

Table 14.3.1.5a Summary of Treatment-Related Adverse Events by System Organ Class, Preferred Term, Treatment and Overall
(Safety Population)

Study Period: Controlled Treatment Period

Body System MedDRA Preferred Term	rhNGF 10 µg/ml (N=7)			rhNGF 20 µg/ml (N=7)			Vehicle Control (N=4)			Total (N=18)		
	N*	n	%	N*	n	%	N*	n	%	N*	n	%
Any Adverse Events	4	1	(14.3%)	12	3	(42.9%)	1	1	(25.0%)	17	5	(27.8%)
Eye disorders	3	1	(14.3%)	5	3	(42.9%)	1	1	(25.0%)	9	5	(27.8%)
Eye pain	0	0		2	2	(28.6%)	0	0		2	2	(11.1%)
Conjunctival hyperaemia	2	1	(14.3%)	0	0		0	0		2	1	(5.6%)
Erythema of eyelid	1	1	(14.3%)	0	0		0	0		1	1	(5.6%)
Eye inflammation	0	0		1	1	(14.3%)	0	0		1	1	(5.6%)
Eye irritation	0	0		1	1	(14.3%)	0	0		1	1	(5.6%)
Foreign body sensation in eyes	0	0		0	0		1	1	(25.0%)	1	1	(5.6%)
Photophobia	0	0		1	1	(14.3%)	0	0		1	1	(5.6%)
General disorders and administration site conditions	1	1	(14.3%)	3	2	(28.6%)	0	0		4	3	(16.7%)
Disease progression	1	1	(14.3%)	0	0		0	0		1	1	(5.6%)
Fatigue	0	0		1	1	(14.3%)	0	0		1	1	(5.6%)
Instillation site pruritus	0	0		1	1	(14.3%)	0	0		1	1	(5.6%)
Irritability	0	0		1	1	(14.3%)	0	0		1	1	(5.6%)

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.

Body system and preferred terms are sorted by descending frequency of patient count in the Total column.

The data presented in this Table are contained in Listing 16.2.7.2a

Table 14.3.1.5a Summary of Treatment-Related Adverse Events by System Organ Class, Preferred Term, Treatment and Overall
(Safety Population)

Study Period: Controlled Treatment Period

Body System MedDRA Preferred Term	rhNGF 10 µg/ml (N=7)			rhNGF 20 µg/ml (N=7)			Vehicle Control (N=4)			Total (N=18)		
	N*	n	%	N*	n	%	N*	n	%	N*	n	%
Nervous system disorders	0	0		2	2	(28.6%)	0	0		2	2	(11.1%)
Headache	0	0		2	2	(28.6%)	0	0		2	2	(11.1%)
Cardiac disorders	0	0		1	1	(14.3%)	0	0		1	1	(5.6%)
Cardiovascular disorder	0	0		1	1	(14.3%)	0	0		1	1	(5.6%)
Musculoskeletal and connective tissue disorders	0	0		1	1	(14.3%)	0	0		1	1	(5.6%)
Muscle spasms	0	0		1	1	(14.3%)	0	0		1	1	(5.6%)

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.

Body system and preferred terms are sorted by descending frequency of patient count in the Total column.

The data presented in this Table are contained in Listing 16.2.7.2a

Table 14.3.1.5a Summary of Treatment-Related Adverse Events by System Organ Class, Preferred Term, Treatment and Overall
(Safety Population)

Study Period: Uncontrolled Treatment Period

Body System MedDRA Preferred Term	rhNGF 10 µg/ml (N=0)			rhNGF 20 µg/ml (N=0)			Total (N=0)		
	N*	n	%	N*	n	%	N*	n	%
Any Adverse Events	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.

Body system and preferred terms are sorted by descending frequency of patient count in the Total column.

The data presented in this Table are contained in Listing 16.2.7.2a

Table 14.3.1.5a Summary of Treatment-Related Adverse Events by System Organ Class, Preferred Term, Treatment and Overall
(Safety Population)

Study Period: Follow-Up Period

Body System MedDRA Preferred Term	rhNGF 10 µg/ml (N=7)			rhNGF 20 µg/ml (N=7)			Vehicle Control (N=4)			Total (N=18)		
	N*	n	%	N*	n	%	N*	n	%	N*	n	%
Any Adverse Events	0	0		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.

Body system and preferred terms are sorted by descending frequency of patient count in the Total column.

Events 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 16.2.7.2a