Table 14.3.2.3b Listing of Adverse Events Leading to Death

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]
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
313003	rhNGF 10 µg/ml	3	1		Cardiac disorders/ Cardiac failure/ HEART FAILURE	17AUG2014	17AUG2014	3	Yes	1	1	5	4		3
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
315005	rhNGF 10 µg/ml	3	1		Cardiac disorders/ Myocardial infarction/ DEATH FOR HEART ATTACK	03MAY2015	03MAY2015	3	Yes	1	1	5	1		3

* 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[5] Action Taken with Study Treatment: 1: Drug Withdrawn, 2: Dose Not Changed, 3: Unknown, 4: Drug Interrupted 5: Not Applicable
[6] Other Action Taken: 1: None, 2: Concomitant Medication, 3: Concomitant Procedures, 4: Withdrawn, 5: Other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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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]
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
335002	rhNGF 10 µg/ml	3	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

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353002	rhNGF 10 µg/ml	1	4		Neoplasms benign, malignant and unspecified (incl cysts and polyps)/ Malignant neoplasm progression/ EVOLUTION OF SQUAMOUS CELL CARCINOMA	01APR2015	01APR2015	3	Yes	1	1	2	1		3
354001	rhNGF 10 µg/ml	3	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

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