

Listing 16.2.7.1b Adverse Events

Unique Patient Number	Treatment Group	Study Period [1]	AE #	Eye*	SOC PT AE Term	Onset Date	Resolution Date	Int [2]	SAE [3]	SAE Criteria [3]	Rel [4]	Act [5]	Other Action [6]	Other Action Specify	Out [7]
310003	rhNGF 20 µg/ml	1	1	Left	Immune system disorders/ Corneal graft rejection/ ENDOTHELIAL REJECTION (KERATOPLASTY)	14JAN2014	05FEB2014	2	Yes	6	2	1	4		1
310004	rhNGF 20 µg/ml	3	1	Left	Eye disorders/ Conjunctivitis/ CONJUNCTIVITES	15JAN2015	22JAN2015	1	No		1	5	2		1
310006	rhNGF 20 µg/ml	1	1		Nervous system disorders/ Headache/ HEADACHE	24DEC2014	24DEC2014	1	No		1	2	2		1
310007	rhNGF 10 µg/ml	2	1	Left	General disorders and administration site conditions/ Disease progression/ NEUROTROPHIC KERATITIS WORSENING	25FEB2015	04MAR2015	3	Yes	6	3	1	1		1

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[1] Study Period: 1: Controlled Treatment Period, 2: Uncontrolled Treatment Period, 3: Follow-Up Period

[2] Intensity: 1: Mild, 2: Moderate, 3: Severe

[3] SAE Criteria: 1: Death, 2: Life-threatening, 3: Requires hospitalization or prolongs hospitalization, 4: Significant incapacity/substantial disruption, 5: Congenital anomaly or birth defect, 6: Other medically important condition

[4] Relationship to Study Treatment: 1: None (Intercurrent Event), 2: Unlikely (Remote), 3: Possible, 4: Probable, 5: Highly Probable

[5] Action Taken with Study Treatment: 1: Drug Withdrawn, 2: Dose Not Changed, 3: Unknown, 4: Drug Interrupted 5: Not Applicable

[6] Other Action Taken: 1: None, 2: Concomitant Medication, 3: Concomitant Procedures, 4: Withdrawn, 5: Other

[7] Outcome: 1: Resolved, 2: Not Resolved, 3: Fatal, 4: Unknown

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311004	rhNGF 10 µg/ml	1	1		Nervous system disorders/ Trigeminal neuralgia/ LEFT TRIGEMINAL NEURALGIA	11MAR2014	Ongoing	2	No		1	2	2		2
		3	2		Injury, poisoning and procedural complications/ Pelvic fracture/ TRAUMATIC PELVIS BONE FRACTURE	NOV2014	DEC2014	2	No		1	5	1		1
311006	rhNGF 20 µg/ml	1	1		Gastrointestinal disorders/ Vomiting/ VOMITING	01DEC2014	04DEC2014	1	No		1	2	1		1
311007	Vehicle Control	3	1		Respiratory, thoracic and mediastinal disorders/ Respiratory failure/ RESPIRATORY FAILURE	17JAN2015	17JAN2015	3	Yes	1	1	5	5	NOT APPLICABLE	3

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312004	rhNGF 20 µg/ml	2	1	Left	Eye disorders/ Visual acuity reduced/ VISUAL ACUITY LOSS OF 20 LETTERS AT 4 METRES IN BCDVA	13MAR2015	10APR2015	1	No	1	5	1		1
312006	Vehicle Control	3	1	Left	Infections and infestations/ Herpes simplex ophthalmic/ NEW INFECTION DUE TO HERPES SIMPLEX VIRUS - EYES	03JUL2015	Ongoing	3	No	1	1	2/4		4
313003	rhNGF 10 µg/ml	3	1		Cardiac disorders/ Cardiac failure/ HEART FAILURE	17AUG2014	17AUG2014	3	Yes	1	5	4		3
313004	Vehicle Control	3	1		Injury, poisoning and procedural complications/ Femur fracture/ FEMUR FRACTURE	JUN2014	JUL2014	3	Yes	3	5	1		1

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313008	rhNGF 20 µg/ml	1	1		Infections and infestations/ Influenza/ COMMON FLU	22OCT2014	31OCT2014	1	No	1	2	2		1
		3	2		Respiratory, thoracic and mediastinal disorders/ Respiratory failure/ RESPIRATORY FAILURE	05JAN2015	05JAN2015	3	Yes	1	1	5	1	3
314002	rhNGF 10 µg/ml	3	1	Right	Eye disorders/ Lenticular opacities/ LENS OPACIFICATION	22JAN2015	Ongoing	2	No	1	5	1		2
314004	rhNGF 10 µg/ml	3	1	Both	Eye disorders/ Blepharitis/ BLEPHARITIS	17DEC2014	Ongoing	3	No	1	5	2		2
314007	Vehicle Control	3	1	Both	Eye disorders/ Blepharitis/ BLEPHARITIS	18DEC2014	Ongoing	2	No	1	5	2		2

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314008	rhNGF 20 µg/ml	1	1	Left	Eye disorders/ Blepharitis/ BLEPHARITIS	23OCT2014	Ongoing	1	No	3	2	2		4
314009	rhNGF 20 µg/ml	2	1	Right	Eye disorders/ Blepharitis/ BLEPHARITIS	16DEC2014	Ongoing	2	No	2	2	2		2
314011	rhNGF 10 µg/ml	1	1	Left	Eye disorders/ Eye irritation/ WORSENING OF EXISTING BURNING/STINGING SYMPTOM IN THE STUDY LEFT EYE	18DEC2014	30DEC2014	1	No	3	2	1		1
314013	rhNGF 10 µg/ml	1	1	Right	Eye disorders/ Visual acuity reduced/ VISUAL ACUITY LOSS OF 10 LETTERS AT 4 METERS AND 5 LETTERS AT 1 METER	12FEB2015	Ongoing	2	No	1	2	1		4

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314013	rhNGF 10 µg/ml	1	2	Right	Eye disorders/ Blepharitis/ BLEPHARITIS	19FEB2015	Ongoing	2	No	2	2	2		4
315004	rhNGF 20 µg/ml	1	1	Left	Eye disorders/ Eye inflammation/ INTRAOCULAR INFLAMMATION	20MAR2014	27MAR2014	2	Yes	6	2	1	4	1
315005	rhNGF 10 µg/ml	3	1		Cardiac disorders/ Myocardial infarction/ DEATH FOR HEART ATTACK	03MAY2015	03MAY2015	3	Yes	1	1	5	1	3
315009	rhNGF 10 µg/ml	1	1	Left	Eye disorders/ Blepharitis/ BLEPHARITIS	22OCT2014	29OCT2014	1	No	3	2	1		1

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315013	Vehicle Control	1	1	Left	General disorders and administration site conditions/ Disease progression/ INCREASED SIZE LESION- NEUROTROPHIC KERATITIS ULCER	11FEB2015	19FEB2015	2	No	5	1	1		1
315014	rhNGF 20 µg/ml	1	1		Vascular disorders/ Aortic dissection/ AORTIC DISSECTION	26JAN2015	Ongoing	3	Yes	3	1	4	1	4
		3	2	Right	Eye disorders/ Lacrimation decreased/ TEARING DECREASED	01JUN2015	Ongoing	1	No	1	5	2		4
316002	rhNGF 10 µg/ml	1	1	Left	Eye disorders/ Lacrimation increased/ INCREASED TEARING	24MAR2014	27MAR2014	1	No	1	5	1		1

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316002	rhNGF 10 µg/ml	1	2		Infections and infestations/ Oral herpes/ HERPES LABIALIS	06APR2014	12APR2014	1	No	1	2	1		1
318002	Vehicle Control	1	1	Left	Eye disorders/ Visual acuity reduced/ DECREASE OF VISUAL ACUITY	29JAN2015	26FEB2015	2	No	2	1	5	UNBLIND	1
			2	Left	General disorders and administration site conditions/ Disease progression/ WORSENING OF THE NEUROTROPHIC CORNEAL ULCER IN OS	29JAN2015	26FEB2015	2	Yes	6	1	5	UNBLIND	1
318005	Vehicle Control	1	1	Left	Eye disorders/ Visual acuity reduced/ DECREASE VISUAL ACUITY (LESS 5 LETTERS)	19FEB2015	05MAR2015	2	Yes	6	1	5	UNBLIND	1

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318005	Vehicle Control	1	2	Left	General disorders and administration site conditions/ Disease progression/ INCREASE OF PUNCTATE KERATOPATHY	19FEB2015	05MAR2015	2	No		2	1	5	UNBLIND	1
318011	rhNGF 20 µg/ml	2	1	Left	Eye disorders/ Visual acuity reduced/ DECREASE VISUAL ACUITY(MORE THAN 10 LETTERS).	16MAR2015	31MAR2015	2	Yes	6	2	4	4		1
			2	Left	General disorders and administration site conditions/ Disease progression/ INCREASED SIZE LESION OF THE CORNEA	16MAR2015	31MAR2015	2	No		2	4	5	UNBLIND	1

