

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

Study Period: Controlled Treatment Period

Visit	Eye Structure		rhNGF 10 µg/ml (N=7)	rhNGF 20 µg/ml (N=7)	Vehicle Control (N=4)
Baseline	Vitreous	Normal	4 (100.0%)	4 (100.0%)	1 (50.0%)
		Abnormal	0	0	1 (50.0%)
	Retina/Macula	Normal	3 (75.0%)	3 (75.0%)	1 (50.0%)
		Abnormal	1 (25.0%)	1 (25.0%)	1 (50.0%)
	Choroid	Normal	4 (100.0%)	4 (100.0%)	1 (50.0%)
		Abnormal	0	0	1 (50.0%)
	Optic Nerve	Normal	3 (75.0%)	4 (100.0%)	1 (50.0%)
		Abnormal	1 (25.0%)	0	1 (50.0%)
Week 2	Vitreous	Normal	3 (75.0%)	4 (100.0%)	2 (100.0%)
		Abnormal	1 (25.0%)	0	0
	Retina/Macula	Normal	3 (75.0%)	3 (75.0%)	1 (50.0%)
		Abnormal	1 (25.0%)	1 (25.0%)	1 (50.0%)
	Choroid	Normal	4 (100.0%)	4 (100.0%)	1 (50.0%)
		Abnormal	0	0	1 (50.0%)
	Optic Nerve	Normal	3 (75.0%)	4 (100.0%)	1 (50.0%)
		Abnormal	1 (25.0%)	0	1 (50.0%)

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 16.2.9.5a

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

Study Period: Controlled Treatment Period

Visit	Eye Structure		rhNGF 10 µg/ml (N=7)	rhNGF 20 µg/ml (N=7)	Vehicle Control (N=4)
Week 4	Vitreous	Normal	4 (100.0%)	4 (100.0%)	2 (100.0%)
		Abnormal	0	0	0
	Retina/Macula	Normal	3 (75.0%)	3 (75.0%)	1 (50.0%)
		Abnormal	1 (25.0%)	1 (25.0%)	1 (50.0%)
Choroid	Normal	4 (100.0%)	3 (100.0%)	2 (100.0%)	
	Abnormal	0	0	0	
Optic Nerve	Normal	3 (75.0%)	3 (100.0%)	2 (100.0%)	
	Abnormal	1 (25.0%)	0	0	
Week 8	Vitreous	Normal	4 (100.0%)	4 (100.0%)	1 (100.0%)
		Abnormal	0	0	0
	Retina/Macula	Normal	3 (75.0%)	3 (75.0%)	0
		Abnormal	1 (25.0%)	1 (25.0%)	1 (100.0%)
Choroid	Normal	4 (100.0%)	3 (75.0%)	1 (100.0%)	
	Abnormal	0	1 (25.0%)	0	
Optic Nerve	Normal	3 (75.0%)	4 (100.0%)	0	
	Abnormal	1 (25.0%)	0	1 (100.0%)	

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

Study Period: Uncontrolled Treatment Period

Visit	Eye Structure	rhNGF 10 µg/ml (N=0)	rhNGF 20 µg/ml (N=0)
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No data for this study period

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.

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Table 14.3.8.1a 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=7)	rhNGF 20 µg/ml (N=7)	Vehicle Control (N=4)
Week 12/20	Vitreous	Normal	3 (75.0%)	3 (100.0%)	1 (100.0%)
		Abnormal	1 (25.0%)	0	0
	Retina/Macula	Normal	3 (75.0%)	3 (100.0%)	0
		Abnormal	1 (25.0%)	0	1 (100.0%)
Choroid	Normal	4 (100.0%)	3 (100.0%)	0	
	Abnormal	0	0	1 (100.0%)	
Optic Nerve	Normal	3 (75.0%)	3 (100.0%)	1 (100.0%)	
	Abnormal	1 (25.0%)	0	0	
Week 56/64	Vitreous	Normal	4 (100.0%)	4 (100.0%)	1 (100.0%)
		Abnormal	0	0	0
	Retina/Macula	Normal	3 (75.0%)	4 (100.0%)	0
Abnormal		1 (25.0%)	0	1 (100.0%)	
Choroid	Normal	4 (100.0%)	4 (100.0%)	0	
	Abnormal	0	0	1 (100.0%)	

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 14.3.8.1a 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=7)	rhNGF 20 µg/ml (N=7)	Vehicle Control (N=4)
Week 56/64	Optic Nerve	Normal	3 (75.0%)	4 (100.0%)	1 (100.0%)
		Abnormal	1 (25.0%)	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 14.3.8.1a 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=7)	rhNGF 20 µg/ml (N=7)	Vehicle Control (N=4)
Week 12	Vitreous	Normal	3 (75.0%)	3 (100.0%)	1 (100.0%)
		Abnormal	1 (25.0%)	0	0
	Retina/Macula	Normal	3 (75.0%)	3 (100.0%)	0
		Abnormal	1 (25.0%)	0	1 (100.0%)
Choroid	Normal	4 (100.0%)	3 (100.0%)	0	
	Abnormal	0	0	1 (100.0%)	
Optic Nerve	Normal	3 (75.0%)	3 (100.0%)	1 (100.0%)	
	Abnormal	1 (25.0%)	0	0	
Week 56	Vitreous	Normal	4 (100.0%)	4 (100.0%)	1 (100.0%)
		Abnormal	0	0	0
	Retina/Macula	Normal	3 (75.0%)	4 (100.0%)	0
Abnormal		1 (25.0%)	0	1 (100.0%)	
Choroid	Normal	4 (100.0%)	4 (100.0%)	0	
	Abnormal	0	0	1 (100.0%)	

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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(Safety Population)

Study Period: Follow-Up Period (48 Weeks)

Visit	Eye Structure		rhNGF 10 µg/ml (N=7)	rhNGF 20 µg/ml (N=7)	Vehicle Control (N=4)
Week 56	Optic Nerve	Normal	3 (75.0%)	4 (100.0%)	1 (100.0%)
		Abnormal	1 (25.0%)	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 14.3.8.1a 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=0)	rhNGF 20 µg/ml (N=0)
No data for this study period			

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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