

Table 14.3.6.2c Summary of Ocular Tolerability as Measured by the VAS (mm) by Treatment and Visit  
(Safety Population)

Study Period: Controlled Treatment Period, Symptom: Foreign Body Sensation

Visit		rhNGF 10 µg/ml (N=52)		rhNGF 20 µg/ml (N=52)		Vehicle Control (N=52)	
		Actual	CFB	Actual	CFB	Actual	CFB
Baseline	n	52		52		52	
	Mean (SD)	34.8 (29.40)		35.4 (34.79)		37.7 (36.49)	
	Median	30.0		30.0		27.5	
	Min, Max	0, 100		0, 100		0, 100	

CFB: Change from Baseline

Top N counts relate to the number of patients who have received each treatment in the specified study period. Patients allocated to Vehicle Control who are not completely healed at Week 8 are counted in the Vehicle Control group in the Controlled Treatment Period and their Uncontrolled Treatment group in the Follow-Up Period.

The data presented in this Table are contained in Listing 16.2.9.3c

Program path: \Dompe\rhNGF\NGF0212\Stat\programs\tables\rtvassm.sas

Executed: 11OCT2016, 05:16

Table 14.3.6.2c Summary of Ocular Tolerability as Measured by the VAS (mm) by Treatment and Visit  
(Safety Population)

Study Period: Controlled Treatment Period, Symptom: Burning/Stinging

Visit		rhNGF 10 µg/ml (N=52)		rhNGF 20 µg/ml (N=52)		Vehicle Control (N=52)	
		Actual	CFB	Actual	CFB	Actual	CFB
Baseline	n	52		52		52	
	Mean (SD)	32.5 (32.88)		26.5 (30.86)		30.2 (32.21)	
	Median	20.0		15.0		15.0	
	Min, Max	0, 100		0, 100		0, 100	

CFB: Change from Baseline

Top N counts relate to the number of patients who have received each treatment in the specified study period. Patients allocated to Vehicle Control who are not completely healed at Week 8 are counted in the Vehicle Control group in the Controlled Treatment Period and their Uncontrolled Treatment group in the Follow-Up Period.

The data presented in this Table are contained in Listing 16.2.9.3c

Table 14.3.6.2c Summary of Ocular Tolerability as Measured by the VAS (mm) by Treatment and Visit  
(Safety Population)

Study Period: Controlled Treatment Period, Symptom: Itching

Visit		rhNGF 10 µg/ml (N=52)		rhNGF 20 µg/ml (N=52)		Vehicle Control (N=52)	
		Actual	CFB	Actual	CFB	Actual	CFB
Baseline	n	52		52		52	
	Mean (SD)	24.1 (27.48)		21.8 (28.68)		22.9 (28.43)	
	Median	10.0		5.5		10.0	
	Min, Max	0, 90		0, 100		0, 90	

CFB: Change from Baseline

Top N counts relate to the number of patients who have received each treatment in the specified study period. Patients allocated to Vehicle Control who are not completely healed at Week 8 are counted in the Vehicle Control group in the Controlled Treatment Period and their Uncontrolled Treatment group in the Follow-Up Period.

The data presented in this Table are contained in Listing 16.2.9.3c

Program path: \Dompe\rhNGF\NGF0212\Stat\programs\tables\rtvassm.sas

Executed: 11OCT2016, 05:16

Table 14.3.6.2c Summary of Ocular Tolerability as Measured by the VAS (mm) by Treatment and Visit  
(Safety Population)

Study Period: Controlled Treatment Period, Symptom: Ocular Pain

Visit		rhNGF 10 µg/ml (N=52)		rhNGF 20 µg/ml (N=52)		Vehicle Control (N=52)	
		Actual	CFB	Actual	CFB	Actual	CFB
Baseline	n	51		52		52	
	Mean (SD)	32.8 (34.86)		21.1 (28.38)		28.8 (32.82)	
	Median	20.0		7.5		15.0	
	Min, Max	0, 100		0, 100		0, 90	

CFB: Change from Baseline

Top N counts relate to the number of patients who have received each treatment in the specified study period. Patients allocated to Vehicle Control who are not completely healed at Week 8 are counted in the Vehicle Control group in the Controlled Treatment Period and their Uncontrolled Treatment group in the Follow-Up Period.

The data presented in this Table are contained in Listing 16.2.9.3c

Program path: \Dompe\rhNGF\NGF0212\Stat\programs\tables\rtvassm.sas

Executed: 11OCT2016, 05:16

Table 14.3.6.2c Summary of Ocular Tolerability as Measured by the VAS (mm) by Treatment and Visit  
(Safety Population)

Study Period: Controlled Treatment Period, Symptom: Sticky Feeling

Visit		rhNGF 10 µg/ml (N=52)		rhNGF 20 µg/ml (N=52)		Vehicle Control (N=52)	
		Actual	CFB	Actual	CFB	Actual	CFB
Baseline	n	52		52		52	
	Mean (SD)	26.6 (29.65)		17.4 (22.07)		26.1 (31.93)	
	Median	15.0		5.0		10.0	
	Min, Max	0, 100		0, 80		0, 100	

CFB: Change from Baseline

Top N counts relate to the number of patients who have received each treatment in the specified study period. Patients allocated to Vehicle Control who are not completely healed at Week 8 are counted in the Vehicle Control group in the Controlled Treatment Period and their Uncontrolled Treatment group in the Follow-Up Period.

The data presented in this Table are contained in Listing 16.2.9.3c

Program path: \Dompe\rhNGF\NGF0212\Stat\programs\tables\rtvassm.sas

Executed: 11OCT2016, 05:16

Table 14.3.6.2c Summary of Ocular Tolerability as Measured by the VAS (mm) by Treatment and Visit  
(Safety Population)

Study Period: Controlled Treatment Period, Symptom: Blurred Vision

Visit		rhNGF 10 µg/ml (N=52)		rhNGF 20 µg/ml (N=52)		Vehicle Control (N=52)	
		Actual	CFB	Actual	CFB	Actual	CFB
Baseline	n	52		52		52	
	Mean (SD)	80.2 (25.18)		83.2 (24.45)		78.5 (24.68)	
	Median	90.0		95.0		89.0	
	Min, Max	0, 100		0, 100		0, 100	

CFB: Change from Baseline

Top N counts relate to the number of patients who have received each treatment in the specified study period. Patients allocated to Vehicle Control who are not completely healed at Week 8 are counted in the Vehicle Control group in the Controlled Treatment Period and their Uncontrolled Treatment group in the Follow-Up Period.

The data presented in this Table are contained in Listing 16.2.9.3c

Program path: \Dompe\rhNGF\NGF0212\Stat\programs\tables\rtvassm.sas

Executed: 11OCT2016, 05:16

Table 14.3.6.2c Summary of Ocular Tolerability as Measured by the VAS (mm) by Treatment and Visit  
(Safety Population)

Study Period: Controlled Treatment Period, Symptom: Photophobia

Visit		rhNGF 10 µg/ml (N=52)		rhNGF 20 µg/ml (N=52)		Vehicle Control (N=52)	
		Actual	CFB	Actual	CFB	Actual	CFB
Baseline	n	52		52		52	
	Mean (SD)	64.3 (32.07)		57.6 (36.10)		65.2 (34.71)	
	Median	77.0		60.0		80.0	
	Min, Max	0, 100		0, 100		0, 100	

CFB: Change from Baseline

Top N counts relate to the number of patients who have received each treatment in the specified study period. Patients allocated to Vehicle Control who are not completely healed at Week 8 are counted in the Vehicle Control group in the Controlled Treatment Period and their Uncontrolled Treatment group in the Follow-Up Period.

The data presented in this Table are contained in Listing 16.2.9.3c

Program path: \Dompe\rhNGF\NGF0212\Stat\programs\tables\rtvassm.sas

Executed: 11OCT2016, 05:16

Table 14.3.6.2c Summary of Ocular Tolerability as Measured by the VAS (mm) by Treatment and Visit  
(Safety Population)

Study Period: Controlled Treatment Period, Symptom: Overall Ocular Tolerability VAS Score

Visit		rhNGF 10 µg/ml (N=52)		rhNGF 20 µg/ml (N=52)		Vehicle Control (N=52)	
		Actual	CFB	Actual	CFB	Actual	CFB
Baseline	n	52		52		52	
	Mean (SD)	42.1 (20.03)		37.6 (20.27)		41.3 (19.40)	
	Median	36.5		32.1		43.0	
	Min, Max	6, 86		4, 84		0, 75	

CFB: Change from Baseline

Top N counts relate to the number of patients who have received each treatment in the specified study period. Patients allocated to Vehicle Control who are not completely healed at Week 8 are counted in the Vehicle Control group in the Controlled Treatment Period and their Uncontrolled Treatment group in the Follow-Up Period.

The data presented in this Table are contained in Listing 16.2.9.3c

Program path: \Dompe\rhNGF\NGF0212\Stat\programs\tables\rtvassm.sas

Executed: 11OCT2016, 05:16



Table 14.3.6.2c Summary of Ocular Tolerability as Measured by the VAS (mm) by Treatment and Visit  
(Safety Population)

Study Period: Follow-Up Period (48/56 Weeks), Symptom: Foreign Body Sensation

Visit		rhNGF 10 µg/ml (N=62)		rhNGF 20 µg/ml (N=65)		Vehicle Control (N=29)	
		Actual	CFB	Actual	CFB	Actual	CFB
Week 12/20	n	51	51	49	49	23	23
	Mean (SD)	17.2 (20.76)	-16.6 (31.26)	17.8 (23.62)	-22.4 (38.77)	25.4 (27.05)	-20.7 (30.57)
	Median	10.0	-20.0	5.0	-6.0	19.0	-19.0
	Min, Max	0, 65	-80, 50	0, 100	-100, 60	0, 80	-80, 20
Week 20/28	n	49	49	49	49	22	22
	Mean (SD)	17.8 (21.12)	-16.4 (32.35)	17.6 (26.54)	-23.1 (34.06)	31.2 (30.25)	-17.0 (31.45)
	Median	10.0	-10.0	5.0	-6.0	25.0	-14.5
	Min, Max	0, 75	-80, 50	0, 100	-100, 50	0, 88	-80, 50
Week 32/40	n	42	42	45	45	22	22
	Mean (SD)	13.4 (19.67)	-21.0 (30.01)	25.4 (30.56)	-17.2 (40.89)	33.6 (33.34)	-14.5 (30.38)
	Median	5.0	-15.0	12.0	-20.0	25.0	-5.0
	Min, Max	0, 81	-80, 50	0, 100	-100, 100	0, 100	-70, 60
Week 44/52	n	40	40	46	46	22	22
	Mean (SD)	16.4 (21.57)	-16.7 (31.65)	23.6 (28.89)	-19.1 (35.47)	27.8 (28.60)	-20.4 (26.80)
	Median	5.0	-12.5	10.0	-5.0	15.0	-15.0
	Min, Max	0, 80	-85, 80	0, 100	-100, 80	0, 80	-80, 20

CFB: Change from Baseline

Top N counts relate to the number of patients who have received each treatment in the specified study period. Patients allocated to Vehicle Control who are not completely healed at Week 8 are counted in the Vehicle Control group in the Controlled Treatment Period and their Uncontrolled Treatment group in the Follow-Up Period.

Findings are categorised according to the last treatment received from the controlled or uncontrolled treatment periods.

The data presented in this Table are contained in Listing 16.2.9.3c

Table 14.3.6.2c Summary of Ocular Tolerability as Measured by the VAS (mm) by Treatment and Visit  
(Safety Population)

Study Period: Follow-Up Period (48/56 Weeks), Symptom: Foreign Body Sensation

Visit		rhNGF 10 µg/ml (N=62)		rhNGF 20 µg/ml (N=65)		Vehicle Control (N=29)	
		Actual	CFB	Actual	CFB	Actual	CFB
Week 56/64	n	39	39	42	42	22	22
	Mean (SD)	14.3 (20.43)	-20.3 (32.05)	20.5 (26.70)	-22.0 (35.89)	34.9 (33.49)	-13.3 (40.47)
	Median	5.0	-20.0	7.5	-15.0	25.0	-10.0
	Min, Max	0, 70	-85, 60	0, 90	-100, 70	0, 100	-70, 100
Early Exit	n	3	3	1	1	0	0
	Mean (SD)	1.7 (2.89)	-26.7 (23.09)	0.0 (-)	-30.0 (-)		
	Median	0.0	-40.0	0.0	-30.0		
	Min, Max	0, 5	-40, 0	0, 0	-30, -30		

CFB: Change from Baseline

Top N counts relate to the number of patients who have received each treatment in the specified study period. Patients allocated to Vehicle Control who are not completely healed at Week 8 are counted in the Vehicle Control group in the Controlled Treatment Period and their Uncontrolled Treatment group in the Follow-Up Period.

