment in dry eye (SANDE, Full analysis set)

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

Parameter	Visit	Statistics	Full Analysis Set N=20	
			Value	Change from Baseline
Severity of Symptoms (mm)	Screening - Day -15/-1	N	20	
		Mean	60.1	
		SD	29.6	
		CV%	49.2	
		Min	5	
		Median	64.0	
		Max	100	
Severity of Symptoms (mm)	Visit 2 - Day 1	N	20	20
		Mean	50.3	-9.9
		SD	21.6	21.9
		CV%	43.1	-222.0
		Min	13	-52
		Median	46.5	-6.0
		Max	91	41
Severity of Symptoms (mm)	Visit 3 - Day 8±1	N	20	20
		Mean	39.1	-21.1
		SD	27.0	29.6

Table 14.2.1.1 Symptom assessment in dry eye (SANDE, Full analysis set)

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

Parameter	Visit	Statistics	Full Analysis Set N=20	
			Value	Change from Baseline
Severity of Symptoms (mm)	Visit 6 - Day 29±1	CV%	69.1	-140.8
		Min	4	-94
		Median	35.0	-14.5
		Max	86	25
		N	19	19
		Mean	31.5	-28.9
		SD	25.5	28.4
		CV%	80.9	-98.4
		Min	1	-98
		Median	23.0	-22.0
Severity of Symptoms (mm)	Final Visit - Day 56±4/ETV	Max	95	15
		N	20	20
		Mean	31.9	-28.2
		SD	27.9	26.9
		CV%	87.5	-95.3
		Min	2	-79
		Median	21.5	-27.5

Table 14.2.1.1 Symptom assessment in dry eye (SANDE, Full analysis set)

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

Parameter	Visit	Statistics	Value	Full Analysis Set N=20	Change from Baseline
		Max	91		16

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

Baseline: Screening visit assessment (all assessments were performed using a 100 mm Visual Analogue Scale)

Source: [Listing 16.2.6.1](#) - Symptom assessment in dry eye (SANDE)

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

Table 14.2.1.16 Symptom assessment in dry eye (SANDE, Per protocol set)

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

Parameter	Visit	Statistics	Per Protocol Set N=14	
			Value	Change from Baseline
Frequency of Symptoms (mm)	Screening - Day -15/-1	N	14	
		Mean	56.6	
		SD	29.2	
		CV%	51.7	
		Min	11	
		Median	56.0	
		Max	100	
Frequency of Symptoms (mm)	Visit 2 - Day 1	N	14	14
		Mean	45.1	-11.4
		SD	24.8	18.0
		CV%	54.9	-157.9
		Min	4	-49
		Median	47.0	-11.5
		Max	94	25
Frequency of Symptoms (mm)	Visit 3 - Day 8±1	N	14	14
		Mean	39.4	-17.2

Table 14.2.1.16 Symptom assessment in dry eye (SANDE, Per protocol set)

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

Parameter	Visit	Statistics	Per Protocol Set N=14	
			Value	Change from Baseline
		SD	22.3	22.9
		CV%	56.6	-132.8
		Min	5	-82
		Median	36.0	-14.0
		Max	80	14
Frequency of Symptoms (mm)	Visit 6 - Day 29±1	N	14	14
		Mean	27.1	-29.4
		SD	25.3	28.9
		CV%	93.4	-98.2
		Min	1	-88
		Median	19.0	-20.5
		Max	79	9
Frequency of Symptoms (mm)	Final Visit - Day 56±4/ETV	N	14	14
		Mean	26.9	-29.6
		SD	26.8	21.1
		CV%	99.6	-71.3
		Min	0	-66
		Median	22.5	-30.0

Table 14.2.1.16 Symptom assessment in dry eye (SANDE, Per protocol set)

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

Parameter	Visit	Statistics	Per Protocol Set N=14	
			Value	Change from Baseline
Severity of Symptoms (mm)	Screening - Day -15/-1	Max	81	5
		N	14	
		Mean	54.1	
		SD	23.3	
		CV%	43.0	
		Min	7	
		Median	54.0	
		Max	90	
Severity of Symptoms (mm)	Visit 2 - Day 1	N	14	14
		Mean	43.1	-11.0
		SD	23.8	23.4
		CV%	55.1	-212.3
		Min	7	-68
		Median	39.0	-7.0
		Max	86	27
Severity of Symptoms (mm)	Visit 3 - Day 8±1	N	14	14
		Mean	39.6	-14.6

Table 14.2.1.16 Symptom assessment in dry eye (SANDE, Per protocol set)

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

Parameter	Visit	Statistics	Per Protocol Set N=14	
			Value	Change from Baseline
		SD	22.2	23.2
		CV%	56.0	-159.4
		Min	8	-56
		Median	36.0	-13.5
		Max	78	23
Severity of Symptoms (mm)	Visit 6 - Day 29±1	N	14	14
		Mean	24.7	-29.4
		SD	25.7	33.4
		CV%	104.0	-113.6
		Min	0	-79
		Median	16.0	-18.5
		Max	78	23
Severity of Symptoms (mm)	Final Visit - Day 56±4/ETV	N	14	14
		Mean	25.8	-28.4
		SD	28.1	28.2
		CV%	109.1	-99.4
		Min	0	-78

