

Table 14.3.9c Summary of BCDVA Score 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	52		52		52	
	Mean (SD)	30.7 (28.35)		24.2 (25.88)		32.4 (26.07)	
	Median	27.0		14.5		34.0	
	Min, Max	0, 75		0, 77		0, 72	

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 16.2.6.2.1.2c

Table 14.3.9c Summary of BCDVA Score 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	51	51	50	50	23	23
	Mean (SD)	42.0 (32.59)	13.2 (16.80)	41.2 (31.25)	14.2 (19.06)	47.6 (32.36)	8.8 (14.27)
	Median	51.0	11.0	47.5	8.5	58.0	6.0
	Min, Max	0, 98	-14, 64	0, 94	-14, 74	0, 85	-16, 49
Week 20/28	n	49	49	49	49	22	22
	Mean (SD)	42.1 (33.24)	11.5 (24.07)	41.5 (31.70)	14.3 (20.81)	48.0 (31.66)	9.9 (12.79)
	Median	51.0	7.0	50.0	7.0	57.5	5.5
	Min, Max	0, 98	-72, 74	0, 94	-16, 75	0, 84	-10, 46
Week 32/40	n	42	42	45	45	22	22
	Mean (SD)	47.0 (33.62)	14.6 (22.07)	43.2 (31.15)	15.6 (19.65)	45.3 (31.23)	7.1 (15.50)
	Median	53.5	8.0	50.0	9.0	52.5	7.5
	Min, Max	0, 99	-30, 75	0, 94	-20, 75	0, 84	-24, 44
Week 44/52	n	39	39	46	46	22	22
	Mean (SD)	48.6 (34.80)	17.5 (21.62)	42.8 (31.14)	14.5 (21.90)	45.0 (29.75)	6.8 (17.46)
	Median	57.0	17.0	45.0	7.5	51.0	2.5
	Min, Max	0, 99	-27, 75	0, 96	-40, 75	0, 82	-24, 48

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.

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Table 14.3.9c Summary of BCDVA Score 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 56/64	n	39	39	42	42	22	22
	Mean (SD)	47.1 (35.02)	13.4 (25.52)	40.8 (32.39)	15.1 (23.08)	47.8 (29.87)	9.6 (17.74)
	Median	58.0	13.0	45.0	9.0	55.5	6.0
	Min, Max	0, 99	-61, 75	0, 100	-20, 82	0, 82	-24, 58
Early Exit	n	3	3	1	1	0	0
	Mean (SD)	34.0 (30.79)	13.0 (40.78)	0.0 (-)	0.0 (-)		
	Median	42.0	-8.0	0.0	0.0		
	Min, Max	0, 60	-13, 60	0, 0	0, 0		

CFB: Change from Baseline

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Table 14.3.9c Summary of BCDVA Score 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	43	43	37	37	23	23
	Mean (SD)	44.9 (32.91)	15.6 (16.79)	41.9 (32.50)	14.7 (20.08)	47.6 (32.36)	8.8 (14.27)
	Median	53.0	16.0	48.0	9.0	58.0	6.0
	Min, Max	0, 98	-13, 64	0, 94	-14, 74	0, 85	-16, 49
Week 20	n	42	42	37	37	22	22
	Mean (SD)	45.1 (33.39)	13.7 (25.15)	42.4 (33.32)	15.6 (22.23)	48.0 (31.66)	9.9 (12.79)
	Median	54.0	14.5	51.0	11.0	57.5	5.5
	Min, Max	0, 98	-72, 74	0, 94	-16, 75	0, 84	-10, 46
Week 32	n	36	36	35	35	22	22
	Mean (SD)	49.6 (33.89)	16.5 (22.78)	44.2 (32.32)	17.6 (20.74)	45.3 (31.23)	7.1 (15.50)
	Median	56.5	10.5	50.0	10.0	52.5	7.5
	Min, Max	0, 99	-30, 75	0, 94	-20, 75	0, 84	-24, 44
Week 44	n	33	33	36	36	22	22
	Mean (SD)	52.0 (35.02)	20.2 (21.07)	44.4 (32.20)	16.8 (21.34)	45.0 (29.75)	6.8 (17.46)
	Median	62.0	17.0	54.0	9.0	51.0	2.5
	Min, Max	0, 99	-17, 75	0, 96	-20, 75	0, 82	-24, 48

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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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 56	n	32	32	33	33	22	22
	Mean (SD)	53.0 (34.21)	17.6 (23.27)	42.9 (33.04)	17.8 (24.41)	47.8 (29.87)	9.6 (17.74)
	Median	60.5	16.0	46.0	11.0	55.5	6.0
	Min, Max	0, 99	-32, 75	0, 100	-20, 82	0, 82	-24, 58
Early Exit	n	3	3	1	1	0	0
	Mean (SD)	34.0 (30.79)	13.0 (40.78)	0.0 (-)	0.0 (-)		
	Median	42.0	-8.0	0.0	0.0		
	Min, Max	0, 60	-13, 60	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.

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Table 14.3.9c Summary of BCDVA Score 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	8	8	13	13
	Mean (SD)	26.6 (27.66)	0.1 (9.73)	38.9 (28.51)	12.7 (16.45)
	Median	19.5	-0.5	42.0	8.0
	Min, Max	0, 66	-14, 20	0, 83	-9, 40
Week 28	n	7	7	12	12
	Mean (SD)	24.3 (28.05)	-1.7 (8.62)	38.7 (27.21)	10.3 (15.76)
	Median	16.0	0.0	46.0	5.0
	Min, Max	0, 73	-14, 12	0, 83	-8, 34
Week 40	n	6	6	10	10
	Mean (SD)	31.3 (29.74)	3.5 (13.74)	39.5 (27.87)	8.6 (13.91)
	Median	27.5	3.0	47.0	2.5
	Min, Max	0, 74	-18, 22	0, 85	-8, 35
Week 52	n	6	6	10	10
	Mean (SD)	30.0 (29.39)	2.2 (19.47)	37.1 (27.76)	6.2 (23.03)
	Median	28.0	7.5	39.5	1.5
	Min, Max	0, 76	-27, 22	0, 85	-40, 37

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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(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 64	n	7	7	9	9
	Mean (SD)	20.1 (26.26)	-5.9 (28.35)	33.0 (30.34)	5.4 (14.58)
	Median	5.0	0.0	37.0	0.0
	Min, Max	0, 68	-61, 31	0, 85	-17, 35

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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