Findings are categorised according to the last treatment received from the controlled or uncontrolled treatment periods.

The data presented in this Table are contained in Listing 16.2.9.3c

Table 14.3.6.2c Summary of Ocular Tolerability as Measured by the VAS (mm) by Treatment and Visit  
(Safety Population)

Study Period: Follow-Up Period (48/56 Weeks), Symptom: Burning/Stinging

Visit		rhNGF 10 µg/ml (N=62)		rhNGF 20 µg/ml (N=65)		Vehicle Control (N=29)	
		Actual	CFB	Actual	CFB	Actual	CFB
Week 12/20	n	51	51	49	49	23	23
	Mean (SD)	19.3 (25.68)	-14.9 (40.35)	17.9 (26.14)	-10.8 (31.51)	17.3 (27.63)	-14.7 (37.54)
	Median	5.0	-10.0	7.0	0.0	0.0	-9.0
	Min, Max	0, 95	-100, 95	0, 90	-80, 80	0, 90	-80, 60
Week 20/28	n	49	49	49	49	22	22
	Mean (SD)	18.2 (24.31)	-16.2 (41.24)	17.4 (22.41)	-11.7 (27.74)	17.4 (26.21)	-16.0 (37.23)
	Median	10.0	-10.0	5.0	-5.0	3.0	-10.0
	Min, Max	0, 90	-100, 90	0, 85	-80, 50	0, 93	-80, 70
Week 32/40	n	42	42	45	45	22	22
	Mean (SD)	15.8 (24.29)	-17.1 (35.17)	21.9 (29.83)	-8.8 (34.79)	15.1 (22.78)	-18.3 (40.23)
	Median	5.0	-10.0	10.0	-1.0	7.0	-5.5
	Min, Max	0, 100	-100, 60	0, 99	-80, 89	0, 80	-80, 70
Week 44/52	n	40	40	46	46	22	22
	Mean (SD)	15.0 (18.43)	-17.2 (37.01)	15.9 (24.95)	-14.3 (30.11)	18.1 (20.85)	-15.3 (30.20)
	Median	8.0	-10.0	3.0	-5.0	10.0	-12.5
	Min, Max	0, 59	-100, 55	0, 85	-100, 80	0, 70	-70, 40

CFB: Change from Baseline

Top N counts relate to the number of patients who have received each treatment in the specified study period. Patients allocated to Vehicle Control who are not completely healed at Week 8 are counted in the Vehicle Control group in the Controlled Treatment Period and their Uncontrolled Treatment group in the Follow-Up Period.

Findings are categorised according to the last treatment received from the controlled or uncontrolled treatment periods.

The data presented in this Table are contained in Listing 16.2.9.3c

Table 14.3.6.2c Summary of Ocular Tolerability as Measured by the VAS (mm) by Treatment and Visit  
(Safety Population)

Study Period: Follow-Up Period (48/56 Weeks), Symptom: Burning/Stinging

Visit		rhNGF 10 µg/ml (N=62)		rhNGF 20 µg/ml (N=65)		Vehicle Control (N=29)	
		Actual	CFB	Actual	CFB	Actual	CFB
Week 56/64	n	39	39	42	42	22	22
	Mean (SD)	14.8 (22.32)	-20.8 (39.39)	16.4 (22.19)	-14.5 (27.65)	20.2 (27.96)	-13.2 (43.77)
	Median	0.0	-15.0	5.0	-5.0	9.0	-15.5
	Min, Max	0, 70	-100, 70	0, 80	-100, 50	0, 100	-80, 100
Early Exit	n	3	3	1	1	0	0
	Mean (SD)	7.0 (11.27)	-11.3 (20.50)	1.0 (-)	1.0 (-)		
	Median	1.0	0.0	1.0	1.0		
	Min, Max	0, 20	-35, 1	1, 1	1, 1		

CFB: Change from Baseline

Top N counts relate to the number of patients who have received each treatment in the specified study period. Patients allocated to Vehicle Control who are not completely healed at Week 8 are counted in the Vehicle Control group in the Controlled Treatment Period and their Uncontrolled Treatment group in the Follow-Up Period.

Findings are categorised according to the last treatment received from the controlled or uncontrolled treatment periods.

The data presented in this Table are contained in Listing 16.2.9.3c

Table 14.3.6.2c Summary of Ocular Tolerability as Measured by the VAS (mm) by Treatment and Visit  
(Safety Population)

Study Period: Follow-Up Period (48/56 Weeks), Symptom: Itching

Visit		rhNGF 10 µg/ml (N=62)		rhNGF 20 µg/ml (N=65)		Vehicle Control (N=29)	
		Actual	CFB	Actual	CFB	Actual	CFB
Week 12/20	n	51	51	49	49	23	23
	Mean (SD)	15.2 (17.72)	-10.2 (30.62)	9.7 (17.47)	-11.9 (23.05)	18.9 (22.05)	-4.8 (30.71)
	Median	5.0	-3.0	0.0	-1.0	10.0	0.0
	Min, Max	0, 80	-80, 80	0, 85	-90, 20	0, 70	-80, 50
Week 20/28	n	49	49	49	49	22	22
	Mean (SD)	15.7 (20.57)	-10.4 (33.53)	10.8 (20.54)	-10.3 (21.67)	19.6 (21.14)	-3.8 (32.52)
	Median	5.0	-2.0	0.0	-1.0	10.0	0.0
	Min, Max	0, 80	-85, 70	0, 86	-90, 20	0, 70	-80, 70
Week 32/40	n	42	42	45	45	22	22
	Mean (SD)	16.1 (17.61)	-7.0 (28.99)	14.8 (22.78)	-8.0 (29.36)	19.9 (20.40)	-3.5 (25.19)
	Median	10.0	-1.0	0.0	-2.0	12.5	0.0
	Min, Max	0, 51	-75, 50	0, 85	-85, 79	0, 60	-53, 35
Week 44/52	n	40	40	46	46	22	22
	Mean (SD)	18.0 (17.74)	-4.3 (28.73)	11.1 (22.06)	-11.4 (29.09)	17.0 (17.66)	-6.4 (22.42)
	Median	15.0	-1.0	0.0	-2.5	10.0	0.0
	Min, Max	0, 59	-70, 55	0, 85	-90, 50	0, 60	-53, 30

CFB: Change from Baseline

Top N counts relate to the number of patients who have received each treatment in the specified study period. Patients allocated to Vehicle Control who are not completely healed at Week 8 are counted in the Vehicle Control group in the Controlled Treatment Period and their Uncontrolled Treatment group in the Follow-Up Period.

Findings are categorised according to the last treatment received from the controlled or uncontrolled treatment periods.

The data presented in this Table are contained in Listing 16.2.9.3c

Table 14.3.6.2c Summary of Ocular Tolerability as Measured by the VAS (mm) by Treatment and Visit  
(Safety Population)

Study Period: Follow-Up Period (48/56 Weeks), Symptom: Itching

Visit		rhNGF 10 µg/ml (N=62)		rhNGF 20 µg/ml (N=65)		Vehicle Control (N=29)	
		Actual	CFB	Actual	CFB	Actual	CFB
Week 56/64	n	39	39	42	42	22	22
	Mean (SD)	13.7 (16.27)	-11.3 (27.16)	13.1 (22.64)	-8.7 (24.72)	27.2 (28.96)	3.8 (36.68)
	Median	10.0	-5.0	0.0	-1.5	15.0	0.0
	Min, Max	0, 50	-80, 40	0, 70	-90, 60	0, 100	-48, 100
Early Exit	n	3	3	1	1	0	0
	Mean (SD)	32.0 (49.39)	30.3 (50.82)	0.0 (-)	0.0 (-)		
	Median	5.0	2.0	0.0	0.0		
	Min, Max	2, 89	0, 89	0, 0	0, 0		

CFB: Change from Baseline

Top N counts relate to the number of patients who have received each treatment in the specified study period. Patients allocated to Vehicle Control who are not completely healed at Week 8 are counted in the Vehicle Control group in the Controlled Treatment Period and their Uncontrolled Treatment group in the Follow-Up Period.

Findings are categorised according to the last treatment received from the controlled or uncontrolled treatment periods.

The data presented in this Table are contained in Listing 16.2.9.3c

Table 14.3.6.2c Summary of Ocular Tolerability as Measured by the VAS (mm) by Treatment and Visit  
(Safety Population)

Study Period: Follow-Up Period (48/56 Weeks), Symptom: Ocular Pain

Visit		rhNGF 10 µg/ml (N=62)		rhNGF 20 µg/ml (N=65)		Vehicle Control (N=29)	
		Actual	CFB	Actual	CFB	Actual	CFB
Week 12/20	n	51	50	49	49	23	23
	Mean (SD)	16.0 (22.85)	-16.7 (34.66)	11.0 (19.38)	-12.1 (31.25)	17.4 (25.99)	-18.3 (34.30)
	Median	5.0	-8.5	0.0	-1.0	5.0	-14.0
	Min, Max	0, 90	-100, 90	0, 95	-90, 65	0, 76	-90, 50
Week 20/28	n	49	48	49	49	22	22
	Mean (SD)	13.6 (23.35)	-19.1 (35.62)	11.1 (20.18)	-12.2 (27.68)	16.6 (22.71)	-20.7 (30.36)
	Median	3.0	-13.0	0.0	-1.0	7.5	-15.0
	Min, Max	0, 90	-100, 82	0, 72	-100, 35	0, 88	-90, 30
Week 32/40	n	42	42	45	45	22	22
	Mean (SD)	12.0 (22.99)	-21.5 (37.33)	12.9 (22.71)	-12.4 (26.09)	19.0 (23.96)	-18.3 (31.67)
	Median	1.5	-15.0	0.0	-1.0	9.5	-7.5
	Min, Max	0, 100	-100, 70	0, 80	-90, 40	0, 85	-80, 35
Week 44/52	n	40	40	46	46	22	22
	Mean (SD)	13.1 (23.44)	-19.8 (34.16)	13.8 (21.53)	-10.5 (26.13)	17.6 (24.68)	-19.7 (27.18)
	Median	2.0	-14.5	5.0	-1.0	10.0	-12.5
	Min, Max	0, 100	-100, 71	0, 80	-85, 39	0, 100	-80, 20

CFB: Change from Baseline

Top N counts relate to the number of patients who have received each treatment in the specified study period. Patients allocated to Vehicle Control who are not completely healed at Week 8 are counted in the Vehicle Control group in the Controlled Treatment Period and their Uncontrolled Treatment group in the Follow-Up Period.

Findings are categorised according to the last treatment received from the controlled or uncontrolled treatment periods.

The data presented in this Table are contained in Listing 16.2.9.3c

Table 14.3.6.2c Summary of Ocular Tolerability as Measured by the VAS (mm) by Treatment and Visit  
(Safety Population)

Study Period: Follow-Up Period (48/56 Weeks), Symptom: Ocular Pain

Visit		rhNGF 10 µg/ml (N=62)		rhNGF 20 µg/ml (N=65)		Vehicle Control (N=29)	
		Actual	CFB	Actual	CFB	Actual	CFB
Week 56/64	n	39	39	42	42	22	22
	Mean (SD)	15.4 (27.14)	-17.0 (35.63)	16.0 (26.06)	-7.1 (26.26)	21.1 (33.61)	-16.2 (46.24)
	Median	0.0	-10.0	5.0	0.0	5.0	-12.5
	Min, Max	0, 100	-100, 80	0, 100	-80, 49	0, 100	-90, 100
Early Exit	n	3	3	1	1	0	0
	Mean (SD)	5.7 (8.14)	4.0 (10.15)	0.0 (-)	-25.0 (-)		
	Median	2.0	2.0	0.0	-25.0		
	Min, Max	0, 15	-5, 15	0, 0	-25, -25		

CFB: Change from Baseline

Top N counts relate to the number of patients who have received each treatment in the specified study period. Patients allocated to Vehicle Control who are not completely healed at Week 8 are counted in the Vehicle Control group in the Controlled Treatment Period and their Uncontrolled Treatment group in the Follow-Up Period.