Table 14.2.1.16 Symptom assessment in dry eye (SANDE, Per protocol set)

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

Parameter	Visit	Statistics	Value	Per Protocol Set N=14	Change from Baseline
		Median	14.5		-28.5
		Max	89		34

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

Baseline: Screening visit assessment (all assessments were performed using a 100 mm Visual Analogue Scale)

Source: [Listing 16.2.6.1](#) - Symptom assessment in dry eye (SANDE)

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

Table 14.2.1.16 Symptom assessment in dry eye (SANDE, Per protocol set)

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

Parameter	Visit	Statistics	Value	Per Protocol Set N=11	Change from Baseline
Frequency of Symptoms (mm)	Screening - Day -15/-1	N	11		
		Mean	46.3		
		SD	27.8		
		CV%	60.1		

Table 14.2.1.16 Symptom assessment in dry eye (SANDE, Per protocol set)

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

Parameter	Visit	Statistics	Value	Per Protocol Set N=5	Change from Baseline
		Median	45.0		-36.0
		Max	73		9

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

Baseline: Screening visit assessment (all assessments were performed using a 100 mm Visual Analogue Scale)

Source: [Listing 16.2.6.1](#) - Symptom assessment in dry eye (SANDE)

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

Table 14.2.1.16 Symptom assessment in dry eye (SANDE, Per protocol set)

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

Parameter	Visit	Statistics	Value	Per Protocol Set N=16	Change from Baseline
Frequency of Symptoms (mm)	Screening - Day -15/-1	N	16		
		Mean	50.6		
		SD	25.2		
		CV%	49.8		

Table 14.2.1.16 Symptom assessment in dry eye (SANDE, Per protocol set)

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

Parameter	Visit	Statistics	Per Protocol Set N=16	
			Value	Change from Baseline
Frequency of Symptoms (mm)	Visit 2 - Day 1	Min	7	
		Median	47.5	
		Max	88	
		N	16	16
		Mean	45.8	-4.8
		SD	21.0	23.2
		CV%	45.9	-483.1
		Min	9	-43
		Median	45.0	-0.5
		Max	87	40
Frequency of Symptoms (mm)	Visit 3 - Day 8±1	N	16	16
		Mean	32.3	-18.4
		SD	24.9	26.6
		CV%	77.3	-144.6
		Min	3	-59
		Median	22.5	-20.5
		Max	87	48

Table 14.2.1.16 Symptom assessment in dry eye (SANDE, Per protocol set)

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

Parameter	Visit	Statistics	Per Protocol Set N=16	
			Value	Change from Baseline
Frequency of Symptoms (mm)	Visit 6 - Day 29±1	N	16	16
		Mean	28.4	-22.3
		SD	23.1	20.8
		CV%	81.4	-93.6
		Min	0	-75
		Median	19.0	-18.0
		Max	73	13
Frequency of Symptoms (mm)	Final Visit - Day 56±4/ETV	N	16	16
		Mean	23.3	-27.4
		SD	22.0	25.1
		CV%	94.5	-91.7
		Min	1	-84
		Median	19.0	-26.0
		Max	82	14
Severity of Symptoms (mm)	Screening - Day -15/-1	N	16	
		Mean	54.1	
		SD	28.7	
		CV%	53.0	

Table 14.2.1.16 Symptom assessment in dry eye (SANDE, Per protocol set)

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

Parameter	Visit	Statistics	Per Protocol Set N=16		Change from Baseline
			Value		
Severity of Symptoms (mm)	Visit 2 - Day 1	Min	5		
		Median	52.5		
		Max	99		
		N	16		16
		Mean	46.9		-7.1
		SD	21.9		23.2
		CV%	46.6		-325.6
		Min	13		-52
		Median	43.5		-2.0
		Max	91		41
Severity of Symptoms (mm)	Visit 3 - Day 8±1	N	16		16
		Mean	33.5		-20.6
		SD	26.6		31.8
		CV%	79.3		-154.8
		Min	4		-94
		Median	23.0		-12.5
		Max	86		25

Table 14.2.1.16 Symptom assessment in dry eye (SANDE, Per protocol set)

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

Parameter	Visit	Statistics	Per Protocol Set N=16	
			Value	Change from Baseline
Severity of Symptoms (mm)	Visit 6 - Day 29±1	N	16	16
		Mean	26.9	-27.1
		SD	21.7	28.1
		CV%	80.5	-103.6
		Min	1	-98
		Median	20.5	-21.0
		Max	74	15
Severity of Symptoms (mm)	Final Visit - Day 56±4/ETV	N	16	16
		Mean	22.4	-31.7
		SD	20.9	27.6
		CV%	93.3	-87.0
		Min	2	-79
		Median	19.5	-32.5
		Max	73	16

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

Baseline: Screening visit assessment (all assessments were performed using a 100 mm Visual Analogue Scale)

Source: [Listing 16.2.6.1](#) - Symptom assessment in dry eye (SANDE)

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