

Listing 16.2.7.1c Adverse Events

Unique Patient Number	Treatment Group	Study Period [1]	AE #	Eye*	SOC PT AE Term	Onset Date	Resolution Date	Int [2]	SAE SAE	Criteria [3]	Rel [4]	Act [5]	Other Action [6]	Other Action Specify	Out [7]
310004	rhNGF 20 µg/ml	3	1	Left	Eye disorders/ Conjunctivitis/ CONJUNCTIVITES	15JAN2015	22JAN2015	1	No		1	5	2		1
311004	rhNGF 10 µg/ml	3	2		Injury, poisoning and procedural complications/ Pelvic fracture/ TRAUMATIC PELVIS BONE FRACTURE	NOV2014	DEC2014	2	No		1	5	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
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

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[5] Action Taken with Study Treatment: 1: Drug Withdrawn, 2: Dose Not Changed, 3: Unknown, 4: Drug Interrupted 5: Not Applicable

[6] Other Action Taken: 1: None, 2: Concomitant Medication, 3: Concomitant Procedures, 4: Withdrawn, 5: Other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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313003	rhNGF 10 µg/ml	3	1		Cardiac disorders/ Cardiac failure/ HEART FAILURE	17AUG2014	17AUG2014	3	Yes	1	1	5	4		3
313004	Vehicle Control	3	1		Injury, poisoning and procedural complications/ Femur fracture/ FEMUR FRACTURE	JUN2014	JUL2014	3	Yes	3	1	5	1		1
313008	rhNGF 20 µg/ml	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

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314007	Vehicle Control	3	1	Both	Eye disorders/ Blepharitis/ BLEPHARITIS	18DEC2014	Ongoing	2	No		1	5	2		2
315005	rhNGF 10 µg/ml	3	1		Cardiac disorders/ Myocardial infarction/ DEATH FOR HEART ATTACK	03MAY2015	03MAY2015	3	Yes	1	1	5	1		3
315014	rhNGF 20 µg/ml	3	2	Right	Eye disorders/ Lacrimation decreased/ TEARING DECREASED	01JUN2015	Ongoing	1	No		1	5	2		4
315015	rhNGF 20 µg/ml	3	2		Nervous system disorders/ Brain oedema/ EDAEMA CEREBRI	13AUG2015	13AUG2015	2	No		1	2	2		1
320001	rhNGF 10 µg/ml	3	2	Right	Eye disorders/ Corneal neovascularisation/ SEVERE NEOVASCULARIZATION	23APR2014	20JUN2014	3	Yes	4	2	5	3/4		1

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320001	rhNGF 10 µg/ml	3	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
322003	Vehicle Control	3	1	Right	Eye disorders/ Ocular hyperaemia/ RED EYE	03OCT2014	14OCT2014	2	No		1	5	1		1
322004	rhNGF 20 µg/ml	3	1	Left	Eye disorders/ Keratitis/ CORNEAL INFLAMMATION	26AUG2014	29OCT2014	1	No		2	5	2		1
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

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326002	rhNGF 20 µg/ml	3	4	Right	Eye disorders/ Keratitis/ RECURRENT DISCIFORM KERATITIS	26JUN2015	24JUL2015	2	No		1	1	2		1
			5	Right	Eye disorders/ Uveitis/ UVEITIS	26JUN2015	24JUL2015	2	No		1	5	2		1
			6	Right	Infections and infestations/ Bacterial infection/ BACTERIAL INFECTION	26JUN2015	24JUL2015	2	No		1	1	2		1
			7	Right	Eye disorders/ Visual acuity reduced/ VISUAL ACUITY LOSS (MORE THAN 60 LETTERS)	26JUN2015	28AUG2015	3	Yes	6	2	1	1		1
			8	Right	Nervous system disorders/ Visual field defect/ VISUAL FIELD LOSS	26JUN2015	28AUG2015	3	Yes	6	2	1	1		1

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326002	rhNGF 20 µg/ml	3	9	Right	Infections and infestations/ Keratitis herpetic/ RECURRENCE OF EPITHELIAL HERPETIC KERATITIS	13NOV2015	15APR2016	2	No		1	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
			2		Renal and urinary disorders/ Renal colic/ RENAL COLIC	19NOV2015	11DEC2015	1	No		1	5	2		1
331003	rhNGF 10 µg/ml	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

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332003	rhNGF 20 µg/ml	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
332010	rhNGF 20 µg/ml	3	2		Nervous system disorders/ Headache/ HEADACHE	10FEB2015	13FEB2015	1	No		1	5	2		1
333002	rhNGF 10 µg/ml	3	4		Metabolism and nutrition disorders/ Decreased appetite/ ANOREXIA	10JUN2014	18JUN2014	3	Yes	3	1	5	3		1

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333002	rhNGF 10 µg/ml	3	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
			8	Left	Eye disorders/ Corneal erosion/ CORNEAL EROSIO RECURRENCE	25AUG2014	08SEP2014	2	No	1	5	2		1