Findings are categorised according to the last treatment received from the controlled or uncontrolled treatment periods.

The data presented in this Table are contained in Listing 16.2.9.3c



Table 14.3.6.2c Summary of Ocular Tolerability as Measured by the VAS (mm) by Treatment and Visit  
(Safety Population)

Study Period: Follow-Up Period (48/56 Weeks), Symptom: Sticky Feeling

Visit		rhNGF 10 µg/ml (N=62)		rhNGF 20 µg/ml (N=65)		Vehicle Control (N=29)	
		Actual	CFB	Actual	CFB	Actual	CFB
Week 12/20	n	51	51	49	49	23	23
	Mean (SD)	17.2 (22.41)	-13.3 (30.75)	12.2 (22.16)	-11.4 (31.11)	16.7 (20.87)	-8.3 (30.62)
	Median	10.0	-10.0	0.0	0.0	5.0	-10.0
	Min, Max	0, 80	-100, 80	0, 90	-100, 55	0, 60	-65, 60
Week 20/28	n	49	49	49	49	22	22
	Mean (SD)	14.2 (21.19)	-16.6 (30.63)	13.5 (24.12)	-10.4 (30.67)	20.0 (23.40)	-6.1 (34.12)
	Median	2.0	-10.0	0.0	0.0	9.5	0.0
	Min, Max	0, 70	-85, 60	0, 90	-100, 60	0, 70	-70, 60
Week 32/40	n	42	42	45	45	22	22
	Mean (SD)	15.2 (21.13)	-17.0 (25.88)	19.4 (29.55)	-6.4 (35.39)	17.8 (22.66)	-8.3 (32.91)
	Median	9.0	-10.0	1.0	0.0	8.5	0.0
	Min, Max	0, 95	-90, 25	0, 100	-100, 80	0, 70	-80, 50
Week 44/52	n	40	40	46	46	22	22
	Mean (SD)	13.6 (19.45)	-18.1 (30.09)	17.3 (26.88)	-8.1 (33.44)	24.7 (27.59)	-1.5 (31.73)
	Median	5.5	-15.0	7.0	0.0	10.5	0.0
	Min, Max	0, 80	-85, 80	0, 100	-100, 80	0, 90	-65, 65

CFB: Change from Baseline

Top N counts relate to the number of patients who have received each treatment in the specified study period. Patients allocated to Vehicle Control who are not completely healed at Week 8 are counted in the Vehicle Control group in the Controlled Treatment Period and their Uncontrolled Treatment group in the Follow-Up Period.

Findings are categorised according to the last treatment received from the controlled or uncontrolled treatment periods.

The data presented in this Table are contained in Listing 16.2.9.3c

Table 14.3.6.2c Summary of Ocular Tolerability as Measured by the VAS (mm) by Treatment and Visit  
(Safety Population)

Study Period: Follow-Up Period (48/56 Weeks), Symptom: Sticky Feeling

Visit		rhNGF 10 µg/ml (N=62)		rhNGF 20 µg/ml (N=65)		Vehicle Control (N=29)	
		Actual	CFB	Actual	CFB	Actual	CFB
Week 56/64	n	39	39	42	42	22	22
	Mean (SD)	14.7 (20.57)	-17.9 (25.19)	16.7 (24.86)	-9.5 (33.19)	22.1 (29.04)	-4.0 (34.30)
	Median	8.0	-10.0	5.0	0.0	7.5	-2.5
	Min, Max	0, 75	-90, 21	0, 100	-100, 58	0, 90	-70, 70
Early Exit	n	3	3	1	1	0	0
	Mean (SD)	9.7 (8.96)	3.0 (18.08)	0.0 (-)	0.0 (-)		
	Median	5.0	5.0	0.0	0.0		
	Min, Max	4, 20	-16, 20	0, 0	0, 0		

CFB: Change from Baseline

Top N counts relate to the number of patients who have received each treatment in the specified study period. Patients allocated to Vehicle Control who are not completely healed at Week 8 are counted in the Vehicle Control group in the Controlled Treatment Period and their Uncontrolled Treatment group in the Follow-Up Period.

Findings are categorised according to the last treatment received from the controlled or uncontrolled treatment periods.

The data presented in this Table are contained in Listing 16.2.9.3c

Table 14.3.6.2c Summary of Ocular Tolerability as Measured by the VAS (mm) by Treatment and Visit  
(Safety Population)

Study Period: Follow-Up Period (48/56 Weeks), Symptom: Blurred Vision

Visit		rhNGF 10 µg/ml (N=62)		rhNGF 20 µg/ml (N=65)		Vehicle Control (N=29)	
		Actual	CFB	Actual	CFB	Actual	CFB
Week 12/20	n	51	51	49	49	23	23
	Mean (SD)	62.6 (34.06)	-16.5 (38.43)	58.7 (34.61)	-25.7 (34.41)	60.9 (33.93)	-17.4 (27.14)
	Median	70.0	-15.0	70.0	-20.0	70.0	-10.0
	Min, Max	1, 100	-85, 100	0, 100	-100, 35	0, 100	-70, 40
Week 20/28	n	49	49	49	49	22	22
	Mean (SD)	58.4 (33.78)	-22.2 (34.87)	54.3 (34.59)	-30.9 (34.63)	58.7 (33.21)	-20.5 (32.78)
	Median	60.0	-25.0	55.0	-20.0	65.0	-7.5
	Min, Max	0, 100	-90, 60	0, 100	-100, 28	0, 100	-100, 30
Week 32/40	n	42	42	45	45	22	22
	Mean (SD)	51.1 (37.30)	-31.0 (36.60)	59.0 (31.55)	-25.9 (30.55)	61.8 (34.88)	-17.4 (32.30)
	Median	50.0	-27.5	55.0	-20.0	62.5	-7.5
	Min, Max	0, 100	-100, 60	0, 100	-95, 40	0, 100	-91, 39
Week 44/52	n	40	40	46	46	22	22
	Mean (SD)	49.1 (35.27)	-33.2 (33.43)	62.5 (35.02)	-22.4 (33.78)	58.9 (29.88)	-20.3 (30.38)
	Median	50.0	-30.5	70.0	-15.5	60.0	-22.5
	Min, Max	0, 100	-100, 30	0, 100	-100, 40	0, 100	-70, 40

CFB: Change from Baseline

Top N counts relate to the number of patients who have received each treatment in the specified study period. Patients allocated to Vehicle Control who are not completely healed at Week 8 are counted in the Vehicle Control group in the Controlled Treatment Period and their Uncontrolled Treatment group in the Follow-Up Period.

Findings are categorised according to the last treatment received from the controlled or uncontrolled treatment periods.

The data presented in this Table are contained in Listing 16.2.9.3c

Table 14.3.6.2c Summary of Ocular Tolerability as Measured by the VAS (mm) by Treatment and Visit  
(Safety Population)

Study Period: Follow-Up Period (48/56 Weeks), Symptom: Blurred Vision

Visit		rhNGF 10 µg/ml (N=62)		rhNGF 20 µg/ml (N=65)		Vehicle Control (N=29)	
		Actual	CFB	Actual	CFB	Actual	CFB
Week 56/64	n	39	39	42	42	22	22
	Mean (SD)	48.9 (37.74)	-32.5 (33.99)	57.5 (32.63)	-27.5 (32.05)	61.8 (34.82)	-17.4 (33.84)
	Median	50.0	-30.0	60.0	-21.0	67.0	-12.5
	Min, Max	0, 100	-100, 22	0, 100	-100, 40	0, 100	-80, 45
Early Exit	n	3	3	1	1	0	0
	Mean (SD)	60.7 (45.54)	-16.0 (67.01)	100.0 (-)	0.0 (-)		
	Median	78.0	5.0	100.0	0.0		
	Min, Max	9, 95	-91, 38	100, 100	0, 0		

CFB: Change from Baseline

Top N counts relate to the number of patients who have received each treatment in the specified study period. Patients allocated to Vehicle Control who are not completely healed at Week 8 are counted in the Vehicle Control group in the Controlled Treatment Period and their Uncontrolled Treatment group in the Follow-Up Period.

Findings are categorised according to the last treatment received from the controlled or uncontrolled treatment periods.

The data presented in this Table are contained in Listing 16.2.9.3c

Table 14.3.6.2c Summary of Ocular Tolerability as Measured by the VAS (mm) by Treatment and Visit  
(Safety Population)

Study Period: Follow-Up Period (48/56 Weeks), Symptom: Photophobia

Visit		rhNGF 10 µg/ml (N=62)		rhNGF 20 µg/ml (N=65)		Vehicle Control (N=29)	
		Actual	CFB	Actual	CFB	Actual	CFB
Week 12/20	n	51	51	49	49	23	23
	Mean (SD)	36.6 (35.48)	-24.2 (37.51)	39.6 (33.48)	-21.0 (38.76)	55.7 (28.92)	-14.6 (29.19)
	Median	30.0	-15.0	35.0	-10.0	50.0	-10.0
	Min, Max	0, 100	-100, 87	0, 100	-100, 80	0, 100	-80, 50
Week 20/28	n	49	49	49	49	22	22
	Mean (SD)	39.3 (34.12)	-22.3 (35.12)	34.5 (32.25)	-27.3 (38.33)	57.7 (31.82)	-11.7 (24.21)
	Median	35.0	-15.0	30.0	-20.0	60.0	-10.5
	Min, Max	0, 100	-100, 80	0, 100	-100, 71	0, 100	-70, 50
Week 32/40	n	42	42	45	45	22	22
	Mean (SD)	34.4 (31.89)	-28.5 (35.58)	35.3 (32.31)	-27.7 (40.46)	57.3 (36.15)	-12.1 (28.12)
	Median	30.0	-20.0	30.0	-22.0	65.0	-4.5
	Min, Max	0, 100	-100, 50	0, 100	-100, 71	0, 100	-85, 30
Week 44/52	n	40	40	46	46	22	22
	Mean (SD)	30.2 (32.60)	-33.7 (33.06)	37.3 (36.38)	-24.7 (43.34)	50.7 (33.68)	-18.7 (32.00)
	Median	20.0	-29.0	35.0	-20.0	52.5	-17.5
	Min, Max	0, 100	-100, 22	0, 100	-100, 80	0, 100	-95, 50

CFB: Change from Baseline

Top N counts relate to the number of patients who have received each treatment in the specified study period. Patients allocated to Vehicle Control who are not completely healed at Week 8 are counted in the Vehicle Control group in the Controlled Treatment Period and their Uncontrolled Treatment group in the Follow-Up Period.

Findings are categorised according to the last treatment received from the controlled or uncontrolled treatment periods.

The data presented in this Table are contained in Listing 16.2.9.3c

Table 14.3.6.2c Summary of Ocular Tolerability as Measured by the VAS (mm) by Treatment and Visit  
(Safety Population)

Study Period: Follow-Up Period (48/56 Weeks), Symptom: Photophobia

Visit		rhNGF 10 µg/ml (N=62)		rhNGF 20 µg/ml (N=65)		Vehicle Control (N=29)	
		Actual	CFB	Actual	CFB	Actual	CFB
Week 56/64	n	39	39	42	42	22	22
	Mean (SD)	29.1 (31.35)	-35.4 (32.72)	43.4 (35.29)	-17.1 (37.86)	47.5 (36.62)	-22.0 (31.95)
	Median	15.0	-33.0	47.5	-15.0	47.5	-17.5
	Min, Max	0, 100	-100, 12	0, 100	-100, 65	0, 100	-95, 25
Early Exit	n	3	3	1	1	0	0
	Mean (SD)	1.3 (2.31)	-2.0 (7.21)	0.0 (-)	-90.0 (-)		
	Median	0.0	0.0	0.0	-90.0		
	Min, Max	0, 4	-10, 4	0, 0	-90, -90		

CFB: Change from Baseline

Top N counts relate to the number of patients who have received each treatment in the specified study period. Patients allocated to Vehicle Control who are not completely healed at Week 8 are counted in the Vehicle Control group in the Controlled Treatment Period and their Uncontrolled Treatment group in the Follow-Up Period.