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320001	rhNGF 10 µg/ml	1	1	Right	Eye disorders/ Vision blurred/ BLURRED VISION GRADE 2	06FEB2014	13MAR2014	2	No		2	2	1		1
			3	Right	Eye disorders/ Corneal neovascularisation/ SEVERE NEOVASCULARIZATION	23APR2014	20JUN2014	3	Yes	4	2	5	3/4		1
			3	Right	Eye disorders/ Corneal opacity/ CORNEAL OPACITY	13MAY2014	20JUN2014	3	Yes	4	2	5	3		1
			4	Right	Eye disorders/ Ulcerative keratitis/ NEW CORNEAL ULCER	13MAY2014	20JUN2014	3	Yes	4	2	5	3/4		1
320003	Vehicle Control	1	1	Left	Eye disorders/ Corneal oedema/ CORNEAL EDEMA-NEW	25NOV2014	02DEC2014	3	Yes	4	2	2	2		1

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321002	rhNGF 10 µg/ml	1	1	Left	Infections and infestations/ Corneal infection/ CORNEAL INFECTION	22FEB2015	25FEB2015	2	No		1	1	4		1
321003	rhNGF 20 µg/ml	1	1		Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Malignant neoplasm progression/ LUNG CANCER PROGRESSION	2015	07APR2015	3	Yes	1	1	1	1		3
			2	Left	General disorders and administration site conditions/ Disease progression/ PROGRESSION OF CORNEAL ULCER OS	09MAR2015	Ongoing	2	Yes	6	2	1	4		2
322003	Vehicle Control	3	1	Right	Eye disorders/ Ocular hyperaemia/ RED EYE	03OCT2014	14OCT2014	2	No		1	5	1		1

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322004	rhNGF 20 µg/ml	3	1	Left	Eye disorders/ Keratitis/ CORNEAL INFLAMMATION	26AUG2014	29OCT2014	1	No	2	5	2		1
322005	rhNGF 20 µg/ml	1	1	Right	Eye disorders/ Keratitis/ CORNEAL INFLAMMATION	25JUN2014	Ongoing	2	No	2	1	4		2
323001	rhNGF 10 µg/ml	1	1		Vascular disorders/ Hypertension/ HIGH BLOOD PRESSURE- PUNCTUAL EVENT OF PREVIOUS MEDICAL CONDITION	16DEC2014	22DEC2014	1	No	2	2	1		1
			2	Right	Eye disorders/ Corneal endotheliitis/ CORNEAL ENDOTHELIAL INFLAMMATION	22DEC2014	15JAN2015	1	Yes	6	1	1	2	1

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326001	rhNGF 20 µg/ml	1	1	Right	Infections and infestations/ Conjunctivitis bacterial/ POSSIBLE BACTERIAL CONJUNCTIVITIS	07NOV2014	26NOV2014	1	No	1	2	2		1
			2		Blood and lymphatic system disorders/ Neutropenia/ REMOTE MEDICAMENTOUS SECONDARY NEUTROPHENY	05DEC2014	06FEB2015	1	No	3	5	1		1
326002	rhNGF 20 µg/ml	1	1	Right	Eye disorders/ Eye pain/ PERIOcular PAIN	30OCT2014	Ongoing	1	No	2	2	1		2
			2	Right	Eye disorders/ Macular fibrosis/ EPIRETINAL MEMBRANE	12DEC2014	Ongoing	1	No	3	5	1		2

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[3] SAE Criteria: 1: Death, 2: Life-threatening, 3: Requires hospitalization or prolongs hospitalization, 4: Significant incapacity/substantial disruption, 5: Congenital anomaly or birth defect, 6: Other medically important condition

[4] Relationship to Study Treatment: 1: None (Intercurrent Event), 2: Unlikely (Remote), 3: Possible, 4: Probable, 5: Highly Probable

[5] Action Taken with Study Treatment: 1: Drug Withdrawn, 2: Dose Not Changed, 3: Unknown, 4: Drug Interrupted 5: Not Applicable

[6] Other Action Taken: 1: None, 2: Concomitant Medication, 3: Concomitant Procedures, 4: Withdrawn, 5: Other

[7] Outcome: 1: Resolved, 2: Not Resolved, 3: Fatal, 4: Unknown

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Listing 16.2.7.1b Adverse Events

Unique Patient Number	Treatment Group	Study Period [1]	AE #	Eye*	SOC PT AE Term	Onset Date	Resolution Date	Int [2]	SAE [3]	Rel [4]	Act [5]	Other Action [6]	Other Action Specify	Out [7]
326002	rhNGF 20 µg/ml	3	3	Right	Infections and infestations/ Keratitis herpetic/ HERPETIC CORNEAL ULCER (NEW LESION)	06MAR2015	13MAR2015	2	No	2	5	2		1
326003	rhNGF 20 µg/ml	3	1	Left	Eye disorders/ Dry eye/ DRY EYE	30APR2015	Ongoing	1	No	1	5	2		4
331003	Vehicle Control	1	1	Left	Immune system disorders/ Corneal graft rejection/ GRAFT FAILURE (CONDITION AFTER PERFORATING KERATOPLASTIC, POSSIBLY DUE TO A IMMUNOLOGICAL REACTION)	06JAN2014	08JAN2014	3	No	2	2	2		1
			2	Left	Eye disorders/ Eyelid oedema/ BLEPHARAL SWELLING	20JAN2014	22JAN2014	1	No	3	2	1		1

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Listing 16.2.7.1b Adverse Events

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331003	rhNGF 10 µg/ml	2	3	Left	Eye disorders/ Ulcerative keratitis/ PERFORATING ULCER (CORNEA, OS)(RECURRENCE)	07FEB2014	10FEB2014	3	No	1	2	2		1
		3	4	Left	General disorders and administration site conditions/ Disease progression/ CORNEAL PERFORATION OS- AGGRAVATION OF CONDITION	27MAR2014	08APR2014	3	No	1	5	2		4
331004	rhNGF 20 µg/ml	1	1	Left	Eye disorders/ Eye pain/ EYE PAIN	16JUL2014	24JUL2014	2	No	3	2	2		1

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331004	rhNGF 20 µg/ml	1	2	Left	General disorders and administration site conditions/ Disease progression/ CORNEAL PERFORATION OS- AGGRAVATION OF CONDITION	23JUL2014	31JUL2014	3	Yes	3	2	1	2/3/4	1
331005	Vehicle Control	1	1	Right	Eye disorders/ Blepharitis/ BLEPHARITIS ANTERIOR	22DEC2014	29DEC2014	1	No		3	2	1	1
	rhNGF 10 µg/ml	2	2		Investigations/ Blood creatinine increased/ INCREASED CREATININE LAB RESULTS	30MAR2015	Ongoing	1	No		3	5	1	2
332003	rhNGF 20 µg/ml	2	1	Right	Eye disorders/ Eye irritation/ BURNING IN THE RIGHT EYE	21JAN2014	03APR2014	1	No		3	2	1	1

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332003	rhNGF 20 µg/ml	2	2	Right	Eye disorders/ Eye pain/ PAIN IN THE RIGHT EYE	21JAN2014	03APR2014	1	No		3	2	1		1
			3	Right	Eye disorders/ Blepharitis/ BLEPHARITIS	03FEB2014	24MAR2014	2	No		1	2	5	LIDRAISING	1
			4		Nervous system disorders/ Headache/ HEADACHE	09FEB2014	17FEB2014	1	No		1	2	1		1
		3	5		Infections and infestations/ Onychomycosis/ NAIL FUNGUS AT FOOT	06MAY2014	Ongoing	1	No		1	5	2		2
			6	Right	Eye disorders/ Corneal epithelium defect/ RECURRENCE PERSISTENT CORNEAL DEFECT; AMNIO INLAY+ONLAY	12JUN2014	16JUN2014	1	Yes	3	1	5	3		1

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332004	rhNGF 10 µg/ml	1	1	Right	Eye disorders/ Lacrimation increased/ RIGHT EYE STRONG LACRIMANTS	20MAR2014	26MAR2014	2	No	2	2	1		1
332010	rhNGF 20 µg/ml	1	1		Ear and labyrinth disorders/ Vertigo/ VERTIGO	20OCT2014	22OCT2014	2	Yes	3	1	2	1	1
		3	2		Nervous system disorders/ Headache/ HEADACHE	10FEB2015	13FEB2015	1	No	1	5	2		1
332011	Vehicle Control	1	1		Investigations/ Alanine aminotransferase increased/ ALT INCREASED	30SEP2014	25NOV2014	1	No	1	5	1		1
			2	Left	Eye disorders/ Eye pain/ PAIN IN THE LEFT EYE	02OCT2014	Ongoing	1	No	1	2	2		4

