

Table 14.3.8.1b Summary of Fundus Ophthalmoscopy by Treatment and Visit
(Safety Population)

Study Period: Controlled Treatment Period

Visit	Eye Structure		rhNGF 10 µg/ml (N=52)	rhNGF 20 µg/ml (N=52)	Vehicle Control (N=52)
Baseline	Vitreous	Normal	30 (90.9%)	29 (85.3%)	30 (90.9%)
		Abnormal	3 (9.1%)	5 (14.7%)	3 (9.1%)
	Retina/Macula	Normal	27 (84.4%)	22 (68.8%)	24 (75.0%)
		Abnormal	5 (15.6%)	10 (31.3%)	8 (25.0%)
	Choroid	Normal	31 (96.9%)	28 (90.3%)	29 (93.5%)
		Abnormal	1 (3.1%)	3 (9.7%)	2 (6.5%)
	Optic Nerve	Normal	31 (96.9%)	29 (87.9%)	29 (90.6%)
		Abnormal	1 (3.1%)	4 (12.1%)	3 (9.4%)
Week 8	Vitreous	Normal	29 (85.3%)	27 (81.8%)	26 (89.7%)
		Abnormal	5 (14.7%)	6 (18.2%)	3 (10.3%)
	Retina/Macula	Normal	28 (82.4%)	23 (76.7%)	20 (71.4%)
		Abnormal	6 (17.6%)	7 (23.3%)	8 (28.6%)
	Choroid	Normal	31 (91.2%)	29 (93.5%)	23 (85.2%)
		Abnormal	3 (8.8%)	2 (6.5%)	4 (14.8%)
	Optic Nerve	Normal	30 (88.2%)	28 (87.5%)	24 (92.3%)
		Abnormal	4 (11.8%)	4 (12.5%)	2 (7.7%)

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 Uncontrolled Treatment Period and Follow-Up Period.
Percentages are calculated using the number of non-missing responses in each treatment group as the denominator.
The data presented in this Table are contained in Listing 16.2.9.5b

Table 14.3.8.1b Summary of Fundus Ophthalmoscopy by Treatment and Visit
(Safety Population)

Study Period: Uncontrolled Treatment Period

Visit	Eye Structure		rhNGF 10 µg/ml (N=10)	rhNGF 20 µg/ml (N=13)
Week 16	Vitreous	Normal	3 (100.0%)	8 (72.7%)
		Abnormal	0	3 (27.3%)
	Retina/Macula	Normal	1 (50.0%)	9 (90.0%)
		Abnormal	1 (50.0%)	1 (10.0%)
	Choroid	Normal	3 (100.0%)	9 (90.0%)
		Abnormal	0	1 (10.0%)
	Optic Nerve	Normal	2 (66.7%)	7 (70.0%)
		Abnormal	1 (33.3%)	3 (30.0%)

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 Uncontrolled Treatment Period and Follow-Up Period.
Percentages are calculated using the number of non-missing responses in each treatment group as the denominator.
The data presented in this Table are contained in Listing 16.2.9.5b

Table 14.3.8.1b Summary of Fundus Ophthalmoscopy by Treatment and Visit
(Safety Population)

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

Visit	Eye Structure		rhNGF 10 µg/ml (N=62)	rhNGF 20 µg/ml (N=65)	Vehicle Control (N=29)
Week 12/20	Vitreous	Normal	28 (93.3%)	33 (86.8%)	17 (94.4%)
		Abnormal	2 (6.7%)	5 (13.2%)	1 (5.6%)
	Retina/Macula	Normal	23 (79.3%)	32 (86.5%)	14 (77.8%)
		Abnormal	6 (20.7%)	5 (13.5%)	4 (22.2%)
	Choroid	Normal	29 (96.7%)	36 (97.3%)	15 (88.2%)
		Abnormal	1 (3.3%)	1 (2.7%)	2 (11.8%)
	Optic Nerve	Normal	29 (96.7%)	33 (89.2%)	15 (93.8%)
		Abnormal	1 (3.3%)	4 (10.8%)	1 (6.3%)
Week 56/64	Vitreous	Normal	11 (100.0%)	10 (100.0%)	6 (100.0%)
		Abnormal	0	0	0
	Retina/Macula	Normal	8 (72.7%)	10 (90.9%)	4 (66.7%)
		Abnormal	3 (27.3%)	1 (9.1%)	2 (33.3%)
	Choroid	Normal	11 (100.0%)	10 (90.9%)	5 (83.3%)
		Abnormal	0	1 (9.1%)	1 (16.7%)

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 Uncontrolled Treatment Period and Follow-Up Period.

Percentages are calculated using the number of non-missing responses in each treatment group as the denominator.