Findings are categorised according to the last treatment received from the controlled or uncontrolled treatment periods.

The data presented in this Table are contained in Listing 16.2.9.3c

Table 14.3.6.2c Summary of Ocular Tolerability as Measured by the VAS (mm) by Treatment and Visit  
(Safety Population)

Study Period: Follow-Up Period (48/56 Weeks), Symptom: Overall Ocular Tolerability VAS Score

Visit		rhNGF 10 µg/ml (N=62)		rhNGF 20 µg/ml (N=65)		Vehicle Control (N=29)	
		Actual	CFB	Actual	CFB	Actual	CFB
Week 12/20	n	51	51	49	49	23	23
	Mean (SD)	26.3 (16.90)	-16.0 (22.37)	23.9 (16.12)	-16.5 (21.06)	30.3 (16.28)	-14.1 (20.70)
	Median	22.9	-17.3	21.7	-16.9	31.4	-15.0
	Min, Max	0, 62	-64, 45	0, 71	-56, 41	1, 70	-65, 17
Week 20/28	n	49	49	49	49	22	22
	Mean (SD)	25.3 (16.81)	-17.6 (22.83)	22.7 (17.25)	-18.0 (18.09)	31.6 (18.44)	-13.7 (21.20)
	Median	22.3	-19.3	18.6	-17.0	27.5	-17.1
	Min, Max	1, 64	-74, 39	0, 67	-57, 25	10, 74	-52, 30
Week 32/40	n	42	42	45	45	22	22
	Mean (SD)	22.6 (16.61)	-20.4 (22.88)	27.0 (19.71)	-15.2 (20.72)	32.1 (19.25)	-13.2 (20.75)
	Median	17.1	-17.1	21.6	-16.9	27.9	-15.4
	Min, Max	1, 84	-68, 29	0, 84	-54, 54	11, 76	-52, 34
Week 44/52	n	40	40	46	46	22	22
	Mean (SD)	22.2 (14.81)	-20.4 (20.48)	25.9 (18.91)	-15.8 (18.85)	30.7 (17.24)	-14.6 (18.11)
	Median	22.9	-19.6	20.0	-15.3	29.3	-14.6
	Min, Max	0, 55	-67, 26	1, 74	-68, 24	3, 77	-50, 13

CFB: Change from Baseline

Top N counts relate to the number of patients who have received each treatment in the specified study period. Patients allocated to Vehicle Control who are not completely healed at Week 8 are counted in the Vehicle Control group in the Controlled Treatment Period and their Uncontrolled Treatment group in the Follow-Up Period.

Findings are categorised according to the last treatment received from the controlled or uncontrolled treatment periods.

The data presented in this Table are contained in Listing 16.2.9.3c

Table 14.3.6.2c Summary of Ocular Tolerability as Measured by the VAS (mm) by Treatment and Visit  
(Safety Population)

Study Period: Follow-Up Period (48/56 Weeks), Symptom: Overall Ocular Tolerability VAS Score

Visit		rhNGF 10 µg/ml (N=62)		rhNGF 20 µg/ml (N=65)		Vehicle Control (N=29)	
		Actual	CFB	Actual	CFB	Actual	CFB
Week 56/64	n	39	39	42	42	22	22
	Mean (SD)	21.6 (18.55)	-22.2 (22.88)	26.2 (18.92)	-15.2 (19.06)	33.5 (24.49)	-11.8 (28.10)
	Median	17.1	-22.9	20.5	-13.4	23.1	-12.9
	Min, Max	0, 66	-71, 37	0, 71	-81, 31	6, 89	-50, 60
Early Exit	n	3	3	1	1	0	0
	Mean (SD)	16.9 (1.65)	-2.7 (10.86)	14.4 (-)	-20.6 (-)		
	Median	16.7	-6.4	14.4	-20.6		
	Min, Max	15, 19	-11, 10	14, 14	-21, -21		

CFB: Change from Baseline

Top N counts relate to the number of patients who have received each treatment in the specified study period. Patients allocated to Vehicle Control who are not completely healed at Week 8 are counted in the Vehicle Control group in the Controlled Treatment Period and their Uncontrolled Treatment group in the Follow-Up Period.

Findings are categorised according to the last treatment received from the controlled or uncontrolled treatment periods.

The data presented in this Table are contained in Listing 16.2.9.3c



Table 14.3.6.2c Summary of Ocular Tolerability as Measured by the VAS (mm) by Treatment and Visit  
(Safety Population)

Study Period: Follow-Up Period (48 Weeks), Symptom: Foreign Body Sensation

Visit		rhNGF 10 µg/ml (N=52)		rhNGF 20 µg/ml (N=52)		Vehicle Control (N=29)	
		Actual	CFB	Actual	CFB	Actual	CFB
Week 12	n	43	43	36	36	23	23
	Mean (SD)	18.6 (21.23)	-17.9 (31.06)	21.6 (25.52)	-21.0 (38.33)	25.4 (27.05)	-20.7 (30.57)
	Median	10.0	-20.0	10.0	-10.0	19.0	-19.0
	Min, Max	0, 65	-75, 50	0, 100	-100, 60	0, 80	-80, 20
Week 20	n	42	42	37	37	22	22
	Mean (SD)	19.4 (22.21)	-16.8 (33.10)	21.1 (29.00)	-20.8 (33.17)	31.2 (30.25)	-17.0 (31.45)
	Median	12.5	-10.0	10.0	-15.0	25.0	-14.5
	Min, Max	0, 75	-80, 50	0, 100	-100, 50	0, 88	-80, 50
Week 32	n	36	36	35	35	22	22
	Mean (SD)	13.5 (20.42)	-24.5 (30.63)	29.4 (32.86)	-12.7 (41.90)	33.6 (33.34)	-14.5 (30.38)
	Median	5.0	-20.0	20.0	-20.0	25.0	-5.0
	Min, Max	0, 81	-80, 50	0, 100	-100, 100	0, 100	-70, 60
Week 44	n	34	34	36	36	22	22
	Mean (SD)	17.6 (22.77)	-19.0 (33.56)	25.1 (29.94)	-17.3 (36.05)	27.8 (28.60)	-20.4 (26.80)
	Median	5.0	-17.5	10.0	-5.0	15.0	-15.0
	Min, Max	0, 80	-85, 80	0, 100	-100, 80	0, 80	-80, 20

CFB: Change from Baseline

Top N counts relate to the number of patients who have received each treatment in the specified study period. Patients allocated to Vehicle Control who are not completely healed at Week 8 are counted in the Vehicle Control group in the Controlled Treatment Period and their Uncontrolled Treatment group in the Follow-Up Period.

Findings are categorised according to the last treatment received from the controlled or uncontrolled treatment periods.

The data presented in this Table are contained in Listing 16.2.9.3c

Table 14.3.6.2c Summary of Ocular Tolerability as Measured by the VAS (mm) by Treatment and Visit  
(Safety Population)

Study Period: Follow-Up Period (48 Weeks), Symptom: Foreign Body Sensation

Visit		rhNGF 10 µg/ml (N=52)		rhNGF 20 µg/ml (N=52)		Vehicle Control (N=29)	
		Actual	CFB	Actual	CFB	Actual	CFB
Week 56	n	32	32	33	33	22	22
	Mean (SD)	13.9 (21.09)	-23.4 (29.86)	22.6 (29.17)	-18.1 (36.17)	34.9 (33.49)	-13.3 (40.47)
	Median	5.0	-20.0	5.0	-10.0	25.0	-10.0
	Min, Max	0, 70	-85, 60	0, 90	-100, 70	0, 100	-70, 100
Early Exit	n	3	3	1	1	0	0
	Mean (SD)	1.7 (2.89)	-26.7 (23.09)	0.0 (-)	-30.0 (-)		
	Median	0.0	-40.0	0.0	-30.0		
	Min, Max	0, 5	-40, 0	0, 0	-30, -30		

CFB: Change from Baseline

Top N counts relate to the number of patients who have received each treatment in the specified study period. Patients allocated to Vehicle Control who are not completely healed at Week 8 are counted in the Vehicle Control group in the Controlled Treatment Period and their Uncontrolled Treatment group in the Follow-Up Period.

Findings are categorised according to the last treatment received from the controlled or uncontrolled treatment periods.

The data presented in this Table are contained in Listing 16.2.9.3c

Table 14.3.6.2c Summary of Ocular Tolerability as Measured by the VAS (mm) by Treatment and Visit  
(Safety Population)

Study Period: Follow-Up Period (48 Weeks), Symptom: Burning/Stinging

Visit		rhNGF 10 µg/ml (N=52)		rhNGF 20 µg/ml (N=52)		Vehicle Control (N=29)	
		Actual	CFB	Actual	CFB	Actual	CFB
Week 12	n	43	43	36	36	23	23
	Mean (SD)	21.0 (27.29)	-14.6 (41.65)	19.4 (25.19)	-9.1 (32.52)	17.3 (27.63)	-14.7 (37.54)
	Median	5.0	-10.0	10.0	0.0	0.0	-9.0
	Min, Max	0, 95	-100, 95	0, 90	-80, 80	0, 90	-80, 60
Week 20	n	42	42	37	37	22	22
	Mean (SD)	20.1 (25.56)	-15.2 (42.53)	16.9 (20.15)	-11.3 (26.06)	17.4 (26.21)	-16.0 (37.23)
	Median	10.0	-10.0	5.0	-5.0	3.0	-10.0
	Min, Max	0, 90	-100, 90	0, 65	-70, 42	0, 93	-80, 70
Week 32	n	36	36	35	35	22	22
	Mean (SD)	16.1 (25.87)	-19.4 (36.77)	22.1 (29.16)	-7.5 (35.42)	15.1 (22.78)	-18.3 (40.23)
	Median	5.0	-10.0	10.0	0.0	7.0	-5.5
	Min, Max	0, 100	-100, 60	0, 99	-80, 89	0, 80	-80, 70
Week 44	n	34	34	36	36	22	22
	Mean (SD)	13.4 (17.03)	-21.5 (36.45)	16.7 (24.70)	-12.3 (28.02)	18.1 (20.85)	-15.3 (30.20)
	Median	5.5	-17.5	9.0	-10.0	10.0	-12.5
	Min, Max	0, 55	-100, 50	0, 80	-100, 80	0, 70	-70, 40

CFB: Change from Baseline

Top N counts relate to the number of patients who have received each treatment in the specified study period. Patients allocated to Vehicle Control who are not completely healed at Week 8 are counted in the Vehicle Control group in the Controlled Treatment Period and their Uncontrolled Treatment group in the Follow-Up Period.

Findings are categorised according to the last treatment received from the controlled or uncontrolled treatment periods.

The data presented in this Table are contained in Listing 16.2.9.3c

Table 14.3.6.2c Summary of Ocular Tolerability as Measured by the VAS (mm) by Treatment and Visit  
(Safety Population)

Study Period: Follow-Up Period (48 Weeks), Symptom: Burning/Stinging

Visit		rhNGF 10 µg/ml (N=52)		rhNGF 20 µg/ml (N=52)		Vehicle Control (N=29)	
		Actual	CFB	Actual	CFB	Actual	CFB
Week 56	n	32	32	33	33	22	22
	Mean (SD)	13.6 (22.82)	-23.4 (39.64)	16.2 (22.17)	-15.2 (26.56)	20.2 (27.96)	-13.2 (43.77)
	Median	0.0	-15.0	5.0	-6.0	9.0	-15.5
	Min, Max	0, 70	-100, 70	0, 80	-100, 34	0, 100	-80, 100
Early Exit	n	3	3	1	1	0	0
	Mean (SD)	7.0 (11.27)	-11.3 (20.50)	1.0 (-)	1.0 (-)		
	Median	1.0	0.0	1.0	1.0		
	Min, Max	0, 20	-35, 1	1, 1	1, 1		

CFB: Change from Baseline

Top N counts relate to the number of patients who have received each treatment in the specified study period. Patients allocated to Vehicle Control who are not completely healed at Week 8 are counted in the Vehicle Control group in the Controlled Treatment Period and their Uncontrolled Treatment group in the Follow-Up Period.