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332011	Vehicle Control	1	3		Infections and infestations/ Nasopharyngitis/ COMMON COLD	25OCT2014	29OCT2014	1	No		1	2	1		1
332012	rhNGF 20 µg/ml	1	1		Vascular disorders/ Venous thrombosis/ VENOUS THROMBOSIS	05NOV2014	19NOV2014	3	Yes	3	1	2	2		1
333002	rhNGF 10 µg/ml	1	1	Left	Nervous system disorders/ Neuralgia/ NEUROPATHIC PAIN AROUND THE UPPER EYELID	21FEB2014	20APR2014	1	No		3	2	1		1
			2	Left	Eye disorders/ Lacrimation increased/ EPIPHORA	23FEB2014	20APR2014	1	No		3	2	1		1
			3		Metabolism and nutrition disorders/ Hypertriglyceridaemia/ HYPERTRIGLYCERINEMIA	15APR2014	Ongoing	1	No		1	2	1		2

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333002	rhNGF 10 µg/ml	3	4		Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	10JUN2014	18JUN2014	3	Yes	3	1	5	3	1
			5		Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	19JUN2014	Ongoing	2	No		1	5	2	2
			6		Infections and infestations/ Helicobacter gastritis/ HELICOBACTER PYLORI TYP B GASTRITIS	19JUN2014	25JUN2014	2	No		1	5	2	1
			7	Left	Eye disorders/ Corneal erosion/ CORNEAL EROSIO RECURRENCE	10JUL2014	24JUL2014	2	No		1	5	2/3	1

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333002	rhNGF 10 µg/ml	3	8	Left	Eye disorders/ Corneal erosion/ CORNEAL EROSIO RECURRENCE	25AUG2014	08SEP2014	2	No	1	5	2		1
			9	Left	Eye disorders/ Corneal erosion/ CORNEAL EROSIO RECURRENCE	15SEP2014	11NOV2014	2	No	1	5	2		1
			10	Left	Infections and infestations/ Herpes ophthalmic/ HERPETIC RECURRENCE LEFT EYE	30SEP2014	04NOV2014	2	No	1	2	2		1
			11	Left	Eye disorders/ Conjunctival haemorrhage/ CONJUNCTIVAL HEMETOMA	14OCT2014	11NOV2014	1	No	1	2	1		1
			12		Infections and infestations/ Nasopharyngitis/ COMMON COLD	02NOV2014	20NOV2014	1	No	1	2	1		1

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333002	rhNGF 10 µg/ml	3	13	Both	Eye disorders/ Conjunctivitis/ CONJUNCTIVITIS BOTH EYES	06NOV2014	09NOV2014	1	No	1	2	1		1
333003	rhNGF 20 µg/ml	1	1	Right	Immune system disorders/ Corneal graft rejection/ ENDOTHELIAL GRAFT REJECTION	09APR2014	30APR2014	2	No	1	2	2		1
			2		Metabolism and nutrition disorders/ Hypercholesterolaemia/ HYPERCHOLESTERINEMIA	14MAY2014	Ongoing	1	No	1	2	1		2
			3	Right	Immune system disorders/ Corneal graft rejection/ CHRONIC ENDOTHELIAL GRAFT REJECTION	14MAY2014	04AUG2014	2	No	1	5	2		1

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333003	rhNGF 20 µg/ml	3	4	Left	Eye disorders/ Keratitis/ KERATITIS FILIFORMIS	04AUG2014	22AUG2014	2	No	1	5	2		1
			5	Right	Eye disorders/ Corneal epithelium defect/ PERSISTENT EPITHELIAL DEFECT RECURRENCE	25AUG2014	31AUG2014	2	No	1	5	1		1
			6	Right	Immune system disorders/ Corneal graft rejection/ ENDOTHELIAL GRAFT REJECTION	25AUG2014	23SEP2014	2	No	1	5	2		1
			7	Right	Eye disorders/ Corneal erosion/ CORNEAL EROSIO RECURRENCE	01SEP2014	30SEP2014	2	No	1	2	2/5	2ND TREAT	1
			8		Infections and infestations/ Urinary tract infection/ URINARY TRACT INFECTION	12SEP2014	16SEP2014	2	No	1	2	2		1

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333003	rhNGF 20 µg/ml	3	9	Left	Eye disorders/ Keratitis/ KERATITIS FILIFORMIS	23SEP2014	28OCT2014	2	No	1	5	2		1
			10	Right	Infections and infestations/ Keratitis herpetic/ CORNEAL HERPETIC RECURRENCE	12OCT2014	26NOV2014	2	No	1	2	2		1
			11		Gastrointestinal disorders/ Abdominal pain upper/ STOMACHE PAIN	14OCT2014	15OCT2014	2	No	1	2	1		1
			12	Left	Eye disorders/ Keratitis/ KERATITIS FILIFORMIS	15NOV2014	19NOV2014	1	No	1	5	2		1
			13	Both	Eye disorders/ Blepharitis/ BLEPHARITIS	26NOV2014	Ongoing	1	No	1	5	2		2

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333003	rhNGF 20 µg/ml	3	14		Infections and infestations/ Cystitis/ CYSTITIS	15DEC2014	19DEC2014	2	No	1	5	2		1	
			15		Metabolism and nutrition disorders/ Hypokalaemia/ HYPOKALEMIA	21APR2015	27APR2015	2	No	1	5	2		1	
			16		Nervous system disorders/ Syncope/ VASOVAGAL SYNCOPE	21APR2015	06MAY2015	3	Yes	3	1	5	1		1
			17		Infections and infestations/ Cystitis/ CYSTITIS	28APR2015	30APR2015	2	No	1	5	2		1	
333004	Vehicle Control	1	1		Infections and infestations/ Gastroenteritis/ GASTROENTERITIS	20APR2014	26APR2014	2	No	1	2	2		1	

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Listing 16.2.7.1b Adverse Events

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333004	Vehicle Control	1	2	Right	Eye disorders/ Conjunctival hyperaemia/ INTERMITTENT CONJUNCTIVAL REDNESS FROM THE MORNING UNTIL ABOUT NOON	03MAY2014	25JUL2014	1	No	3	2	1		1
			3	Right	Eye disorders/ Lacrimation increased/ EPIPHORA	25MAY2014	25JUL2014	1	No	2	2	1		1
		3	4	Both	Eye disorders/ Ocular discomfort/ OCULAR DISCOMFORT	07JUN2014	Ongoing	2	No	1	5	2		2
			5	Right	Eye disorders/ Eye pain/ PAIN IN THE EYE	06JUL2014	06JUL2014	1	No	1	5	1		1
			6	Both	Eye disorders/ Blepharitis/ BLEPHARITIS	27NOV2014	29NOV2014	1	No	1	5	2		1

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[1] Study Period: 1: Controlled Treatment Period, 2: Uncontrolled Treatment Period, 3: Follow-Up Period

[2] Intensity: 1: Mild, 2: Moderate, 3: Severe

[3] SAE Criteria: 1: Death, 2: Life-threatening, 3: Requires hospitalization or prolongs hospitalization, 4: Significant incapacity/substantial disruption, 5: Congenital anomaly or birth defect, 6: Other medically important condition

[4] Relationship to Study Treatment: 1: None (Intercurrent Event), 2: Unlikely (Remote), 3: Possible, 4: Probable, 5: Highly Probable

[5] Action Taken with Study Treatment: 1: Drug Withdrawn, 2: Dose Not Changed, 3: Unknown, 4: Drug Interrupted 5: Not Applicable

[6] Other Action Taken: 1: None, 2: Concomitant Medication, 3: Concomitant Procedures, 4: Withdrawn, 5: Other

[7] Outcome: 1: Resolved, 2: Not Resolved, 3: Fatal, 4: Unknown

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Listing 16.2.7.1b Adverse Events

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333004	Vehicle Control	3	7		Infections and infestations/ Nasopharyngitis/ COMMON COLD	07FEB2015	14FEB2015	2	No	1	5	2		1
333005	Vehicle Control	1	1	Left	Eye disorders/ Abnormal sensation in eye/ STICKY FEELING IN THE EYE	31MAY2014	07JUN2014	1	No	5	2	5	UNMASKED	1
			2	Left	Eye disorders/ Vision blurred/ BLURRED VISION	31MAY2014	26JUN2014	2	No	5	2	5	UNMASKED	1
	rhNGF 10 µg/ml	2	3	Left	Immune system disorders/ Corneal graft rejection/ ENDOTHELIAL GRAFT REJECTION	18JUN2014	14SEP2014	3	No	1	2	2/3		2
			4	Left	Eye disorders/ Vision blurred/ BLURRY VISION	05JUL2014	13JUL2014	2	No	1	2	1		1

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333005	rhNGF 10 µg/ml	2	5		Renal and urinary disorders/ Renal colic/ RENAL COLIC	27JUL2014	28JUL2014	2	No	1	2	2		1		
			3	6	Left	Eye disorders/ Corneal erosion/ CORNEAL EROSIO RECURRENCE	12SEP2014	29OCT2014	2	No	1	5	2		1	
			7	7	Left	Injury, poisoning and procedural complications/ Transplant failure/ CHRONIC GRAFT FAILURE	15SEP2014	Ongoing	1	No	1	5	1		2	
			8	8	Left	Infections and infestations/ Herpes ophthalmic/ OPHTHALMIC HERPETIC RECURRENCE LEFT EYE	06OCT2014	09OCT2014	2	Yes	3	1	5	2		1
			9	9		Infections and infestations/ Nasopharyngitis/ COMMON COLD	23DEC2014	06JAN2015	1	No	1	5	1		1	