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333002	rhNGF 10 µg/ml	3	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
			13	Both	Eye disorders/ Conjunctivitis/ CONJUNCTIVITIS BOTH EYES	06NOV2014	09NOV2014	1	No		1	2	1		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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			15		Metabolism and nutrition disorders/ Hypokalaemia/ HYPOKALEMIA	21APR2015	27APR2015	2	No		1	5	2		1
			16		Nervous system disorders/ Syncope/ VASOVAGAL SYNCOPÉ	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	3	4	Both	Eye disorders/ Ocular discomfort/ OCULAR DISCOMFORT	07JUN2014	Ongoing	2	No		1	5	2		2

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			6	Both	Eye disorders/ Blepharitis/ BLEPHARITIS	27NOV2014	29NOV2014	1	No	1	5	2		1
			7		Infections and infestations/ Nasopharyngitis/ COMMON COLD	07FEB2015	14FEB2015	2	No	1	5	2		1
333005	rhNGF 10 µg/ml	3	6	Left	Eye disorders/ Corneal erosion/ CORNEAL EROSIO RECURRENCE	12SEP2014	29OCT2014	2	No	1	5	2		1
			7	Left	Injury, poisoning and procedural complications/ Transplant failure/ CHRONIC GRAFT FAILURE	15SEP2014	Ongoing	1	No	1	5	1		2

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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]	SAE Criteria [3]	Rel [4]	Act [5]	Other Action [6]	Other Action Specify	Out [7]
333005	rhNGF 10 µg/ml	3	8	Left	Infections and infestations/ Herpes ophthalmic/ OPHTHALMIC HERPETIC RECURRENCE LEFT EYE	06OCT2014	09OCT2014	2	Yes	3	1	5	2		1
			9		Infections and infestations/ Nasopharyngitis/ COMMON COLD	23DEC2014	06JAN2015	1	No		1	5	1		1
			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

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333005	rhNGF 10 µg/ml	3	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
333006	rhNGF 10 µg/ml	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

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333006	rhNGF 10 µg/ml	3	8	Right	Eye disorders/ Vitreous haemorrhage/ VITREAL HEMORRHAGE	05NOV2014	27NOV2014	2	No	1	5	1		1
			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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335002	rhNGF 10 µg/ml	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
			7		Respiratory, thoracic and mediastinal disorders/ Dyspnoea/ DYSPNOE	08APR2014	08APR2014	3	Yes	1	1	5	1		3
335003	rhNGF 20 µg/ml	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	1	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	3	3	Left	Eye disorders/ Corneal neovascularisation/ NEOVASCULARIZATION OF THE CORNEA	16MAY2014	Ongoing	2	No	1	5	1		2
335005	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

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335005	rhNGF 10 µg/ml	3	6		Respiratory, thoracic and mediastinal disorders/ Epistaxis/ HOSPITALISATION DUE TO NOSE BLEEDING	16SEP2014	23SEP2014	1	Yes	3	1	5	2		1
			7		Metabolism and nutrition disorders/ Hyperuricaemia/ HYPERURICAEMIA	16SEP2014	24SEP2014	2	No		1	5	2		1
			8		Vascular disorders/ Diastolic hypotension/ DIASTILOC 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

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335006	rhNGF 10 µg/ml	3	2		Renal and urinary disorders/ Bladder prolapse/ ELECTIVE HYSTERECTOMY WITH VESCIOPEXY DUE TO DROPPING OF BLADDER	04AUG2014	10AUG2014	2	Yes	3	1	5	1		1
			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		1

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335007	rhNGF 20 µg/ml	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
			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

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335007	rhNGF 20 µg/ml	3	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
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

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335009	rhNGF 20 µg/ml	3	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
			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

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335009	rhNGF 20 µg/ml	3	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
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	3	4		Nervous system disorders/ Burning sensation/ BURNING SENSATION OF FOOT	24SEP2014	08DEC2014	1	No		1	5	2/3		1

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335011	rhNGF 10 µg/ml	3	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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[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

Listing 16.2.7.1c Adverse Events

Unique Patient Number	Treatment Group	Study Period [1]	AE #	Eye*	SOC PT AE Term	Onset Date	Resolution Date	Int [2]	SAE SAE	SAE Criteria [3]	Rel [4]	Act [5]	Other Action [6]	Other Action Specify	Out [7]
335011	rhNGF 10 µg/ml	3	12		Cardiac disorders/ Coronary artery stenosis/ WORSENING OF CORONARY STENOSIS	19OCT2015	29DEC2015	3	Yes	2/3	1	5	3		1
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
			6	Right	Eye disorders/ Corneal epithelium defect/ PERSISTANT EPITHELIAL DEFECT - NEW	10NOV2015	Ongoing	2	No		1	5	1		2
			7	Right	Eye disorders/ Corneal erosion/ EROSIO CORNEAE SUPERIOR - NEW	10NOV2015	Ongoing	2	No		1	5	1		2