Findings are categorised according to the last treatment received from the controlled or uncontrolled treatment periods.

The data presented in this Table are contained in Listing 16.2.9.3c

Table 14.3.6.2c Summary of Ocular Tolerability as Measured by the VAS (mm) by Treatment and Visit  
(Safety Population)

Study Period: Follow-Up Period (48 Weeks), Symptom: Itching

Visit		rhNGF 10 µg/ml (N=52)		rhNGF 20 µg/ml (N=52)		Vehicle Control (N=29)	
		Actual	CFB	Actual	CFB	Actual	CFB
Week 12	n	43	43	36	36	23	23
	Mean (SD)	15.5 (18.38)	-11.1 (30.16)	10.5 (15.11)	-12.8 (23.51)	18.9 (22.05)	-4.8 (30.71)
	Median	5.0	-5.0	0.5	-2.5	10.0	0.0
	Min, Max	0, 80	-65, 80	0, 50	-90, 20	0, 70	-80, 50
Week 20	n	42	42	37	37	22	22
	Mean (SD)	15.8 (20.71)	-11.1 (33.22)	11.3 (19.55)	-10.7 (21.44)	19.6 (21.14)	-3.8 (32.52)
	Median	7.5	-1.0	0.0	-2.0	10.0	0.0
	Min, Max	0, 80	-85, 70	0, 86	-90, 20	0, 70	-80, 70
Week 32	n	36	36	35	35	22	22
	Mean (SD)	15.1 (17.71)	-9.9 (29.06)	15.2 (21.93)	-7.9 (29.68)	19.9 (20.40)	-3.5 (25.19)
	Median	7.5	-3.5	0.0	-5.0	12.5	0.0
	Min, Max	0, 51	-75, 50	0, 79	-80, 79	0, 60	-53, 35
Week 44	n	34	34	36	36	22	22
	Mean (SD)	15.6 (16.25)	-8.6 (26.93)	11.4 (21.07)	-11.2 (29.69)	17.0 (17.66)	-6.4 (22.42)
	Median	12.5	-5.0	0.0	-4.0	10.0	0.0
	Min, Max	0, 50	-70, 50	0, 80	-90, 50	0, 60	-53, 30

CFB: Change from Baseline

Top N counts relate to the number of patients who have received each treatment in the specified study period. Patients allocated to Vehicle Control who are not completely healed at Week 8 are counted in the Vehicle Control group in the Controlled Treatment Period and their Uncontrolled Treatment group in the Follow-Up Period.

Findings are categorised according to the last treatment received from the controlled or uncontrolled treatment periods.

The data presented in this Table are contained in Listing 16.2.9.3c

Table 14.3.6.2c Summary of Ocular Tolerability as Measured by the VAS (mm) by Treatment and Visit  
(Safety Population)

Study Period: Follow-Up Period (48 Weeks), Symptom: Itching

Visit		rhNGF 10 µg/ml (N=52)		rhNGF 20 µg/ml (N=52)		Vehicle Control (N=29)	
		Actual	CFB	Actual	CFB	Actual	CFB
Week 56	n	32	32	33	33	22	22
	Mean (SD)	13.9 (16.77)	-11.8 (24.95)	14.4 (23.49)	-9.3 (27.34)	27.2 (28.96)	3.8 (36.68)
	Median	7.5	-5.0	0.0	0.0	15.0	0.0
	Min, Max	0, 50	-80, 40	0, 70	-90, 60	0, 100	-48, 100
Early Exit	n	3	3	1	1	0	0
	Mean (SD)	32.0 (49.39)	30.3 (50.82)	0.0 (-)	0.0 (-)		
	Median	5.0	2.0	0.0	0.0		
	Min, Max	2, 89	0, 89	0, 0	0, 0		

CFB: Change from Baseline

Top N counts relate to the number of patients who have received each treatment in the specified study period. Patients allocated to Vehicle Control who are not completely healed at Week 8 are counted in the Vehicle Control group in the Controlled Treatment Period and their Uncontrolled Treatment group in the Follow-Up Period.

Findings are categorised according to the last treatment received from the controlled or uncontrolled treatment periods.

The data presented in this Table are contained in Listing 16.2.9.3c

Table 14.3.6.2c Summary of Ocular Tolerability as Measured by the VAS (mm) by Treatment and Visit  
(Safety Population)

Study Period: Follow-Up Period (48 Weeks), Symptom: Ocular Pain

Visit		rhNGF 10 µg/ml (N=52)		rhNGF 20 µg/ml (N=52)		Vehicle Control (N=29)	
		Actual	CFB	Actual	CFB	Actual	CFB
Week 12	n	43	42	36	36	23	23
	Mean (SD)	17.0 (23.90)	-18.9 (36.75)	12.0 (19.49)	-13.1 (33.91)	17.4 (25.99)	-18.3 (34.30)
	Median	5.0	-15.0	0.0	-1.0	5.0	-14.0
	Min, Max	0, 90	-100, 90	0, 95	-90, 65	0, 76	-90, 50
Week 20	n	42	41	37	37	22	22
	Mean (SD)	15.1 (24.87)	-20.1 (37.72)	12.2 (20.41)	-12.6 (29.27)	16.6 (22.71)	-20.7 (30.36)
	Median	2.5	-14.0	0.0	-1.0	7.5	-15.0
	Min, Max	0, 90	-100, 82	0, 72	-100, 35	0, 88	-90, 30
Week 32	n	36	36	35	35	22	22
	Mean (SD)	12.4 (24.43)	-23.3 (39.66)	13.9 (22.80)	-12.2 (26.83)	19.0 (23.96)	-18.3 (31.67)
	Median	0.0	-17.5	0.0	-1.0	9.5	-7.5
	Min, Max	0, 100	-100, 70	0, 80	-90, 40	0, 85	-80, 35
Week 44	n	34	34	36	36	22	22
	Mean (SD)	12.6 (23.60)	-22.4 (35.82)	13.6 (21.47)	-11.2 (25.85)	17.6 (24.68)	-19.7 (27.18)
	Median	1.5	-15.0	5.0	-1.5	10.0	-12.5
	Min, Max	0, 100	-100, 71	0, 80	-85, 30	0, 100	-80, 20

CFB: Change from Baseline

Top N counts relate to the number of patients who have received each treatment in the specified study period. Patients allocated to Vehicle Control who are not completely healed at Week 8 are counted in the Vehicle Control group in the Controlled Treatment Period and their Uncontrolled Treatment group in the Follow-Up Period.

Findings are categorised according to the last treatment received from the controlled or uncontrolled treatment periods.

The data presented in this Table are contained in Listing 16.2.9.3c

Table 14.3.6.2c Summary of Ocular Tolerability as Measured by the VAS (mm) by Treatment and Visit  
(Safety Population)

Study Period: Follow-Up Period (48 Weeks), Symptom: Ocular Pain

Visit		rhNGF 10 µg/ml (N=52)		rhNGF 20 µg/ml (N=52)		Vehicle Control (N=29)	
		Actual	CFB	Actual	CFB	Actual	CFB
Week 56	n	32	32	33	33	22	22
	Mean (SD)	14.8 (27.78)	-20.8 (36.96)	14.9 (26.10)	-7.6 (25.37)	21.1 (33.61)	-16.2 (46.24)
	Median	0.0	-12.5	0.0	0.0	5.0	-12.5
	Min, Max	0, 100	-100, 80	0, 100	-80, 40	0, 100	-90, 100
Early Exit	n	3	3	1	1	0	0
	Mean (SD)	5.7 (8.14)	4.0 (10.15)	0.0 (-)	-25.0 (-)		
	Median	2.0	2.0	0.0	-25.0		
	Min, Max	0, 15	-5, 15	0, 0	-25, -25		

CFB: Change from Baseline

Top N counts relate to the number of patients who have received each treatment in the specified study period. Patients allocated to Vehicle Control who are not completely healed at Week 8 are counted in the Vehicle Control group in the Controlled Treatment Period and their Uncontrolled Treatment group in the Follow-Up Period.

Findings are categorised according to the last treatment received from the controlled or uncontrolled treatment periods.

The data presented in this Table are contained in Listing 16.2.9.3c



Table 14.3.6.2c Summary of Ocular Tolerability as Measured by the VAS (mm) by Treatment and Visit  
(Safety Population)

Study Period: Follow-Up Period (48 Weeks), Symptom: Sticky Feeling

Visit		rhNGF 10 µg/ml (N=52)		rhNGF 20 µg/ml (N=52)		Vehicle Control (N=29)	
		Actual	CFB	Actual	CFB	Actual	CFB
Week 12	n	43	43	36	36	23	23
	Mean (SD)	16.9 (22.07)	-14.0 (31.69)	12.9 (21.20)	-6.7 (27.69)	16.7 (20.87)	-8.3 (30.62)
	Median	10.0	-10.0	2.5	0.0	5.0	-10.0
	Min, Max	0, 80	-100, 80	0, 90	-60, 55	0, 60	-65, 60
Week 20	n	42	42	37	37	22	22
	Mean (SD)	14.7 (21.99)	-15.8 (32.30)	14.6 (23.57)	-4.6 (24.90)	20.0 (23.40)	-6.1 (34.12)
	Median	2.5	-10.0	1.0	0.0	9.5	0.0
	Min, Max	0, 70	-85, 60	0, 80	-60, 60	0, 70	-70, 60
Week 32	n	36	36	35	35	22	22
	Mean (SD)	13.5 (21.48)	-17.8 (27.28)	19.2 (28.30)	-1.0 (26.09)	17.8 (22.66)	-8.3 (32.91)
	Median	5.0	-10.0	1.0	0.0	8.5	0.0
	Min, Max	0, 95	-90, 25	0, 100	-50, 70	0, 70	-80, 50
Week 44	n	34	34	36	36	22	22
	Mean (SD)	13.7 (20.20)	-17.1 (30.52)	17.0 (26.51)	-2.8 (29.24)	24.7 (27.59)	-1.5 (31.73)
	Median	5.5	-14.5	7.0	0.0	10.5	0.0
	Min, Max	0, 80	-85, 80	0, 100	-59, 80	0, 90	-65, 65

CFB: Change from Baseline

Top N counts relate to the number of patients who have received each treatment in the specified study period. Patients allocated to Vehicle Control who are not completely healed at Week 8 are counted in the Vehicle Control group in the Controlled Treatment Period and their Uncontrolled Treatment group in the Follow-Up Period.

Findings are categorised according to the last treatment received from the controlled or uncontrolled treatment periods.

The data presented in this Table are contained in Listing 16.2.9.3c

Table 14.3.6.2c Summary of Ocular Tolerability as Measured by the VAS (mm) by Treatment and Visit  
(Safety Population)

Study Period: Follow-Up Period (48 Weeks), Symptom: Sticky Feeling

Visit		rhNGF 10 µg/ml (N=52)		rhNGF 20 µg/ml (N=52)		Vehicle Control (N=29)	
		Actual	CFB	Actual	CFB	Actual	CFB
Week 56	n	32	32	33	33	22	22
	Mean (SD)	13.6 (20.92)	-19.1 (27.15)	17.7 (26.46)	-2.0 (26.68)	22.1 (29.04)	-4.0 (34.30)
	Median	6.5	-10.0	5.0	0.0	7.5	-2.5
	Min, Max	0, 75	-90, 21	0, 100	-58, 58	0, 90	-70, 70
Early Exit	n	3	3	1	1	0	0
	Mean (SD)	9.7 (8.96)	3.0 (18.08)	0.0 (-)	0.0 (-)		
	Median	5.0	5.0	0.0	0.0		
	Min, Max	4, 20	-16, 20	0, 0	0, 0		

CFB: Change from Baseline

Top N counts relate to the number of patients who have received each treatment in the specified study period. Patients allocated to Vehicle Control who are not completely healed at Week 8 are counted in the Vehicle Control group in the Controlled Treatment Period and their Uncontrolled Treatment group in the Follow-Up Period.