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333005	rhNGF 10 µg/ml	3	10	Left	Eye disorders/ Ulcerative keratitis/ ULCUS CORNEAE RECURRENCE	02JAN2015	13JAN2015	2	No	1	5	2		1
			11	Left	Eye disorders/ Corneal erosion/ CORNEAL EROSIO RECURRENCE	03MAR2015	30JUN2015	2	No	1	5	2		1
			12		Musculoskeletal and connective tissue disorders/ Intervertebral disc protrusion/ HERNIATED DISC CERVICAL 4-6	30APR2015	Ongoing	2	No	1	5	2/3		2
			13	Right	Eye disorders/ Cataract/ CATARACT	30JUN2015	Ongoing	1	No	1	5	1		2

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333006	rhNGF 10 µg/ml	1	1	Left	Eye disorders/ Posterior capsule opacification/ POSTERIOR CAPSULE OPACIFICATION (FELLOW EYE)	23JUN2014	02FEB2015	1	No	1	5	1		1
			2	Right	Eye disorders/ Photophobia/ ELEVATED PHOTOPHOBIA	11JUL2014	Ongoing	1	No	3	2	1		2
			3	Right	Eye disorders/ Eyelid pain/ PAIN IN THE UPPER EYELID	11JUL2014	17JUL2014	1	No	4	2	1		1
			4	Right	Eye disorders/ Posterior capsule opacification/ IOL WITH POSTERIOR OPACIFICATION	21JUL2014	28APR2015	1	No	1	2	1		1

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333006	rhNGF 10 µg/ml	1	5	Right	Eye disorders/ Eyelid pain/ PAIN IN THE UPPER EYE LID	30JUL2014	01SEP2014	1	No	4	2	1		1
		3	6		Injury, poisoning and procedural complications/ Tibia fracture/ FU TO MH TIBIA FRACTURE RIGHT SIDE	11SEP2014	11SEP2014	2	No	1	5	2/3		1
			7		Vascular disorders/ Hypertension/ HYPERTENSION	30SEP2014	20OCT2014	2	No	1	5	2		1
			8	Right	Eye disorders/ Vitreous haemorrhage/ VITREAL HEMORRHAGE	05NOV2014	27NOV2014	2	No	1	5	1		1

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333006	rhNGF 10 µg/ml	3	9	Left	Eye disorders/ Cataract/ YAG-CAPSULOTOMY CATARACTS	02FEB2015	02FEB2015	2	No	1	5	2/3		1
			10		Infections and infestations/ Sinusitis/ SINUSITIS	31MAR2015	10MAY2015	2	No	1	5	2		1
			11	Right	Eye disorders/ Vitreous haemorrhage/ VITREAL HEMORRHAGE	30APR2015	15MAY2015	2	No	1	5	1		1
			12		Skin and subcutaneous tissue disorders/ Diabetic foot/ DIABETIC FOOT ULCER	29JUN2015	09JUL2015	2	No	1	5	2		1

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334001	rhNGF 20 µg/ml	1	1	Right	Eye disorders/ Corneal neovascularisation/ INCREASED NEOVASCULARIZATION INTO CORNEAL GRAFT	20MAR2014	Ongoing	2	No		5	1	2/4		2
334002	Vehicle Control	1	1	Left	Eye disorders/ Corneal neovascularisation/ INCREASED CORNEAL NEOVASCULARISATION	27NOV2014	Ongoing	2	No		3	1	2/4		4
335002	rhNGF 10 µg/ml	1	1		Respiratory, thoracic and mediastinal disorders/ Respiratory distress/ RESPIRATORY DISTRESS	27NOV2013	15DEC2013	3	Yes	3	2	2	1		1
			2		Cardiac disorders/ Myocardial infarction/ MYOCARDIAL INFARCTION	28NOV2013	28NOV2013	3	Yes	3	2	2	1		1

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335002	rhNGF 10 µg/ml	1	3		Infections and infestations/ Diverticulitis/ DIVERTICULITIS	01DEC2013	20DEC2013	3	Yes	3	2	2	1	1
			4	Right	Injury, poisoning and procedural complications/ Periorbital haematoma/ LID HÅMATOMA, NOT TRAUMATIC	02JAN2014	27JAN2014	1	No		2	2	1	1
		3	5		Gastrointestinal disorders/ Diverticular perforation/ COVERED PERFORATION OF SIGMADIVERTICULITIS	21MAR2014	Ongoing	3	Yes	3	1	2	2	4
			6		Cardiac disorders/ Arrhythmia/ CARDIAC ARYTHMIA	08APR2014	08APR2014	3	Yes	1	1	5	1	3

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335002	rhNGF 10 µg/ml	3	7		Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DYSPNOE	08APR2014	08APR2014	3	Yes	1	1	5	1		3
335003	rhNGF 20 µg/ml	1	1		Infections and infestations/ Nasopharyngitis/ COLD SYMPTOMS	17DEC2013	24DEC2013	1	No		2	2	2		1
			2		Renal and urinary disorders/ Renal colic/ RENAL COLIC	24DEC2013	25DEC2013	3	Yes	3	2	2	1		1
			3	3	Left Eye disorders/ Blepharitis/ BLEPHARITIS	27JAN2014	06FEB2014	1	No		1	5	2		1
			4		Infections and infestations/ Nasopharyngitis/ COMMON COLD	10MAY2014	24MAY2014	2	No		1	5	2		1

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335003	rhNGF 20 µg/ml	3	5		Hepatobiliary disorders/ Cholelithiasis/ PAIN DUE TO BILIARY SLUSH	08SEP2014	09SEP2014	2	No	1	5	2		1
			6	Left	Eye disorders/ Corneal epithelium defect/ RECURRENCE OF EPITHELIAL DEFECT	01OCT2014	Ongoing	2	No	1	5	5	CONTACT LENS	2
			7		Renal and urinary disorders/ Renal colic/ RENAL COLIC RIGHT SIDE UNDER THERAPY WITH ACETAZOLAMIDE	28OCT2014	30OCT2014	2	Yes	3	5	2		1
			8		Investigations/ Heart rate increased/ HIGH PULSE 106 AFTER EXERCISE	22DEC2014	22DEC2014	1	No	1	5	1		1

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335004	rhNGF 10 µg/ml	1	1		Eye disorders/ Eye allergy/ ALLERGICAL REACTION DUE TO POLLEN COUNT AND HOUSE DUST - EYES	17JAN2014	28JAN2015	1	No	2	2	2		1
			2	Left	Eye disorders/ Dry eye/ SEVERE KERATOKONJUNCTIVIS SICCA PROBLEMS	20FEB2014	04NOV2014	3	No	1	5	1		1
			3	Left	Eye disorders/ Corneal neovascularisation/ NEOVASCULARIZATION OF THE CORNEA	16MAY2014	Ongoing	2	No	1	5	1		2
335005	Vehicle Control	1	1	Right	Eye disorders/ Conjunctival haemorrhage/ HYPOSPHAGHMA	09FEB2014	03MAR2014	1	No	2	2	1		1

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335005	Vehicle Control	1	2	Left	Eye disorders/ Conjunctival haemorrhage/ HYPOSPHAGMA	17FEB2014	03MAR2014	1	No	2	2	1		1
	rhNGF 10 µg/ml	3	3	Left	Eye disorders/ Conjunctival haemorrhage/ HYPOSPHAGMA	11JUN2014	07AUG2014	1	No	1	5	1		1
			4		Gastrointestinal disorders/ Nausea/ NAUSEA	27JUL2014	06AUG2014	2	Yes	3	1	5	1	1
			5		Investigations/ Blood pressure increased/ INCREASED BLOOD PRESSURE	16SEP2014	23SEP2014	1	Yes	3	1	5	2	1
			6		Respiratory, thoracic and mediastinal disorders/ Epistaxis/ HOSPITALISATION DUE TO NOSE BLEEDING	16SEP2014	23SEP2014	1	Yes	3	1	5	2	1

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[4] Relationship to Study Treatment: 1: None (Intercurrent Event), 2: Unlikely (Remote), 3: Possible, 4: Probable, 5: Highly Probable

[5] Action Taken with Study Treatment: 1: Drug Withdrawn, 2: Dose Not Changed, 3: Unknown, 4: Drug Interrupted 5: Not Applicable

[6] Other Action Taken: 1: None, 2: Concomitant Medication, 3: Concomitant Procedures, 4: Withdrawn, 5: Other

[7] Outcome: 1: Resolved, 2: Not Resolved, 3: Fatal, 4: Unknown

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Listing 16.2.7.1b Adverse Events

