

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

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.
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

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	rhNGF 20 µg/ml
		(N=0)	(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. 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

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.
The data presented in this Table are contained in Listing 16.2.9.5a

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. 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 16.2.9.5a

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.
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 16.2.9.5a

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 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. 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 16.2.9.5a

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. 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 16.2.9.5a