Findings are categorised according to the last treatment received from the controlled or uncontrolled treatment periods.

The data presented in this Table are contained in Listing 16.2.9.3c

Table 14.3.6.2c Summary of Ocular Tolerability as Measured by the VAS (mm) by Treatment and Visit  
(Safety Population)

Study Period: Follow-Up Period (48 Weeks), Symptom: Blurred Vision

Visit		rhNGF 10 µg/ml (N=52)		rhNGF 20 µg/ml (N=52)		Vehicle Control (N=29)	
		Actual	CFB	Actual	CFB	Actual	CFB
Week 12	n	43	43	36	36	23	23
	Mean (SD)	62.5 (34.75)	-17.7 (39.51)	62.1 (34.44)	-22.8 (32.78)	60.9 (33.93)	-17.4 (27.14)
	Median	70.0	-15.0	80.0	-10.0	70.0	-10.0
	Min, Max	1, 100	-85, 100	0, 100	-90, 35	0, 100	-70, 40
Week 20	n	42	42	37	37	22	22
	Mean (SD)	57.4 (34.56)	-24.6 (33.68)	55.6 (36.40)	-28.2 (33.59)	58.7 (33.21)	-20.5 (32.78)
	Median	62.5	-26.5	55.0	-20.0	65.0	-7.5
	Min, Max	0, 100	-90, 60	0, 100	-100, 20	0, 100	-100, 30
Week 32	n	36	36	35	35	22	22
	Mean (SD)	49.6 (38.02)	-33.8 (37.69)	62.7 (32.78)	-20.5 (28.66)	61.8 (34.88)	-17.4 (32.30)
	Median	50.0	-37.5	60.0	-10.0	62.5	-7.5
	Min, Max	0, 100	-100, 60	0, 100	-80, 40	0, 100	-91, 39
Week 44	n	34	34	36	36	22	22
	Mean (SD)	46.6 (35.44)	-37.1 (32.58)	62.6 (37.09)	-20.7 (33.18)	58.9 (29.88)	-20.3 (30.38)
	Median	50.0	-33.0	74.5	-12.5	60.0	-22.5
	Min, Max	0, 100	-100, 30	0, 100	-100, 40	0, 100	-70, 40

CFB: Change from Baseline

Top N counts relate to the number of patients who have received each treatment in the specified study period. Patients allocated to Vehicle Control who are not completely healed at Week 8 are counted in the Vehicle Control group in the Controlled Treatment Period and their Uncontrolled Treatment group in the Follow-Up Period.

Findings are categorised according to the last treatment received from the controlled or uncontrolled treatment periods.

The data presented in this Table are contained in Listing 16.2.9.3c

Table 14.3.6.2c Summary of Ocular Tolerability as Measured by the VAS (mm) by Treatment and Visit  
(Safety Population)

Study Period: Follow-Up Period (48 Weeks), Symptom: Blurred Vision

Visit		rhNGF 10 µg/ml (N=52)		rhNGF 20 µg/ml (N=52)		Vehicle Control (N=29)	
		Actual	CFB	Actual	CFB	Actual	CFB
Week 56	n	32	32	33	33	22	22
	Mean (SD)	42.6 (36.68)	-40.9 (31.07)	57.5 (35.31)	-26.2 (33.39)	61.8 (34.82)	-17.4 (33.84)
	Median	37.5	-40.0	60.0	-21.0	67.0	-12.5
	Min, Max	0, 100	-100, 10	0, 100	-100, 40	0, 100	-80, 45
Early Exit	n	3	3	1	1	0	0
	Mean (SD)	60.7 (45.54)	-16.0 (67.01)	100.0 (-)	0.0 (-)		
	Median	78.0	5.0	100.0	0.0		
	Min, Max	9, 95	-91, 38	100, 100	0, 0		

CFB: Change from Baseline

Top N counts relate to the number of patients who have received each treatment in the specified study period. Patients allocated to Vehicle Control who are not completely healed at Week 8 are counted in the Vehicle Control group in the Controlled Treatment Period and their Uncontrolled Treatment group in the Follow-Up Period.

Findings are categorised according to the last treatment received from the controlled or uncontrolled treatment periods.

The data presented in this Table are contained in Listing 16.2.9.3c

Table 14.3.6.2c Summary of Ocular Tolerability as Measured by the VAS (mm) by Treatment and Visit  
(Safety Population)

Study Period: Follow-Up Period (48 Weeks), Symptom: Photophobia

Visit		rhNGF 10 µg/ml (N=52)		rhNGF 20 µg/ml (N=52)		Vehicle Control (N=29)	
		Actual	CFB	Actual	CFB	Actual	CFB
Week 12	n	43	43	36	36	23	23
	Mean (SD)	37.9 (35.74)	-27.7 (37.63)	37.9 (33.61)	-20.2 (42.46)	55.7 (28.92)	-14.6 (29.19)
	Median	35.0	-25.0	32.5	-15.0	50.0	-10.0
	Min, Max	0, 100	-100, 87	0, 100	-100, 80	0, 100	-80, 50
Week 20	n	42	42	37	37	22	22
	Mean (SD)	40.6 (34.25)	-24.6 (35.67)	34.0 (32.65)	-24.2 (40.56)	57.7 (31.82)	-11.7 (24.21)
	Median	37.5	-20.0	30.0	-10.0	60.0	-10.5
	Min, Max	0, 100	-100, 80	0, 100	-100, 71	0, 100	-70, 50
Week 32	n	36	36	35	35	22	22
	Mean (SD)	35.1 (31.58)	-31.8 (35.97)	34.0 (33.34)	-24.6 (42.94)	57.3 (36.15)	-12.1 (28.12)
	Median	30.0	-27.5	30.0	-20.0	65.0	-4.5
	Min, Max	0, 100	-100, 50	0, 100	-100, 71	0, 100	-85, 30
Week 44	n	34	34	36	36	22	22
	Mean (SD)	29.6 (31.39)	-38.6 (32.53)	36.6 (38.10)	-20.8 (46.09)	50.7 (33.68)	-18.7 (32.00)
	Median	20.0	-37.5	30.0	-12.5	52.5	-17.5
	Min, Max	0, 100	-100, 20	0, 100	-100, 80	0, 100	-95, 50

CFB: Change from Baseline

Top N counts relate to the number of patients who have received each treatment in the specified study period. Patients allocated to Vehicle Control who are not completely healed at Week 8 are counted in the Vehicle Control group in the Controlled Treatment Period and their Uncontrolled Treatment group in the Follow-Up Period.

Findings are categorised according to the last treatment received from the controlled or uncontrolled treatment periods.

The data presented in this Table are contained in Listing 16.2.9.3c

Table 14.3.6.2c Summary of Ocular Tolerability as Measured by the VAS (mm) by Treatment and Visit  
(Safety Population)

Study Period: Follow-Up Period (48 Weeks), Symptom: Photophobia

Visit		rhNGF 10 µg/ml (N=52)		rhNGF 20 µg/ml (N=52)		Vehicle Control (N=29)	
		Actual	CFB	Actual	CFB	Actual	CFB
Week 56	n	32	32	33	33	22	22
	Mean (SD)	28.2 (30.35)	-41.8 (32.55)	41.5 (35.78)	-14.3 (40.67)	47.5 (36.62)	-22.0 (31.95)
	Median	15.0	-40.0	45.0	-2.0	47.5	-17.5
	Min, Max	0, 100	-100, 5	0, 100	-100, 65	0, 100	-95, 25
Early Exit	n	3	3	1	1	0	0
	Mean (SD)	1.3 (2.31)	-2.0 (7.21)	0.0 (-)	-90.0 (-)		
	Median	0.0	0.0	0.0	-90.0		
	Min, Max	0, 4	-10, 4	0, 0	-90, -90		

CFB: Change from Baseline

Top N counts relate to the number of patients who have received each treatment in the specified study period. Patients allocated to Vehicle Control who are not completely healed at Week 8 are counted in the Vehicle Control group in the Controlled Treatment Period and their Uncontrolled Treatment group in the Follow-Up Period.

Findings are categorised according to the last treatment received from the controlled or uncontrolled treatment periods.

The data presented in this Table are contained in Listing 16.2.9.3c

Table 14.3.6.2c Summary of Ocular Tolerability as Measured by the VAS (mm) by Treatment and Visit  
(Safety Population)

Study Period: Follow-Up Period (48 Weeks), Symptom: Overall Ocular Tolerability VAS Score

Visit		rhNGF 10 µg/ml (N=52)		rhNGF 20 µg/ml (N=52)		Vehicle Control (N=29)	
		Actual	CFB	Actual	CFB	Actual	CFB
Week 12	n	43	43	36	36	23	23
	Mean (SD)	27.1 (17.55)	-17.4 (23.11)	25.2 (15.17)	-15.1 (21.93)	30.3 (16.28)	-14.1 (20.70)
	Median	23.6	-20.0	24.6	-15.6	31.4	-15.0
	Min, Max	0, 62	-64, 45	0, 71	-56, 41	1, 70	-65, 17
Week 20	n	42	42	37	37	22	22
	Mean (SD)	26.2 (17.79)	-18.3 (24.05)	23.7 (17.14)	-16.1 (17.70)	31.6 (18.44)	-13.7 (21.20)
	Median	23.6	-19.8	20.0	-16.3	27.5	-17.1
	Min, Max	1, 64	-74, 39	0, 59	-55, 25	10, 74	-52, 30
Week 32	n	36	36	35	35	22	22
	Mean (SD)	22.2 (17.72)	-22.9 (23.71)	28.1 (19.88)	-12.3 (21.20)	32.1 (19.25)	-13.2 (20.75)
	Median	16.9	-22.9	23.1	-14.3	27.9	-15.4
	Min, Max	1, 84	-68, 29	0, 84	-54, 54	11, 76	-52, 34
Week 44	n	34	34	36	36	22	22
	Mean (SD)	21.3 (15.57)	-23.5 (20.74)	26.1 (19.02)	-13.8 (18.84)	30.7 (17.24)	-14.6 (18.11)
	Median	19.9	-22.5	20.0	-13.8	29.3	-14.6
	Min, Max	0, 55	-67, 26	3, 74	-68, 24	3, 77	-50, 13

CFB: Change from Baseline

Top N counts relate to the number of patients who have received each treatment in the specified study period. Patients allocated to Vehicle Control who are not completely healed at Week 8 are counted in the Vehicle Control group in the Controlled Treatment Period and their Uncontrolled Treatment group in the Follow-Up Period.

Findings are categorised according to the last treatment received from the controlled or uncontrolled treatment periods.

The data presented in this Table are contained in Listing 16.2.9.3c

Table 14.3.6.2c Summary of Ocular Tolerability as Measured by the VAS (mm) by Treatment and Visit  
(Safety Population)

Study Period: Follow-Up Period (48 Weeks), Symptom: Overall Ocular Tolerability VAS Score

Visit		rhNGF 10 µg/ml (N=52)		rhNGF 20 µg/ml (N=52)		Vehicle Control (N=29)	
		Actual	CFB	Actual	CFB	Actual	CFB
Week 56	n	32	32	33	33	22	22
	Mean (SD)	20.1 (19.24)	-25.9 (22.90)	26.4 (20.10)	-13.3 (19.76)	33.5 (24.49)	-11.8 (28.10)
	Median	14.3	-23.8	20.7	-8.3	23.1	-12.9
	Min, Max	0, 66	-71, 37	0, 71	-81, 31	6, 89	-50, 60
Early Exit	n	3	3	1	1	0	0
	Mean (SD)	16.9 (1.65)	-2.7 (10.86)	14.4 (-)	-20.6 (-)		
	Median	16.7	-6.4	14.4	-20.6		
	Min, Max	15, 19	-11, 10	14, 14	-21, -21		

CFB: Change from Baseline

Top N counts relate to the number of patients who have received each treatment in the specified study period. Patients allocated to Vehicle Control who are not completely healed at Week 8 are counted in the Vehicle Control group in the Controlled Treatment Period and their Uncontrolled Treatment group in the Follow-Up Period.

Findings are categorised according to the last treatment received from the controlled or uncontrolled treatment periods.