Unique Patient Number	Treatment Group	Study Period [1]	AE #	Eye*	SOC PT AE Term	Onset Date	Resolution Date	Int [2]	SAE [3]	Rel [4]	Act [5]	Other Action [6]	Other Action Specify	Out [7]
335005	rhNGF 10 µg/ml	3	7		Metabolism and nutrition disorders/ Hyperuricaemia/ HYPERURICAEMIA	16SEP2014	24SEP2014	2	No	1	5	2		1
			8		Vascular disorders/ Diastolic hypotension/ DIASTILOLOC HYPOTENSION, INSTABILE ARTERIELLE BLOOD PRESSURE	30APR2015	Ongoing	1	No	1	5	1		4
335006	rhNGF 10 µg/ml	3	1	Left	Eye disorders/ Neurotrophic keratopathy/ RECURRENCE OF STAGE 2 NEUROTHROPHIC KERATOPATHY	16JUL2014	09OCT2014	2	No	1	5	3		1
			2		Renal and urinary disorders/ Bladder prolapse/ ELECTIVE HYSTERECTOMY WITH VESCIOPEXY DUE TO DROPPING OF BLADDER	04AUG2014	10AUG2014	2	Yes	3	1	5	1	

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[6] Other Action Taken: 1: None, 2: Concomitant Medication, 3: Concomitant Procedures, 4: Withdrawn, 5: Other

[7] Outcome: 1: Resolved, 2: Not Resolved, 3: Fatal, 4: Unknown

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Listing 16.2.7.1b Adverse Events

Unique Patient Number	Treatment Group	Study Period [1]	AE #	Eye*	SOC PT AE Term	Onset Date	Resolution Date	Int [2]	SAE [3]	Rel [4]	Act [5]	Other Action [6]	Other Action Specify	Out [7]
335006	rhNGF 10 µg/ml	3	3		Reproductive system and breast disorders/ Uterine prolapse/ ELECTIVE HYSTERECTOMY WITH VESCIOPEXY DUE TO DROPPING OF WOMB	04AUG2014	10AUG2014	2	Yes	3	1	5	1	1
				4	Left	Eye disorders/ Neurotrophic keratopathy/ RECURRENCE OF STAGE 2 NEUROTROPHIC KERATITIS	08OCT2014	09OCT2014	2	Yes	3	1	5	3
335007	rhNGF 20 µg/ml	1	1	Left	Eye disorders/ Eye discharge/ SLIGHTLY STICKY EYE IN THE MORNING	28APR2014	02MAY2014	1	No		1	2	1	1
				2	Left	Eye disorders/ Corneal opacity/ CORNEAL HAZE	13MAY2014	15JUL2014	2	No		2	2	1

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335007	rhNGF 20 µg/ml	1	3	Left	Eye disorders/ Keratitis/ CORNEAL INFLAMMATION	13MAY2014	15JUL2014	2	No	2	2	1		1
			4	Left	Eye disorders/ Visual acuity reduced/ REDUCED VISUAL ACUITY (TWO LETTERS AT 4 METERS, AND 19 LETTERS AT 1 METER ONLY)	13MAY2014	15JUL2014	2	No	2	2	1		1
		3	5		Immune system disorders/ Immunodeficiency/ SUSPICIONS OF IMMUN DEFICIENCY, EXAMINATION IN CLINIC TO EXCULDE CANCER/HIV	07AUG2014	07AUG2014	2	No	1	5	1		1

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335007	rhNGF 20 µg/ml	3	6		Immune system disorders/ Immunodeficiency/ SUSPICIONS OF IMMUNE DEFICIENCY, EXAMINATIONS IN CLINIC TO EXCLUDE CANCER/HIV	11AUG2014	11AUG2014	2	No	1	5	1		1
			7	Left	Infections and infestations/ Herpes zoster ophthalmic/ HERPES ZOSTER OPHTHALMICUS	14JAN2015	Ongoing	2	No	1	5	2		2
			8	Left	Investigations/ Intraocular pressure increased/ ELEVATED OCULAR PRESSURE	16JAN2015	16JAN2015	1	No	1	5	2		1
			9		Metabolism and nutrition disorders/ Vitamin D deficiency/ VITAMIN D DEFICIENCY	24FEB2015	Ongoing	1	No	1	5	2		2

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335008	rhNGF 10 µg/ml	1	1	Right	Eye disorders/ Eye irritation/ BURNING SENSATION AFTER REMOVING OF THERAPEUTICAL CONTACT LENS AND BEGINNING OF TREATMENT WITH STUDY DRUG	23APR2014	18JUN2014	1	No	1	5	1		1
			2		Nervous system disorders/ Headache/ HEADACHE	07MAY2014	13MAY2014	2	No	3	2	2		1
335009	rhNGF 20 µg/ml	1	1	Right	Investigations/ Intraocular pressure increased/ HIGH OCULAR PRESSURE	12MAY2014	15MAY2014	2	No	1	2	2		1

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335009	rhNGF 20 µg/ml	3	2	Right	General disorders and administration site conditions/ Disease progression/ INCREASE OF EXISTING EPITHELIAL DEFECT	10JUN2014	Ongoing	1	No	2	1	2		2
			3	Right	Eye disorders/ Corneal epithelium defect/ NEW LESION RECURRENCE OF EPITHELIAL DEFECT	11JUL2014	18JUL2014	2	No	1	5	2		1
			4	Right	General disorders and administration site conditions/ Disease progression/ CORNEAL PERSISTANT EPITHELIAL DEFECT WORSENING OF THE EXISTING LESION	18JUL2014	17SEP2014	2	No	1	5	2		1

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335009	rhNGF 20 µg/ml	3	5	Right	Investigations/ Intraocular pressure increased/ HIGH INTRAOCULAR PRESSURE	17SEP2014	23SEP2014	1	No	1	5	2		1
			6	Right	Infections and infestations/ Corneal infection/ CORNEAL INFECTION	06OCT2014	03NOV2014	2	No	1	5	3		1
			7	Right	General disorders and administration site conditions/ Disease progression/ CORNEAL ULCER OF THE EXISTING LESION REQUIRING AMNION TRANSPLANTATION DISEASE PROGRESSION	20NOV2014	21NOV2014	2	Yes	3	2	5	3	1

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335010	rhNGF 20 µg/ml	3	1		General disorders and administration site conditions/ Inflammation/ INFLAMMATION OF BALL OF THE FOOT	24AUG2014	05SEP2014	2	No	1	5	2		1
335011	rhNGF 10 µg/ml	1	1	Left	Investigations/ Intraocular pressure increased/ HIGH OCULAR PRESSURE IN FELLOW EYE	04AUG2014	11AUG2014	1	No	1	2	2		1
			2	Right	Eye disorders/ Conjunctival hyperaemia/ ERYTHEMA OF CONJUNCTIVA	27AUG2014	28AUG2014	3	No	2	2	1		1
			3		Infections and infestations/ Nasopharyngitis/ COMMON COLD	27AUG2014	01SEP2014	1	No	1	2	1		1

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335011	rhNGF 10 µg/ml	3	4		Nervous system disorders/ Burning sensation/ BURNING SENSATION OF FOOT	24SEP2014	08DEC2014	1	No	1	5	2/3		1
			5	Left	Eye disorders/ Retinal cyst/ CENTRAL INTRARETINAL CYSTIS	15OCT2014	19FEB2015	1	No	2	5	1		1
			6		Infections and infestations/ Blister infected/ INFECTED BLISTER LEFT FOOT	15NOV2014	23FEB2015	2	No	2	5	1		1
			7		General disorders and administration site conditions/ Impaired healing/ IMPAIRED WOUND HEALING	09DEC2014	27JAN2015	3	Yes	3	2	5	2	1

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335011	rhNGF 10 µg/ml	3	8		Vascular disorders/ Diabetic vascular disorder/ AMPUTATION OF TOE V OF THE LEFT FOOT DUE TO DIABETIC PERIPHERAL VASCULAR DISEASE	09DEC2014	27JAN2015	3	Yes	3	2	5	2	1
			9	Both	Investigations/ Intraocular pressure increased/ INCREASE OF IOP	24MAR2015	24MAR2015	1	No		2	2	1	1
			10		Infections and infestations/ Nasopharyngitis/ COMMON COLD	22JUN2015	02JUL2015	1	No		1	5	2	1
			11		General disorders and administration site conditions/ Inflammation/ INFLAMMATION ON FOOT	14JUL2015	24JUL2015	1	No		1	5	2	1

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335012	Vehicle Control	1	1		Metabolism and nutrition disorders/ Iron deficiency/ IRON DEFICIENCY	01SEP2014	01DEC2014	1	No	1	2	2		1
				2	Skin and subcutaneous tissue disorders/ Onychoclasia/ FRAGILE NAILS WORSENING	20OCT2014	Ongoing	2	No	2	2	1		2
				3	Skin and subcutaneous tissue disorders/ Dry skin/ DRY SKIN OF HANDS	20OCT2014	30APR2015	2	No	2	2	1		1
	rhNGF 20 µg/ml	2	4	Both	Investigations/ Intraocular pressure increased/ INCREASE OF INTRAOCULAR PRESSURE	10NOV2014	10NOV2014	2	No	2	2	2		1

