Table 14.3.1.1b Summary of Adverse Events by Treatment and Overall
(Safety Population)

Study Period: Controlled Treatment Period

	rhNGF 10 µg/ml (N=52)			rhNGF 20 µg/ml (N=52)			Vehicle Control (N=52)			Total (N=156)		
	N*	n	%	N*	n	%	N*	n	%	N*	n	%
Any Adverse Events	54	23	(44.2%)	51	27	(51.9%)	50	20	(38.5%)	155	70	(44.9%)
Adverse Events Leading to Discontinuation of Study Treatment	2	2	(3.8%)	14	9	(17.3%)	6	4	(7.7%)	22	15	(9.6%)
Treatment-Related Adverse Events	10	6	(11.5%)	15	9	(17.3%)	20	10	(19.2%)	45	25	(16.0%)
Any Serious Adverse Events	5	3	(5.8%)	10	9	(17.3%)	5	5	(9.6%)	20	17	(10.9%)
Serious Treatment-Related Adverse Events	0	0		0	0		0	0		0	0	
Adverse Events Leading to Death	1	1	(1.9%)	1	1	(1.9%)	0	0		2	2	(1.3%)

N* = Number of Events Reported, n = Number of Patients, % = Percentage of Patients.
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 population number in each treatment group (N) as the denominator.
Treatment-Related Adverse Events are those events having a relationship to study treatment recorded as Possible, Probable or Highly Probable.
The data presented in this Table are contained in Listing 16.2.7.1b

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Table 14.3.1.1b Summary of Adverse Events by Treatment and Overall
(Safety Population)

Study Period: Uncontrolled Treatment Period

	rhNGF 10 µg/ml (N=10)			rhNGF 20 µg/ml (N=13)			Total (N=23)		
	N*	n	%	N*	n	%	N*	n	%
Any Adverse Events	6	4	(40.0%)	16	7	(53.8%)	22	11	(47.8%)
Adverse Events Leading to Discontinuation of Study Treatment	1	1	(10.0%)	0	0		1	1	(4.3%)
Treatment-Related Adverse Events	2	2	(20.0%)	6	2	(15.4%)	8	4	(17.4%)
Any Serious Adverse Events	1	1	(10.0%)	1	1	(7.7%)	2	2	(8.7%)
Serious Treatment-Related Adverse Events	1	1	(10.0%)	0	0		1	1	(4.3%)
Adverse Events Leading to Death	0	0		0	0		0	0	

N* = Number of Events Reported, n = Number of Patients, % = Percentage of Patients.
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 population number in each treatment group (N) as the denominator.
Treatment-Related Adverse Events are those events having a relationship to study treatment recorded as Possible, Probable or Highly Probable.
The data presented in this Table are contained in Listing 16.2.7.1b

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Table 14.3.1.1b Summary of Adverse Events by Treatment and Overall
(Safety Population)

Study Period: Follow-Up Period

	rhNGF 10 µg/ml (N=62)			rhNGF 20 µg/ml (N=65)			Vehicle Control (N=29)			Total (N=156)		
	N*	n	%	N*	n	%	N*	n	%	N*	n	%
Any Adverse Events	75	22	(35.5%)	51	17	(26.2%)	15	9	(31.0%)	141	48	(30.8%)
Adverse Events Leading to Discontinuation of Study Treatment	1	1	(1.6%)	1	1	(1.5%)	1	1	(3.4%)	3	3	(1.9%)
Treatment-Related Adverse Events	1	1	(1.6%)	0	0		2	1	(3.4%)	3	2	(1.3%)
Any Serious Adverse Events	22	10	(16.1%)	7	6	(9.2%)	2	2	(6.9%)	31	18	(11.5%)
Serious Treatment-Related Adverse Events	0	0		0	0		0	0		0	0	
Adverse Events Leading to Death	7	4	(6.5%)	1	1	(1.5%)	1	1	(3.4%)	9	6	(3.8%)

N* = Number of Events Reported, n = Number of Patients, % = Percentage of Patients.
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 population number in each treatment group (N) as the denominator.
Treatment-Related Adverse Events are those events having a relationship to study treatment recorded as Possible, Probable or Highly Probable.
Events are categorised according to the last treatment received from the controlled or uncontrolled treatment periods.
Note: Patient 312006 was allocated to Vehicle Control in the Controlled Treatment Period and is categorised as such in this table, but received an unscheduled course of rhNGF 20 µg/ml, which was discontinued due to the AE, Herpes simplex ophthalmic, during follow-up.
Patient 350002 was allocated to Vehicle Control in the Controlled Treatment Period and is categorised as such in this table; however, the treatment-related AEs 'Dry eye' and 'Eye lid pain' occurred during follow-up, while the patient was being treated with an unscheduled course of rhNGF 10 µg/ml.
The data presented in this Table are contained in Listing 16.2.7.1b

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