The data presented in this Table are contained in Listing 16.2.9.3c



Table 14.3.6.2c Summary of Ocular Tolerability as Measured by the VAS (mm) by Treatment and Visit  
(Safety Population)

Study Period: Follow-Up Period (56 Weeks), Symptom: Foreign Body Sensation

Visit		rhNGF 10 µg/ml (N=10)		rhNGF 20 µg/ml (N=13)	
		Actual	CFB	Actual	CFB
Week 20	n	8	8	13	13
	Mean (SD)	10.0 (17.48)	-9.5 (33.55)	7.5 (13.25)	-26.4 (41.29)
	Median	2.5	0.0	0.0	-5.0
	Min, Max	0, 50	-80, 30	0, 38	-99, 29
Week 28	n	7	7	12	12
	Mean (SD)	8.3 (8.52)	-14.0 (29.60)	6.8 (12.23)	-30.0 (37.33)
	Median	5.0	-4.0	0.0	-5.5
	Min, Max	0, 20	-75, 17	0, 38	-94, 0
Week 40	n	6	6	10	10
	Mean (SD)	13.0 (15.95)	0.3 (13.59)	11.1 (13.99)	-33.0 (34.41)
	Median	6.5	0.0	5.0	-19.0
	Min, Max	0, 40	-18, 20	0, 38	-84, 0
Week 52	n	6	6	10	10
	Mean (SD)	9.2 (11.57)	-3.5 (11.57)	18.3 (25.43)	-25.8 (34.25)
	Median	6.0	-2.0	5.0	-5.5
	Min, Max	0, 30	-17, 10	0, 70	-89, 0

CFB: Change from Baseline

Top N counts relate to the number of patients who have received each treatment in the specified study period. Patients allocated to Vehicle Control who are not completely healed at Week 8 are counted in the Vehicle Control group in the Controlled Treatment Period and their Uncontrolled Treatment group in the Follow-Up Period.

Findings are categorised according to the last treatment received from the controlled or uncontrolled treatment periods.

The data presented in this Table are contained in Listing 16.2.9.3c

Table 14.3.6.2c Summary of Ocular Tolerability as Measured by the VAS (mm) by Treatment and Visit  
(Safety Population)

Study Period: Follow-Up Period (56 Weeks), Symptom: Foreign Body Sensation

Visit		rhNGF 10 µg/ml (N=10)		rhNGF 20 µg/ml (N=13)	
		Actual	CFB	Actual	CFB
Week 64	n	7	7	9	9
	Mean (SD)	16.1 (18.47)	-6.1 (40.18)	12.8 (12.77)	-36.2 (32.84)
	Median	10.0	0.0	10.0	-35.0
	Min, Max	0, 43	-80, 40	0, 40	-94, 4

CFB: Change from Baseline

Top N counts relate to the number of patients who have received each treatment in the specified study period. Patients allocated to Vehicle Control who are not completely healed at Week 8 are counted in the Vehicle Control group in the Controlled Treatment Period and their Uncontrolled Treatment group in the Follow-Up Period.

Findings are categorised according to the last treatment received from the controlled or uncontrolled treatment periods.

The data presented in this Table are contained in Listing 16.2.9.3c

Table 14.3.6.2c Summary of Ocular Tolerability as Measured by the VAS (mm) by Treatment and Visit  
(Safety Population)

Study Period: Follow-Up Period (56 Weeks), Symptom: Burning/Stinging

Visit		rhNGF 10 µg/ml (N=10)		rhNGF 20 µg/ml (N=13)	
		Actual	CFB	Actual	CFB
Week 20	n	8	8	13	13
	Mean (SD)	9.9 (11.15)	-16.6 (34.90)	13.9 (29.32)	-15.5 (29.23)
	Median	5.5	-9.0	0.0	-3.0
	Min, Max	0, 30	-95, 26	0, 88	-80, 10
Week 28	n	7	7	12	12
	Mean (SD)	6.4 (8.72)	-22.4 (34.56)	19.2 (29.30)	-12.7 (33.68)
	Median	3.0	-5.0	2.5	-5.0
	Min, Max	0, 25	-95, 1	0, 85	-80, 50
Week 40	n	6	6	10	10
	Mean (SD)	13.8 (12.14)	-3.2 (20.14)	21.0 (33.73)	-13.2 (33.92)
	Median	15.0	4.0	2.5	-3.5
	Min, Max	0, 30	-38, 16	0, 85	-80, 25
Week 52	n	6	6	10	10
	Mean (SD)	23.8 (24.98)	6.8 (33.16)	13.0 (27.00)	-21.2 (37.57)
	Median	16.0	-2.5	0.0	-5.0
	Min, Max	0, 59	-37, 55	0, 85	-80, 30

CFB: Change from Baseline

Top N counts relate to the number of patients who have received each treatment in the specified study period. Patients allocated to Vehicle Control who are not completely healed at Week 8 are counted in the Vehicle Control group in the Controlled Treatment Period and their Uncontrolled Treatment group in the Follow-Up Period.

Findings are categorised according to the last treatment received from the controlled or uncontrolled treatment periods.

The data presented in this Table are contained in Listing 16.2.9.3c

Table 14.3.6.2c Summary of Ocular Tolerability as Measured by the VAS (mm) by Treatment and Visit  
(Safety Population)

Study Period: Follow-Up Period (56 Weeks), Symptom: Burning/Stinging

Visit		rhNGF 10 µg/ml (N=10)		rhNGF 20 µg/ml (N=13)	
		Actual	CFB	Actual	CFB
Week 64	n	7	7	9	9
	Mean (SD)	20.3 (20.51)	-8.6 (38.67)	17.2 (23.60)	-11.9 (32.98)
	Median	10.0	-10.0	5.0	-5.0
	Min, Max	0, 52	-70, 38	0, 60	-70, 50

CFB: Change from Baseline

Top N counts relate to the number of patients who have received each treatment in the specified study period. Patients allocated to Vehicle Control who are not completely healed at Week 8 are counted in the Vehicle Control group in the Controlled Treatment Period and their Uncontrolled Treatment group in the Follow-Up Period.

Findings are categorised according to the last treatment received from the controlled or uncontrolled treatment periods.

The data presented in this Table are contained in Listing 16.2.9.3c

Table 14.3.6.2c Summary of Ocular Tolerability as Measured by the VAS (mm) by Treatment and Visit  
(Safety Population)

Study Period: Follow-Up Period (56 Weeks), Symptom: Itching

Visit		rhNGF 10 µg/ml (N=10)		rhNGF 20 µg/ml (N=13)	
		Actual	CFB	Actual	CFB
Week 20	n	8	8	13	13
	Mean (SD)	13.6 (14.59)	-5.0 (34.72)	7.5 (23.41)	-9.5 (22.49)
	Median	10.5	-2.0	0.0	0.0
	Min, Max	0, 37	-80, 37	0, 85	-82, 0
Week 28	n	7	7	12	12
	Mean (SD)	14.9 (21.32)	-6.4 (37.85)	9.2 (24.20)	-9.3 (23.32)
	Median	3.0	-4.0	0.0	-0.5
	Min, Max	0, 50	-80, 41	0, 85	-80, 10
Week 40	n	6	6	10	10
	Mean (SD)	22.2 (17.24)	10.7 (23.34)	13.5 (26.78)	-8.7 (29.77)
	Median	25.0	8.0	2.5	-1.0
	Min, Max	1, 41	-19, 38	0, 85	-85, 30
Week 52	n	6	6	10	10
	Mean (SD)	31.7 (21.14)	20.2 (28.50)	10.0 (26.56)	-12.2 (28.32)
	Median	32.5	18.0	0.0	-1.0
	Min, Max	5, 59	-15, 55	0, 85	-90, 9

CFB: Change from Baseline

Top N counts relate to the number of patients who have received each treatment in the specified study period. Patients allocated to Vehicle Control who are not completely healed at Week 8 are counted in the Vehicle Control group in the Controlled Treatment Period and their Uncontrolled Treatment group in the Follow-Up Period.

Findings are categorised according to the last treatment received from the controlled or uncontrolled treatment periods.

The data presented in this Table are contained in Listing 16.2.9.3c

Table 14.3.6.2c Summary of Ocular Tolerability as Measured by the VAS (mm) by Treatment and Visit  
(Safety Population)

Study Period: Follow-Up Period (56 Weeks), Symptom: Itching

Visit		rhNGF 10 µg/ml (N=10)		rhNGF 20 µg/ml (N=13)	
		Actual	CFB	Actual	CFB
Week 64	n	7	7	9	9
	Mean (SD)	12.7 (14.95)	-8.6 (37.99)	8.3 (19.69)	-6.3 (11.67)
	Median	10.0	-10.0	0.0	-2.0
	Min, Max	0, 40	-80, 36	0, 60	-25, 10

CFB: Change from Baseline

Top N counts relate to the number of patients who have received each treatment in the specified study period. Patients allocated to Vehicle Control who are not completely healed at Week 8 are counted in the Vehicle Control group in the Controlled Treatment Period and their Uncontrolled Treatment group in the Follow-Up Period.

Findings are categorised according to the last treatment received from the controlled or uncontrolled treatment periods.

The data presented in this Table are contained in Listing 16.2.9.3c

Table 14.3.6.2c Summary of Ocular Tolerability as Measured by the VAS (mm) by Treatment and Visit  
(Safety Population)

Study Period: Follow-Up Period (56 Weeks), Symptom: Ocular Pain

Visit		rhNGF 10 µg/ml (N=10)		rhNGF 20 µg/ml (N=13)	
		Actual	CFB	Actual	CFB
Week 20	n	8	8	13	13
	Mean (SD)	10.8 (16.24)	-4.8 (17.50)	8.1 (19.53)	-9.4 (23.29)
	Median	5.0	2.5	0.0	0.0
	Min, Max	0, 50	-39, 10	0, 70	-70, 20
Week 28	n	7	7	12	12
	Mean (SD)	4.4 (4.12)	-13.3 (20.11)	7.9 (19.94)	-11.0 (23.16)
	Median	3.0	0.0	0.0	-0.5
	Min, Max	0, 10	-43, 5	0, 70	-70, 10
Week 40	n	6	6	10	10
	Mean (SD)	9.5 (12.21)	-11.2 (16.23)	9.5 (23.27)	-13.2 (24.63)
	Median	5.0	-5.5	0.0	-1.0
	Min, Max	0, 33	-32, 4	0, 75	-70, 5
Week 52	n	6	6	10	10
	Mean (SD)	16.0 (24.45)	-4.7 (17.68)	14.5 (22.91)	-8.2 (28.38)
	Median	3.0	0.5	7.5	-0.5
	Min, Max	0, 60	-35, 16	0, 70	-60, 39

CFB: Change from Baseline

Top N counts relate to the number of patients who have received each treatment in the specified study period. Patients allocated to Vehicle Control who are not completely healed at Week 8 are counted in the Vehicle Control group in the Controlled Treatment Period and their Uncontrolled Treatment group in the Follow-Up Period.

Findings are categorised according to the last treatment received from the controlled or uncontrolled treatment periods.

The data presented in this Table are contained in Listing 16.2.9.3c

Table 14.3.6.2c Summary of Ocular Tolerability as Measured by the VAS (mm) by Treatment and Visit  
(Safety Population)

Study Period: Follow-Up Period (56 Weeks), Symptom: Ocular Pain

Visit		rhNGF 10 µg/ml (N=10)		rhNGF 20 µg/ml (N=13)	
		Actual	CFB	Actual	CFB
Week 64	n	7	7	9	9
	Mean (SD)	18.1 (25.84)	0.4 (23.45)	20.0 (27.04)	-5.2 (30.89)
	Median	5.0	0.0	10.0	-1.0
	Min, Max	0, 70	-35, 30	0, 80	-60, 49

CFB: Change from Baseline

Top N counts relate to the number of patients who have received each treatment in the specified study period. Patients allocated to Vehicle Control who are not completely healed at Week 8 are counted in the Vehicle Control group in the Controlled Treatment Period and their Uncontrolled Treatment group in the Follow-Up Period.

Findings are categorised according to the last treatment received from the controlled or uncontrolled treatment periods.