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335012	rhNGF 20 µg/ml	3	5	Right	General disorders and administration site conditions/ Instillation site pain/ PAIN AT APPLYING EYE DROPS FOR ABOUT 30 MINUTES	16AUG2015	16AUG2015	1	No	1	5	1		1
335013	rhNGF 20 µg/ml	1	1		Metabolism and nutrition disorders/ Folate deficiency/ LACK OF FOLIC ACID	15OCT2014	15OCT2014	1	No	1	2	2		1
			2		Metabolism and nutrition disorders/ Vitamin B12 deficiency/ LACK OF VITAMIN B12	15OCT2014	15OCT2014	1	No	1	2	2		1
		3	3	Left	Eye disorders/ Eye pain/ PAIN IN LEFT EYE	07NOV2014	14NOV2014	2	No	1	5	2		1

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335015	rhNGF 20 µg/ml	1	1		Infections and infestations/ Nasopharyngitis/ COMMON COLD	04MAR2015	12MAR2015	2	No	1	2	2		1
			2	Right	Eye disorders/ Corneal deposits/ CORNEAL CALCIUM DEPOSITS	12MAR2015	Ongoing	2	No	3	2	1		2
			3	Right	Eye disorders/ Eye pain/ PAIN IN THE RIGHT EYE	20MAR2015	Ongoing	1	No	3	2	1		2
			4	Right	Eye disorders/ Eye pruritus/ ITCHING AT THE RIGHT EYE - OCULAR ITCHING	20MAR2015	Ongoing	1	No	3	2	1		2
			5		Infections and infestations/ Nasopharyngitis/ COMMON COLD	20MAR2015	28MAR2015	2	No	1	2	2		1

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[5] Action Taken with Study Treatment: 1: Drug Withdrawn, 2: Dose Not Changed, 3: Unknown, 4: Drug Interrupted 5: Not Applicable

[6] Other Action Taken: 1: None, 2: Concomitant Medication, 3: Concomitant Procedures, 4: Withdrawn, 5: Other

[7] Outcome: 1: Resolved, 2: Not Resolved, 3: Fatal, 4: Unknown

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Listing 16.2.7.1b Adverse Events

Unique Patient Number	Treatment Group	Study Period [1]	AE #	Eye*	SOC PT AE Term	Onset Date	Resolution Date	Int [2]	SAE [3]	Rel [4]	Act [5]	Other Action [6]	Other Action Specify	Out [7]
335015	rhNGF 20 µg/ml	1	6		Blood and lymphatic system disorders/ Anaemia/ ANEMIA	09APR2015	Ongoing	2	No	1	5	1		4
			3		Injury, poisoning and procedural complications/ Fall/ FALL	19APR2015	19APR2015	3	Yes	3	1	5	2	1
			8		Injury, poisoning and procedural complications/ Clavicle fracture/ FRACTURE OF CLAVICULA (LEFT)	19APR2015	22APR2015	3	Yes	3	1	5	2	1
			9	Right	Eye disorders/ Corneal epithelium defect/ NEW EPITHELIAL DEFECT	11MAY2015	18MAY2015	1	No	1	5	1		1

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[1] Study Period: 1: Controlled Treatment Period, 2: Uncontrolled Treatment Period, 3: Follow-Up Period

[2] Intensity: 1: Mild, 2: Moderate, 3: Severe

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Unique Patient Number	Treatment Group	Study Period [1]	AE #	Eye*	SOC PT AE Term	Onset Date	Resolution Date	Int [2]	SAE [3]	Rel [4]	Act [5]	Other Action [6]	Other Action Specify	Out [7]
335016	rhNGF 20 µg/ml	1	1	Right	Eye disorders/ Eye pain/ PAIN IN TREATMENT EYE RIGHT	19MAR2015	Ongoing	2	No	3	1	4		4
			2	Right	Eye disorders/ Visual acuity reduced/ REDUCED VISION FROM 21 LETTERS TO COUNT FINGERS BETWEEN 1 WEEK	19MAR2015	Ongoing	2	No	3	1	4		4
340003	rhNGF 20 µg/ml	1	1	Right	Eye disorders/ Ocular hyperaemia/ RIGHT RED EYE	13FEB2014	06MAR2014	1	No	2	2	2		1
			2		Infections and infestations/ Lower respiratory tract infection/ CHEST INFECTION	27MAR2014	01MAY2014	2	No	1	2	2		1

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340004	rhNGF 10 µg/ml	1	1	Left	Eye disorders/ Lagophthalmos/ LAGOPHTHALMOS	23MAY2014	27MAY2014	1	No	1	2	1		1
340005	Vehicle Control	1	1	Right	Eye disorders/ Eye pain/ PAINFUL RIGHT EYE	31OCT2014	17NOV2014	2	No	3	2	1		1
			2	Right	Eye disorders/ Eye pain/ PAINFUL RIGHT EYE	17NOV2014	09FEB2015	3	No	3	2	1		1
			3	Right	Eye disorders/ Foreign body sensation in eyes/ GRITTY SENSATION RIGHT EYE	21NOV2014	21NOV2014	1	No	2	2	1		1
	rhNGF 20 µg/ml	2	4	Right	Eye disorders/ Eyelid oedema/ SWOLLEN RIGHT EYELID	09JAN2015	09FEB2015	1	No	1	2	1		1

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340005	rhNGF 20 µg/ml	2	5	Left	Eye disorders/ Eyelid oedema/ SWELLING LEFT EYELID	17JAN2015	09FEB2015	1	No	1	2	1		1
340006	Vehicle Control	1	1	Right	Eye disorders/ Eye pain/ ACHE BACK OF RIGHT EYE	17FEB2015	10APR2015	1	No	3	2	1		1
			2	Right	Eye disorders/ Vision blurred/ BLURRRED VISION	01MAR2015	Ongoing	2	No	3	2	1		2
			3	Right	Eye disorders/ Ocular hyperaemia/ RIGHT RED EYE	06MAR2015	27APR2015	2	No	3	2	2		1
			4	Right	Eye disorders/ Corneal epithelium defect/ NEW CORNEAL EPITHELIAL DEFECT	23MAR2015	20APR2015	1	Yes	4	2	2	2	1

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340006	Vehicle Control	1	5	Right	Eye disorders/ Corneal epithelium defect/ TWO NEW PED'S IN RIGHT EYE	07APR2015	20APR2015	1	No	3	2	1		1
			6	Right	General disorders and administration site conditions/ Disease progression/ BREAKDOWN OF ORIGINAL ULCER RIGHT EYE	07APR2015	20APR2015	1	No	2	2	1		1
	rhNGF 20 µg/ml	2	7	Right	Eye disorders/ Conjunctival hyperaemia/ CONJUNCTIVA ERYTHEMA	14MAY2015	27MAY2015	2	No	3	2	1		1
			8	Right	Eye disorders/ Eye discharge/ EYE DISCHARGE RIGHT EYE	14MAY2015	27MAY2015	1	No	3	2	1		1

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340006	rhNGF 20 µg/ml	2	9	Right	Eye disorders/ Erythema of eyelid/ EYELID ERYTHEMA RIGHT EYE	18MAY2015	27MAY2015	2	No	3	2	1		1	
				10	Right	Eye disorders/ Blepharitis/ BLEPHARITIS	22MAY2015	27MAY2015	1	No	3	2	2		1
				11	Right	Eye disorders/ Ulcerative keratitis/ RECURRENCE OF 1ST AND 2ND ULCER RIGHT EYE	03JUN2015	Ongoing	1	No	1	5	2/3/5	SCLERAL LENS FITTED	2
341001	rhNGF 10 µg/ml	1	1	Right	Eye disorders/ Eye pruritus/ R EYE ITCHING/OCULAR ITCHING	09MAR2014	Ongoing	1	No	2	2	1		2	

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341001	rhNGF 10 µg/ml	1	2	Right	Eye disorders/ Eye pain/ PAIN AROUND THE RIGHT EYE	17MAR2014	Ongoing	2	No	2	2	2		2
			3		Gastrointestinal disorders/ Nausea/ NAUSEA	16APR2014	Ongoing	1	No	1	2	1		2
			4		General disorders and administration site conditions/ Fatigue/ TIRED	16APR2014	Ongoing	1	No	1	2	1		2
		3	5	Right	Eye disorders/ Foreign body sensation in eyes/ FOREIGN BODY SENSATION IN THE RIGHT EYE	14MAY2014	Ongoing	1	No	1	5	1		2