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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 SAE	SAE Criteria [3]	Rel [4]	Act [5]	Other Action [6]	Other Action Specify	Out [7]
335013	rhNGF 20 µg/ml	3	3	Left	Eye disorders/ Eye pain/ PAIN IN LEFT EYE	07NOV2014	14NOV2014	2	No		1	5	2		1
335014	Vehicle Control	3	1		Infections and infestations/ Nasopharyngitis/ COMMON COLD	04NOV2015	07NOV2015	1	No		1	5	2		1
			2	Right	Eye disorders/ Ocular vascular disorder/ SURGERY FOR STROMAL VESSEL OBLITERATION CORNEAL RIGHT EYE (OCULAR VASCULAR DISORDER)	16DEC2015	18DEC2015	2	Yes	3	1	5	2/3		1
			3		Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Neurofibroma/ WORSENING OF NEUROFIBROM RIGHT THIGH	30MAR2016	04APR2016	2	Yes	3	1	5	2		1

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Listing 16.2.7.1c Adverse Events

Unique Patient Number	Treatment Group	Study Period [1]	AE #	Eye*	SOC PT AE Term	Onset Date	Resolution Date	Int [2]	SAE SAE	SAE Criteria [3]	Rel [4]	Act [5]	Other Action [6]	Other Action Specify	Out [7]
335015	rhNGF 20 µg/ml	3	7		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
340005	rhNGF 20 µg/ml	3	6	Right	Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Neoplasm recurrence/ INFERIOR LIMBAL/BULBAR RECURRENCE OF CONJUNCTIVAL MALIGNOMA	08OCT2015	20JAN2016	3	Yes	6	1	5	3		1

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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 Criteria [3]	Rel [4]	Act [5]	Other Action [6]	Other Action Specify	Out [7]
340006	rhNGF 20 µg/ml	3	12		Gastrointestinal disorders/ Dental discomfort/ SEVERE DENTAL PAIN	05MAY2016	Ongoing	3	No	1	5	5	DENTIST	2
341001	rhNGF 10 µg/ml	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
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

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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]
342002	rhNGF 20 µg/ml	3	5	Left	Eye disorders/ Neurotrophic keratopathy/ RECURRENT NUEROTROPHIC KERATITIS	11AUG2014	Ongoing	2	No	1	5	3		4
			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		1
343001	rhNGF 10 µg/ml	3	4		Vascular disorders/ Deep vein thrombosis/ SUSPECTED DVT	10FEB2015	13FEB2015	2	No	1	5	2		1

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343001	rhNGF 10 µg/ml	3	5		Infections and infestations/ Catheter site infection/ PERCUTANEOUS ENDOSCOPIC GASTROSTOMY TUBE SITE INFECTION	12MAY2015	22MAY2015	1	No		1	5	2		1
350001	Vehicle Control	3	4	Right	Eye disorders/ Lacrimation increased/ INCREASED TEARING	06AUG2014	20AUG2014	1	No		1	5	1		1
350002	Vehicle Control	3	6	Left	Eye disorders/ Dry eye/ DRY EYE IN THE MORNING	23JAN2015	30JAN2015	1	No		3	2	1		1
			7	Left	Eye disorders/ Eyelid pain/ LOWER EYELID PAIN	05FEB2015	06MAR2015	1	No		3	2	1		1
353001	Vehicle Control	3	3	Left	Eye disorders/ Corneal opacity/ PRE-EXISTING OPAQUE CORNEA	14SEP2015	14SEP2015	2	Yes	3	1	5	3		1

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353001	Vehicle Control	3	4	Both	Eye disorders/ Ocular hyperaemia/ ERYTHEMA IN EACH EYE	17DEC2015	Ongoing	1	No		1	5	1		2
			5	Left	Investigations/ Intraocular pressure increased/ HIGH INTRAOCULAR PRESSURE	17DEC2015	Ongoing	2	No		1	5	2		2
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

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354001	rhNGF 10 µg/ml	3	5		Vascular disorders/ Shock haemorrhagic/ HEMORRHAGIC SHOCK	08JUL2014	Ongoing	3	Yes	1	1	5	1		3
354002	Vehicle Control	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
			7		Injury, poisoning and procedural complications/ Upper limb fracture/ ARM BROKEN	NOV2014	JAN2015	1	No		1	2	1		1
354003	rhNGF 10 µg/ml	3	6	Right	Eye disorders/ Ulcerative keratitis/ RIGHT EYE ULCER INITIAL CONDITION	31DEC2014	25FEB2015	1	No		1	5	2		1

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354003	rhNGF 10 µg/ml	3	7	Left	Eye disorders/ Cataract/ CATARACT	26MAR2015	26MAR2015	1	No		1	5	1		1
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

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360002	rhNGF 10 µg/ml	3	6	Left	General disorders and administration site conditions/ Disease progression/ WORSENING OF THE NK- LACK OF EFFICACY	18AUG2015	Ongoing	2	No	3	1	2		2
			7	Left	Eye disorders/ Eyelid ptosis/ EYELID PTOSIS	15OCT2015	Ongoing	2	No	1	5	4		4
360004	rhNGF 10 µg/ml	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	3	5		Metabolism and nutrition disorders/ Gout/ GOUT	01DEC2015	15DEC2015	1	No	1	5	2		1
			6		Metabolism and nutrition disorders/ Gout/ GOUT	26FEB2016	05MAR2016	1	No	1	5	1		1

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