

Table 14.3.7.1c Summary of Intraocular Pressure (mmHg) by Treatment and Visit
(Safety Population)

Study Period: Controlled Treatment Period

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	47		49		49	
	Mean (SD)	14.3 (3.16)		14.0 (3.06)		14.1 (3.16)	
	Median	15.0		14.0		15.0	
	Min, Max	8, 23		8, 20		8, 24	

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 16.2.9.4c

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Table 14.3.7.1c Summary of Intraocular Pressure (mmHg) by Treatment and Visit
(Safety Population)

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

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	46	42	46	45	22	20
	Mean (SD)	14.0 (3.96)	0.2 (3.25)	14.6 (3.39)	0.1 (3.64)	14.7 (3.39)	0.6 (3.93)
	Median	14.0	0.0	14.5	0.0	14.0	-0.5
	Min, Max	6, 33	-8, 11	7, 25	-11, 9	10, 25	-6, 9
Week 32/40	n	40	37	44	42	18	17
	Mean (SD)	13.6 (2.96)	0.1 (2.71)	14.4 (3.76)	0.1 (4.47)	14.9 (6.54)	0.6 (4.81)
	Median	14.0	0.0	14.0	0.0	14.0	0.0
	Min, Max	7, 20	-4, 7	6, 28	-9, 19	10, 40	-8, 16
Week 56/64	n	38	36	41	39	21	19
	Mean (SD)	12.8 (3.11)	-1.0 (2.96)	13.3 (2.77)	-1.1 (3.21)	14.4 (3.12)	0.3 (4.09)
	Median	12.5	-1.0	14.0	-1.0	14.0	0.0
	Min, Max	5, 19	-9, 5	8, 22	-9, 5	11, 24	-8, 11
Early Exit	n	3	3	1	1	0	0
	Mean (SD)	14.3 (2.52)	0.3 (2.52)	15.0 (-)	3.0 (-)		
	Median	14.0	0.0	15.0	3.0		
	Min, Max	12, 17	-2, 3	15, 15	3, 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 16.2.9.4c

Table 14.3.7.1c Summary of Intraocular Pressure (mmHg) by Treatment and Visit
(Safety Population)

Study Period: Follow-Up Period (48 Weeks)

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	40	36	34	33	22	20
	Mean (SD)	14.2 (4.01)	0.1 (3.39)	14.7 (3.81)	0.5 (3.88)	14.7 (3.39)	0.6 (3.93)
	Median	14.0	0.0	15.0	0.0	14.0	-0.5
	Min, Max	6, 33	-8, 11	7, 25	-11, 9	10, 25	-6, 9
Week 32	n	35	32	34	32	18	17
	Mean (SD)	13.6 (3.03)	-0.2 (2.55)	14.9 (3.98)	0.9 (4.47)	14.9 (6.54)	0.6 (4.81)
	Median	14.0	0.0	14.5	0.0	14.0	0.0
	Min, Max	7, 20	-4, 6	6, 28	-7, 19	10, 40	-8, 16
Week 56	n	31	29	32	30	21	19
	Mean (SD)	13.3 (2.55)	-0.9 (2.81)	13.7 (2.95)	-0.5 (3.01)	14.4 (3.12)	0.3 (4.09)
	Median	14.0	-1.0	14.0	0.0	14.0	0.0
	Min, Max	8, 19	-6, 5	8, 22	-8, 5	11, 24	-8, 11
Early Exit	n	3	3	1	1	0	0
	Mean (SD)	14.3 (2.52)	0.3 (2.52)	15.0 (-)	3.0 (-)		
	Median	14.0	0.0	15.0	3.0		
	Min, Max	12, 17	-2, 3	15, 15	3, 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.

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Table 14.3.7.1c Summary of Intraocular Pressure (mmHg) by Treatment and Visit
(Safety Population)

Study Period: Follow-Up Period (56 Weeks)

Visit		rhNGF 10 µg/ml (N=10)		rhNGF 20 µg/ml (N=13)	
		Actual	CFB	Actual	CFB
Week 20	n	6	6	12	12
	Mean (SD)	13.3 (3.88)	0.7 (2.34)	14.1 (1.78)	-1.1 (2.64)
	Median	15.5	0.0	14.0	-1.0
	Min, Max	7, 16	-2, 5	10, 17	-6, 3
Week 40	n	5	5	10	10
	Mean (SD)	13.4 (2.70)	1.8 (3.42)	12.7 (2.26)	-2.5 (3.54)
	Median	14.0	1.0	13.5	-2.0
	Min, Max	9, 16	-2, 7	8, 15	-9, 3
Week 64	n	7	7	9	9
	Mean (SD)	10.7 (4.54)	-1.3 (3.77)	12.2 (1.72)	-3.3 (3.00)
	Median	12.0	0.0	12.0	-2.0
	Min, Max	5, 17	-9, 2	10, 15	-9, 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 16.2.9.4c