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341002	Vehicle Control	1	1		Nervous system disorders/ Headache/ HEADACHE	31JAN2015	31JAN2015	2	No	2	2	1		1
			2		Injury, poisoning and procedural complications/ Laceration/ PATIENT CUT HER FINGER	05FEB2015	05FEB2015	1	No	1	2	1		1
342002	Vehicle Control	1	1	Right	General disorders and administration site conditions/ Disease progression/ PROGRESSION OF PERSISTENT CORNEAL EPITHELIAL DEFECT STAGE 2 NEUROTROPHIC KERATITIS.	13DEC2013	20DEC2013	3	Yes	6	5	5	UNMASKED	1
			2	Right	Eye disorders/ Photophobia/ TRANSIENT PHOTOPHOBIA	13DEC2013	24JAN2014	1	No	1	2	1		1

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342002	rhNGF 20 µg/ml	3	3	Both	Eye disorders/ Corneal neovascularisation/ CORNEAL VASCULARISATION - LESION OF CORNEA	24MAR2014	06MAY2014	3	No	1	5	3		1
			4	Left	Eye disorders/ Corneal neovascularisation/ CORNEAL VASCULAIRISATION - LESION OF CORNEA	09JUN2014	15JUL2014	3	No	1	5	3		4
			5	Left	Eye disorders/ Neurotrophic keratopathy/ RECURRENT NUEROTROPHIC KERATITIS	11AUG2014	Ongoing	2	No	1	5	3		4

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342002	rhNGF 20 µg/ml	3	6	Left	Eye disorders/ Corneal neovascularisation/ CORNEAL VASCULARISATION - LESION OF CORNEA	18AUG2014	Ongoing	3	No	1	5	3		4
				7	Left	Eye disorders/ Pseudopterygium/ PSEUDOPTERYGIUM	18AUG2014	23SEP2014	3	No	1	5	3	
342003	rhNGF 20 µg/ml	1	1	Left	Eye disorders/ Visual acuity reduced/ DECREASE IN BCVA -15 LETTERS	31JAN2014	05FEB2014	3	Yes	6	2	1	4	1
343001	rhNGF 10 µg/ml	1	1	Left	Eye disorders/ Visual acuity reduced/ REDUCTION IN VISION (41 LETTERS)	28OCT2014	18NOV2014	2	No	1	2	1		1

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343001	rhNGF 10 µg/ml	1	2	Left	Eye disorders/ Conjunctival hyperaemia/ CONJUNCTIVAL HYPERAEMIA	10NOV2014	Ongoing	2	No	1	2	2		2
			3	Left	Eye disorders/ Corneal epithelium defect/ CHANGE IN POSITION OF PERSISTENT EPITHELIAL DEFECT - THIS IS A DISEASE RECURRENCE.	18NOV2014	16DEC2014	2	No	2	2	2		1
		3	4		Vascular disorders/ Deep vein thrombosis/ SUSPECTED DVT	10FEB2015	13FEB2015	2	No	1	5	2		1
			5		Infections and infestations/ Catheter site infection/ PERCUTANEOUS ENDOSCOPIC GASTROSTOMY TUBE SITE INFECTION	12MAY2015	22MAY2015	1	No	1	5	2		1

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350001	Vehicle Control	1	1	Both	Eye disorders/ Asthenopia/ HEAVINESS OF EYELIDS	16MAY2014	11JUL2014	1	No	3	2	1		1	
			2	Right	General disorders and administration site conditions/ Instillation site pain/ EYE PAIN AFTER STUDY DRUG INSTILLATION	23MAY2014	13JUN2014	1	No	4	2	1		1	
			3	Right	Eye disorders/ Ocular discomfort/ DISCOMFORT WHEN CLOSING OD	13JUN2014	Ongoing	1	No	2	2	1		2	
			3	4	Right	Eye disorders/ Lacrimation increased/ INCREASED TEARING	06AUG2014	20AUG2014	1	No	1	5	1		1

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350002	Vehicle Control	1	1	Left	Eye disorders/ Eye irritation/ BURNING FEELING IN THE LEFT EYE	29AUG2014	10OCT2014	1	No	3	2	1		1
			2	Left	Eye disorders/ Dry eye/ DRY EYE IN THE MORNING	05SEP2014	24DEC2014	1	No	3	2	1		1
			3	Left	Eye disorders/ Eye pruritus/ LEFT EYE ITCHING	19SEP2014	24DEC2014	1	No	3	2	1		1
			4		Nervous system disorders/ Headache/ HEADACHE	26SEP2014	24NOV2014	1	No	3	2	1		1

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[4] Relationship to Study Treatment: 1: None (Intercurrent Event), 2: Unlikely (Remote), 3: Possible, 4: Probable, 5: Highly Probable

[5] Action Taken with Study Treatment: 1: Drug Withdrawn, 2: Dose Not Changed, 3: Unknown, 4: Drug Interrupted 5: Not Applicable

[6] Other Action Taken: 1: None, 2: Concomitant Medication, 3: Concomitant Procedures, 4: Withdrawn, 5: Other

[7] Outcome: 1: Resolved, 2: Not Resolved, 3: Fatal, 4: Unknown

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Listing 16.2.7.1b Adverse Events

Unique Patient Number	Treatment Group	Study Period [1]	AE #	Eye*	SOC PT AE Term	Onset Date	Resolution Date	Int [2]	SAE [3]	Rel [4]	Act [5]	Other Action [6]	Other Action Specify	Out [7]
350002	Vehicle Control	1	5	Left	General disorders and administration site conditions/ Disease progression/ PUNCTUATE KERATOPATHY CONDITION AGGRAVATION	10OCT2014	19JUN2015	1	No	3	2	1		1
		3	6	Left	Eye disorders/ Dry eye/ DRY EYE IN THE MORNING	23JAN2015	30JAN2015	1	No	3	2	1		1
		7	7	Left	Eye disorders/ Eyelid pain/ LOWER EYELID PAIN	05FEB2015	06MAR2015	1	No	3	2	1		1
352001	rhNGF 20 µg/ml	1	1	Left	Infections and infestations/ Corneal abscess/ ABSCESS CORNEAL GRAFT	03JUN2014	Ongoing	3	No	3	2	2		2

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353001	Vehicle Control	1	1	Left	Injury, poisoning and procedural complications/ Suture related complication/ SUTURE EXTRUSION (REMOVED TODAY)	03MAR2015	03MAR2015	1	No	1	2	3		1
			2	Left	Injury, poisoning and procedural complications/ Suture related complication/ SUTURE EXTRUSION	17MAR2015	17MAR2015	1	No	1	2	3		1
353002	rhNGF 10 µg/ml	1	1		General disorders and administration site conditions/ Pyrexia/ FEVER	04MAR2015	05MAR2015	2	No	1	5	3		1

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353002	rhNGF 10 µg/ml	1	2		Injury, poisoning and procedural complications/ Fall/ FALL	22MAR2015	22MAR2015	1	No	1	2	1		1
			3		Ear and labyrinth disorders/ Ear pain/ RIGHT EAR PAIN	24MAR2015	Ongoing	2	No	1	2	2/3		2
			4		Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Malignant neoplasm progression/ EVOLUTION OF SQUAMOUS CELL CARCINOMA	01APR2015	01APR2015	3	Yes	1	2	1		3
354001	rhNGF 10 µg/ml	1	1		Infections and infestations/ Gastroenteritis/ GASTROENTERITIS	24MAR2014	29MAR2014	2	No	1	2	2		1

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354001	rhNGF 10 µg/ml	3	2	Left	Infections and infestations/ Corneal abscess/ CORNEAL ABSCESS	21APR2014	15MAY2014	3	Yes	3	1	5	2		1
			3		Vascular disorders/ Aortic dissection/ AORTIC DISSECTION	08JUL2014	Ongoing	3	Yes	1	1	5	1		3
			4		Vascular disorders/ Aortic rupture/ AORTIC RUPTURE	08JUL2014	Ongoing	3	Yes	1	1	5	1		3
			5		Vascular disorders/ Shock haemorrhagic/ HEMORRHAGIC SHOCK	08JUL2014	Ongoing	3	Yes	1	1	5	1		3
354002	Vehicle Control	1	1	Left	Eye disorders/ Eye pain/ LEFT EYE PAIN	02JUL2014	08JUL2014	1	No		1	2	1		1

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354002	Vehicle Control	1	2	Left	Eye disorders/ Eye pain/ PAIN FLOWING LEFT EYE	02JUL2014	18NOV2014	1	No	1	2	1		1
			3		Respiratory, thoracic and mediastinal disorders/ Dysphonia/ DYSPHONIA	31JUL2014	01AUG2014	1	No	1	2	2		1
			4	Right	Eye disorders/ Dry eye/ SYMPTOMATIC TREATMENT OF DRY EYE SYNDROME	19AUG2014	Ongoing	1	No	1	5	1		2
		3	5	Left	Eye disorders/ Meibomianitis/ MEIBOMITE	16SEP2014	16OCT2014	1	No	1	5	1		1
			6		Injury, poisoning and procedural complications/ Facial bones fracture/ NOZE BROKEN	NOV2014	JAN2015	1	No	1	2	2		1