The data presented in this Table are contained in Listing 16.2.9.3c



Table 14.3.6.2c Summary of Ocular Tolerability as Measured by the VAS (mm) by Treatment and Visit  
(Safety Population)

Study Period: Follow-Up Period (56 Weeks), Symptom: Sticky Feeling

Visit		rhNGF 10 µg/ml (N=10)		rhNGF 20 µg/ml (N=13)	
		Actual	CFB	Actual	CFB
Week 20	n	8	8	13	13
	Mean (SD)	18.9 (25.70)	-9.5 (26.64)	10.5 (25.47)	-24.5 (37.19)
	Median	6.5	-7.5	0.0	-1.0
	Min, Max	0, 60	-55, 38	0, 90	-100, 0
Week 28	n	7	7	12	12
	Mean (SD)	11.3 (16.54)	-21.1 (18.65)	9.8 (26.50)	-28.2 (40.25)
	Median	2.0	-18.0	0.0	-3.0
	Min, Max	0, 45	-55, -1	0, 90	-100, 0
Week 40	n	6	6	10	10
	Mean (SD)	25.2 (17.08)	-11.8 (15.69)	20.3 (35.26)	-25.3 (55.14)
	Median	27.5	-14.0	0.0	-10.0
	Min, Max	2, 43	-33, 7	0, 90	-100, 80
Week 52	n	6	6	10	10
	Mean (SD)	13.3 (16.10)	-23.7 (29.52)	18.5 (29.63)	-27.1 (41.84)
	Median	10.0	-22.0	5.0	-10.0
	Min, Max	0, 40	-74, 16	0, 90	-100, 20

CFB: Change from Baseline

Top N counts relate to the number of patients who have received each treatment in the specified study period. Patients allocated to Vehicle Control who are not completely healed at Week 8 are counted in the Vehicle Control group in the Controlled Treatment Period and their Uncontrolled Treatment group in the Follow-Up Period.

Findings are categorised according to the last treatment received from the controlled or uncontrolled treatment periods.

The data presented in this Table are contained in Listing 16.2.9.3c

Table 14.3.6.2c Summary of Ocular Tolerability as Measured by the VAS (mm) by Treatment and Visit  
(Safety Population)

Study Period: Follow-Up Period (56 Weeks), Symptom: Sticky Feeling

Visit		rhNGF 10 µg/ml (N=10)		rhNGF 20 µg/ml (N=13)	
		Actual	CFB	Actual	CFB
Week 64	n	7	7	9	9
	Mean (SD)	19.7 (19.52)	-12.7 (13.03)	13.3 (18.71)	-37.3 (41.13)
	Median	20.0	-10.0	10.0	-35.0
	Min, Max	0, 43	-34, 4	0, 50	-100, 10

CFB: Change from Baseline

Top N counts relate to the number of patients who have received each treatment in the specified study period. Patients allocated to Vehicle Control who are not completely healed at Week 8 are counted in the Vehicle Control group in the Controlled Treatment Period and their Uncontrolled Treatment group in the Follow-Up Period.

Findings are categorised according to the last treatment received from the controlled or uncontrolled treatment periods.

The data presented in this Table are contained in Listing 16.2.9.3c

Table 14.3.6.2c Summary of Ocular Tolerability as Measured by the VAS (mm) by Treatment and Visit  
(Safety Population)

Study Period: Follow-Up Period (56 Weeks), Symptom: Blurred Vision

Visit		rhNGF 10 µg/ml (N=10)		rhNGF 20 µg/ml (N=13)	
		Actual	CFB	Actual	CFB
Week 20	n	8	8	13	13
	Mean (SD)	63.3 (32.31)	-10.1 (33.59)	49.2 (34.59)	-33.7 (38.84)
	Median	64.5	0.0	55.0	-20.0
	Min, Max	20, 100	-65, 20	0, 90	-100, 28
Week 28	n	7	7	12	12
	Mean (SD)	64.4 (30.30)	-8.0 (41.24)	50.4 (29.35)	-39.3 (37.92)
	Median	60.0	-8.0	52.5	-45.0
	Min, Max	20, 100	-65, 50	0, 90	-100, 28
Week 40	n	6	6	10	10
	Mean (SD)	60.3 (34.16)	-14.2 (25.37)	46.0 (23.78)	-44.7 (30.91)
	Median	57.5	-6.5	50.0	-47.5
	Min, Max	20, 100	-53, 10	5, 80	-95, -2
Week 52	n	6	6	10	10
	Mean (SD)	63.2 (33.65)	-11.3 (32.18)	62.4 (27.98)	-28.3 (37.05)
	Median	60.0	1.5	69.5	-23.0
	Min, Max	30, 100	-58, 20	0, 100	-100, 28

CFB: Change from Baseline

Top N counts relate to the number of patients who have received each treatment in the specified study period. Patients allocated to Vehicle Control who are not completely healed at Week 8 are counted in the Vehicle Control group in the Controlled Treatment Period and their Uncontrolled Treatment group in the Follow-Up Period.

Findings are categorised according to the last treatment received from the controlled or uncontrolled treatment periods.

The data presented in this Table are contained in Listing 16.2.9.3c

Table 14.3.6.2c Summary of Ocular Tolerability as Measured by the VAS (mm) by Treatment and Visit  
(Safety Population)

Study Period: Follow-Up Period (56 Weeks), Symptom: Blurred Vision

Visit		rhNGF 10 µg/ml (N=10)		rhNGF 20 µg/ml (N=13)	
		Actual	CFB	Actual	CFB
Week 64	n	7	7	9	9
	Mean (SD)	78.1 (29.23)	5.7 (15.68)	57.7 (21.71)	-32.0 (27.80)
	Median	88.0	10.0	50.0	-36.0
	Min, Max	20, 100	-24, 22	30, 100	-70, 10

CFB: Change from Baseline

Top N counts relate to the number of patients who have received each treatment in the specified study period. Patients allocated to Vehicle Control who are not completely healed at Week 8 are counted in the Vehicle Control group in the Controlled Treatment Period and their Uncontrolled Treatment group in the Follow-Up Period.

Findings are categorised according to the last treatment received from the controlled or uncontrolled treatment periods.

The data presented in this Table are contained in Listing 16.2.9.3c

Table 14.3.6.2c Summary of Ocular Tolerability as Measured by the VAS (mm) by Treatment and Visit  
(Safety Population)

Study Period: Follow-Up Period (56 Weeks), Symptom: Photophobia

Visit		rhNGF 10 µg/ml (N=10)		rhNGF 20 µg/ml (N=13)	
		Actual	CFB	Actual	CFB
Week 20	n	8	8	13	13
	Mean (SD)	29.4 (35.45)	-5.1 (32.52)	44.2 (34.02)	-23.1 (27.31)
	Median	20.0	0.0	40.0	-10.0
	Min, Max	0, 97	-74, 37	0, 90	-89, 0
Week 28	n	7	7	12	12
	Mean (SD)	31.4 (34.85)	-8.0 (29.94)	35.9 (32.33)	-37.0 (29.86)
	Median	30.0	0.0	35.5	-29.5
	Min, Max	0, 99	-64, 21	0, 80	-90, -3
Week 40	n	6	6	10	10
	Mean (SD)	30.3 (36.48)	-9.0 (28.17)	40.0 (29.53)	-38.5 (29.45)
	Median	21.0	-5.0	37.5	-29.5
	Min, Max	0, 95	-62, 17	0, 80	-84, -3
Week 52	n	6	6	10	10
	Mean (SD)	33.7 (42.10)	-5.7 (20.92)	39.9 (31.02)	-38.6 (29.21)
	Median	15.5	-4.0	45.0	-35.0
	Min, Max	1, 100	-33, 22	0, 80	-90, -3

CFB: Change from Baseline

Top N counts relate to the number of patients who have received each treatment in the specified study period. Patients allocated to Vehicle Control who are not completely healed at Week 8 are counted in the Vehicle Control group in the Controlled Treatment Period and their Uncontrolled Treatment group in the Follow-Up Period.

Findings are categorised according to the last treatment received from the controlled or uncontrolled treatment periods.

The data presented in this Table are contained in Listing 16.2.9.3c

Table 14.3.6.2c Summary of Ocular Tolerability as Measured by the VAS (mm) by Treatment and Visit  
(Safety Population)

Study Period: Follow-Up Period (56 Weeks), Symptom: Photophobia

Visit		rhNGF 10 µg/ml (N=10)		rhNGF 20 µg/ml (N=13)	
		Actual	CFB	Actual	CFB
Week 64	n	7	7	9	9
	Mean (SD)	33.1 (37.95)	-6.3 (10.11)	50.0 (34.64)	-27.3 (24.06)
	Median	20.0	-10.0	60.0	-20.0
	Min, Max	0, 90	-20, 12	0, 100	-80, 1

CFB: Change from Baseline

Top N counts relate to the number of patients who have received each treatment in the specified study period. Patients allocated to Vehicle Control who are not completely healed at Week 8 are counted in the Vehicle Control group in the Controlled Treatment Period and their Uncontrolled Treatment group in the Follow-Up Period.

Findings are categorised according to the last treatment received from the controlled or uncontrolled treatment periods.

The data presented in this Table are contained in Listing 16.2.9.3c

Table 14.3.6.2c Summary of Ocular Tolerability as Measured by the VAS (mm) by Treatment and Visit  
(Safety Population)

Study Period: Follow-Up Period (56 Weeks), Symptom: Overall Ocular Tolerability VAS Score

Visit		rhNGF 10 µg/ml (N=10)		rhNGF 20 µg/ml (N=13)	
		Actual	CFB	Actual	CFB
Week 20	n	8	8	13	13
	Mean (SD)	22.3 (13.07)	-8.7 (17.22)	20.1 (18.67)	-20.3 (18.68)
	Median	15.7	-1.4	12.9	-17.4
	Min, Max	10, 43	-36, 7	0, 69	-54, 2
Week 28	n	7	7	12	12
	Mean (SD)	20.2 (7.75)	-13.3 (13.88)	19.9 (18.03)	-23.9 (18.75)
	Median	17.0	-7.9	15.0	-20.7
	Min, Max	12, 31	-30, 6	2, 67	-57, 2
Week 40	n	6	6	10	10
	Mean (SD)	24.9 (7.61)	-5.5 (6.76)	23.1 (19.62)	-25.2 (16.03)
	Median	27.5	-5.7	19.6	-28.6
	Min, Max	15, 34	-15, 2	2, 67	-49, -2
Week 52	n	6	6	10	10
	Mean (SD)	27.3 (8.54)	-3.1 (3.28)	25.2 (19.49)	-23.1 (17.94)
	Median	26.4	-2.5	19.6	-16.5
	Min, Max	17, 41	-8, 1	1, 67	-50, 2

CFB: Change from Baseline

Top N counts relate to the number of patients who have received each treatment in the specified study period. Patients allocated to Vehicle Control who are not completely healed at Week 8 are counted in the Vehicle Control group in the Controlled Treatment Period and their Uncontrolled Treatment group in the Follow-Up Period.

Findings are categorised according to the last treatment received from the controlled or uncontrolled treatment periods.

The data presented in this Table are contained in Listing 16.2.9.3c

Table 14.3.6.2c Summary of Ocular Tolerability as Measured by the VAS (mm) by Treatment and Visit  
(Safety Population)

Study Period: Follow-Up Period (56 Weeks), Symptom: Overall Ocular Tolerability VAS Score

Visit		rhNGF 10 µg/ml (N=10)		rhNGF 20 µg/ml (N=13)	
		Actual	CFB	Actual	CFB
Week 64	n	7	7	9	9
	Mean (SD)	28.3 (14.19)	-5.2 (14.02)	25.6 (14.77)	-22.3 (15.11)
	Median	22.9	-7.0	17.9	-17.3
	Min, Max	13, 49	-29, 13	7, 45	-47, -2

CFB: Change from Baseline

Top N counts relate to the number of patients who have received each treatment in the specified study period. Patients allocated to Vehicle Control who are not completely healed at Week 8 are counted in the Vehicle Control group in the Controlled Treatment Period and their Uncontrolled Treatment group in the Follow-Up Period.

Findings are categorised according to the last treatment received from the controlled or uncontrolled treatment periods.

The data presented in this Table are contained in Listing 16.2.9.3c