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 16.2.9.5b

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Table 14.3.8.1b Summary of Fundus Ophthalmoscopy by Treatment and Visit
(Safety Population)

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

Visit	Eye Structure		rhNGF 10 µg/ml (N=62)	rhNGF 20 µg/ml (N=65)	Vehicle Control (N=29)
Week 56/64	Optic Nerve	Normal	10 (100.0%)	10 (90.9%)	5 (83.3%)
		Abnormal	0	1 (9.1%)	1 (16.7%)
Early Exit	Vitreous	Normal	1 (100.0%)	0	0
		Abnormal	0	0	0
	Retina/Macula	Normal	1 (100.0%)	0	0
		Abnormal	0	0	0
	Choroid	Normal	1 (100.0%)	0	0
		Abnormal	0	0	0
	Optic Nerve	Normal	1 (100.0%)	0	0
		Abnormal	0	0	0

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 Uncontrolled Treatment Period and Follow-Up Period.
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Table 14.3.8.1b Summary of Fundus Ophthalmoscopy by Treatment and Visit
(Safety Population)

Study Period: Follow-Up Period (48 Weeks)

Visit	Eye Structure		rhNGF 10 µg/ml (N=52)	rhNGF 20 µg/ml (N=52)	Vehicle Control (N=29)
Week 12	Vitreous	Normal	25 (92.6%)	25 (86.2%)	17 (94.4%)
		Abnormal	2 (7.4%)	4 (13.8%)	1 (5.6%)
	Retina/Macula	Normal	22 (84.6%)	23 (82.1%)	14 (77.8%)
		Abnormal	4 (15.4%)	5 (17.9%)	4 (22.2%)
	Choroid	Normal	26 (96.3%)	27 (96.4%)	15 (88.2%)
		Abnormal	1 (3.7%)	1 (3.6%)	2 (11.8%)
	Optic Nerve	Normal	26 (96.3%)	25 (89.3%)	15 (93.8%)
		Abnormal	1 (3.7%)	3 (10.7%)	1 (6.3%)
Week 56	Vitreous	Normal	9 (100.0%)	8 (100.0%)	6 (100.0%)
		Abnormal	0	0	0
	Retina/Macula	Normal	7 (77.8%)	8 (88.9%)	4 (66.7%)
		Abnormal	2 (22.2%)	1 (11.1%)	2 (33.3%)
	Choroid	Normal	9 (100.0%)	8 (88.9%)	5 (83.3%)
		Abnormal	0	1 (11.1%)	1 (16.7%)

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 Uncontrolled Treatment Period and Follow-Up Period.

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Table 14.3.8.1b Summary of Fundus Ophthalmoscopy by Treatment and Visit
(Safety Population)

Study Period: Follow-Up Period (48 Weeks)

Visit	Eye Structure		rhNGF 10 µg/ml (N=52)	rhNGF 20 µg/ml (N=52)	Vehicle Control (N=29)
Week 56	Optic Nerve	Normal	8 (100.0%)	8 (88.9%)	5 (83.3%)
		Abnormal	0	1 (11.1%)	1 (16.7%)
Early Exit	Vitreous	Normal	1 (100.0%)	0	0
		Abnormal	0	0	0
	Retina/Macula	Normal	1 (100.0%)	0	0
		Abnormal	0	0	0
	Choroid	Normal	1 (100.0%)	0	0
		Abnormal	0	0	0
	Optic Nerve	Normal	1 (100.0%)	0	0
		Abnormal	0	0	0
		Normal			
		Abnormal			

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 Uncontrolled Treatment Period and Follow-Up Period.

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Table 14.3.8.1b Summary of Fundus Ophthalmoscopy by Treatment and Visit
(Safety Population)

Study Period: Follow-Up Period (56 Weeks)

Visit	Eye Structure		rhNGF 10 µg/ml (N=10)	rhNGF 20 µg/ml (N=13)
Week 20	Vitreous	Normal	3 (100.0%)	8 (88.9%)
		Abnormal	0	1 (11.1%)
	Retina/Macula	Normal	1 (33.3%)	9 (100.0%)
		Abnormal	2 (66.7%)	0
	Choroid	Normal	3 (100.0%)	9 (100.0%)
		Abnormal	0	0
	Optic Nerve	Normal	3 (100.0%)	8 (88.9%)
		Abnormal	0	1 (11.1%)
Week 64	Vitreous	Normal	2 (100.0%)	2 (100.0%)
		Abnormal	0	0
	Retina/Macula	Normal	1 (50.0%)	2 (100.0%)
		Abnormal	1 (50.0%)	0
	Choroid	Normal	2 (100.0%)	2 (100.0%)
		Abnormal	0	0

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 Uncontrolled Treatment Period and Follow-Up Period.

Percentages are calculated using the number of non-missing responses in each treatment group as the denominator.

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

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Table 14.3.8.1b Summary of Fundus Ophthalmoscopy by Treatment and Visit
(Safety Population)

Study Period: Follow-Up Period (56 Weeks)

Visit	Eye Structure		rhNGF 10 µg/ml (N=10)	rhNGF 20 µg/ml (N=13)
Week 64	Optic Nerve	Normal	2 (100.0%)	2 (100.0%)
		Abnormal	0	0

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 Uncontrolled Treatment Period and Follow-Up Period. Percentages are calculated using the number of non-missing responses in each treatment group as the denominator. 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 16.2.9.5b