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354002	Vehicle Control	3	7		Injury, poisoning and procedural complications/ Upper limb fracture/ ARM BROKEN	NOV2014	JAN2015	1	No	1	2	1		1
354003	rhNGF 10 µg/ml	1	1	Right	Eye disorders/ Eye pain/ STINGING IN RIGHT EYE	12OCT2014	15OCT2014	1	No	1	2	1		1
			2	Right	General disorders and administration site conditions/ Disease progression/ CORNEAL ULCER AGGRAVATION	29OCT2014	19NOV2014	2	No	1	2	1		1
			3	Right	Eye disorders/ Eye pruritus/ RIGHT EYE ITCHING	19NOV2014	Ongoing	1	No	1	2	1		2

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354003	rhNGF 10 µg/ml	1	4	Right	Eye disorders/ Eyelid ptosis/ EYELID DOWNING	19NOV2014	Ongoing	1	No	1	2	1		2
			5	Right	Eye disorders/ Photophobia/ LIGHT SENSIBILITY	19NOV2014	Ongoing	1	No	1	2	1		2
			6	Right	Eye disorders/ Ulcerative keratitis/ RIGHT EYE ULCER INITIAL CONDITION	31DEC2014	25FEB2015	1	No	1	5	2		1
			7	Left	Eye disorders/ Cataract/ CATARACT	26MAR2015	26MAR2015	1	No	1	5	1		1
360001	rhNGF 20 µg/ml	1	1		Cardiac disorders/ Arrhythmia/ ARYTHMIA	10FEB2014	12FEB2014	2	No	3	1	4		1

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360001	rhNGF 20 µg/ml	1	2	Left	Eye disorders/ Eye pain/ PAIN AROUND LEFT EYE	10FEB2014	12FEB2014	2	No	4	1	4		1
			3		Investigations/ Blood pressure increased/ INCREASE OF BLOOD PRESURE	10FEB2014	12FEB2014	2	No	3	1	4		1
			4		Nervous system disorders/ Headache/ HEADACHE	10FEB2014	12FEB2014	3	No	4	1	4		1
360002	rhNGF 10 µg/ml	1	1	Left	Eye disorders/ Eye discharge/ WHITISH DISCHARGE FROM LEFT EYE	04NOV2014	06NOV2014	1	No	4	2	1		1

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360002	rhNGF 10 µg/ml	1	2	Left	General disorders and administration site conditions/ Disease progression/ THE INCREASE IN SIZE OF CORNEAL ULCER OF THE LEFT EYE BY 1 MM VERTICALLY AND BY 1 MM HORIZONTALLY	04NOV2014	13NOV2014	2	No	5	2	1		4
			3		Gastrointestinal disorders/ Toothache/ TOOTHACHE - MOLAR 6TH LEFT SIDE OF LOWER JAW, PREVIOUSLY ROOT-CANAL TREATMENT, ON 12-NOV-2014 PREPARATION FOR REVISION OFROOT-CANAL TREATMENT (SOME MEDICATION LEFT IN THE CANAL)	11NOV2014	17DEC2014	1	No	2	2	3		1

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360002	rhNGF 10 µg/ml	3	4	Left	Eye disorders/ Lacrimation decreased/ INSUFFICIENT EYE LUBRICATION	19DEC2014	31MAY2015	1	No	2	2	2		1
			5	Left	Eye disorders/ Neurotrophic keratopathy/ NEUROTROPHIC KERATOPATHY RECURRENCE	01JUN2015	29JUN2015	2	No	2	5	5	WE ORDER STUDY DRUG, AND IN THE MEANTIME PRESCRIBE ARTIFICIAL EYE DROPS AND PRESERVATIVE FREE ANTIBIOTIC EYECREM	1
			6	Left	Investigations/ Vital dye staining cornea present/ INCREASE OF FLUORESCHEIN STAINING OF THE CORNEA EPITHELIUM	18AUG2015	Ongoing	2	No	3	1	2		2

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360004	rhNGF 10 µg/ml	1	1		Infections and infestations/ Staphylococcal infection/ STAPHYLOCOCCUS INFECTION REOCURENCE IN NOSE AND ON HEAD SKIN	16MAR2015	Ongoing	1	No	1	2	2		4
			2		Nervous system disorders/ Headache/ STRONG HEADACHE	16MAR2015	07JUL2015	2	No	2	2	3/5	NEUROLOGICAL CONSULTATION ON 23MARCH2015	1
			3	3 Right	Eye disorders/ Dry eye/ DRY EYE SYNDROME	25APR2015	Ongoing	1	No	1	5	2		2
			4		Blood and lymphatic system disorders/ Anaemia/ ANEMIA	14MAY2015	Ongoing	2	No	1	5	1		4

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360004	rhNGF 10 µg/ml	3	5		Blood and lymphatic system disorders/ Anaemia/ COLONOSCOPY - RESULT WITHIN NORMAL LIMITS - PROCEDURE DONE BECAUSE OF ANEMIA DIAGNOSTICS	25MAY2015	25MAY2015	1	No	1	5	1		1
			6		Blood and lymphatic system disorders/ Anaemia/ GASTROSCOPY- PROCEDURE DONE BECAUSE OF ANEMIA DIAGNOSIS	26MAY2015	26MAY2015	1	No	1	5	1		1
			7		Gastrointestinal disorders/ Gastric polyps/ GASTROSCOPY- RESULT : POLYPS IN STOMACH,	26MAY2015	26MAY2015	1	No	1	5	2		1

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360004	rhNGF 10 µg/ml	3	8		Infections and infestations/ Helicobacter gastritis/ GASTROSCOPY- RESULT : HELICOBACTER PYLORI INFECTION OF STOMACH MUCOSA	26MAY2015	26MAY2015	1	No	1	5	2		1
361001	rhNGF 10 µg/ml	3	1		Infections and infestations/ Tonsillitis/ TONSILLITIS	03MAY2014	11MAY2014	1	No	1	5	2		1
361003	rhNGF 20 µg/ml	1	1		Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY TRACT INFECTION	23FEB2015	27FEB2015	1	No	1	2	2		1
			2		Infections and infestations/ Upper respiratory tract infection/ UPPER RESPIRATORY TRACT INFECTION	01MAR2015	06MAR2015	1	No	1	2	2		1

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[2] Intensity: 1: Mild, 2: Moderate, 3: Severe

[3] SAE Criteria: 1: Death, 2: Life-threatening, 3: Requires hospitalization or prolongs hospitalization, 4: Significant incapacity/substantial disruption, 5: Congenital anomaly or birth defect, 6: Other medically important condition

[4] Relationship to Study Treatment: 1: None (Intercurrent Event), 2: Unlikely (Remote), 3: Possible, 4: Probable, 5: Highly Probable

[5] Action Taken with Study Treatment: 1: Drug Withdrawn, 2: Dose Not Changed, 3: Unknown, 4: Drug Interrupted 5: Not Applicable

[6] Other Action Taken: 1: None, 2: Concomitant Medication, 3: Concomitant Procedures, 4: Withdrawn, 5: Other

[7] Outcome: 1: Resolved, 2: Not Resolved, 3: Fatal, 4: Unknown

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Listing 16.2.7.1b Adverse Events

Unique Patient Number	Treatment Group	Study Period [1]	AE #	Eye*	SOC PT AE Term	Onset Date	Resolution Date	Int [2]	SAE [3]	Rel [4]	Act [5]	Other Action [6]	Other Action Specify	Out [7]
361003	rhNGF 20 µg/ml	1	3	Left	Eye disorders/ Corneal deposits/ SUBCONJUNCTIVAL CALCIFICATION ON UPPER EYELID	24MAR2015	27MAR2015	1	No	2	2	2/5	EXTRACTION OF CALCIFICATION	1
			4	Left	Eye disorders/ Corneal deposits/ SUBCONJUNCTIVAL CALCIFICATION ON LOWER EYELID	27MAR2015	Ongoing	1	No	2	2	1		2

* Eye is only recorded if the event is ocular. SOC: System Organ Class PT: Preferred Term SAE: Serious Adverse Event

[1] Study Period: 1: Controlled Treatment Period, 2: Uncontrolled Treatment Period, 3: Follow-Up Period

[2] Intensity: 1: Mild, 2: Moderate, 3: Severe

[3] SAE Criteria: 1: Death, 2: Life-threatening, 3: Requires hospitalization or prolongs hospitalization, 4: Significant incapacity/substantial disruption, 5: Congenital anomaly or birth defect, 6: Other medically important condition

[4] Relationship to Study Treatment: 1: None (Intercurrent Event), 2: Unlikely (Remote), 3: Possible, 4: Probable, 5: Highly Probable

[5] Action Taken with Study Treatment: 1: Drug Withdrawn, 2: Dose Not Changed, 3: Unknown, 4: Drug Interrupted 5: Not Applicable

[6] Other Action Taken: 1: None, 2: Concomitant Medication, 3: Concomitant Procedures, 4: Withdrawn, 5: Other

[7] Outcome: 1: Resolved, 2: Not Resolved, 3: Fatal, 4: Unknown

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