

Table 14.3.5.2 Vital signs (Safety set)

Parameter	Visit - Time Point	Statistics	rhNGF 20 µg/mL N=20			rhNGF 4 µg/mL N=20			Overall N=40		
			Value	Change from Baseline	Change from Pre-dose	Value	Change from Baseline	Change from Pre-dose	Value	Change from Baseline	Change from Pre-dose
Systolic Blood Pressure (mmHg)	Screening - Day -15/-1	N	20			20			40		
		Mean	126.2			123.1			124.6		
		SD	15.1			18.0			16.4		
		CV%	11.9			14.6			13.2		
		Min	101			91			91		
		Median	124.0			124.5			124.5		
		Max	155			154			155		
Systolic Blood Pressure (mmHg)	Visit 2 - Day 1 - Pre-dose	N	20	20		20	20		40	40	
		Mean	125.3	-0.9		126.5	3.5		125.9	1.3	
		SD	11.9	11.0		13.3	11.9		12.5	11.5	
		CV%	9.5	-1220.8		10.5	344.1		9.9	902.2	
		Min	104	-17		96	-20		96	-20	
		Median	126.0	0.5		125.5	2.5		126.0	2.0	
		Max	142	14		148	23		148	23	
Systolic Blood Pressure (mmHg)	Visit 2 - Day 1 - Post-dose	N	20	20	20	20	20	20	40	40	40
		Mean	118.4	-7.8	-6.9	123.3	0.2	-3.3	120.8	-3.8	-5.1
		SD	12.5	10.9	11.3	15.3	9.8	7.7	14.0	11.0	9.7

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			Value	Change from Baseline	Change from Pre-dose	Value	Change from Baseline	Change from Pre-dose	Value	Change from Baseline	Change from Pre-dose
		CV%	10.5	-140.7	-164.9	12.4	4914.0	-236.8	11.6	-291.6	-192.4
		Min	90	-35	-25	88	-26	-15	88	-35	-25
		Median	122.0	-3.5	-6.5	121.5	0.0	-2.5	122.0	-1.0	-6.0
		Max	136	5	16	144	16	10	144	16	16
Systolic Blood Pressure (mmHg)	Visit 3 - Day 8±1 - Pre-dose	N	19	19		20	20		39	39	
		Mean	123.6	-2.6		120.1	-3.0		121.8	-2.8	
		SD	12.0	8.2		14.4	14.8		13.3	11.9	
		CV%	9.7	-310.6		12.0	-493.3		10.9	-421.3	
		Min	102	-17		89	-31		89	-31	
		Median	124.0	-6.0		115.5	-1.5		122.0	-3.0	
		Max	147	13		145	32		147	32	
Systolic Blood Pressure (mmHg)	Visit 3 - Day 8±1 - Post-dose	N	20	20	19	20	20	20	40	40	39
		Mean	122.0	-4.2	-1.2	123.9	0.9	3.9	122.9	-1.7	1.4
		SD	13.6	10.1	8.9	14.6	12.9	11.1	14.0	11.7	10.3
		CV%	11.1	-240.5	-737.6	11.8	1515.4	287.7	11.4	-699.0	742.4
		Min	99	-23	-17	94	-29	-20	94	-29	-20
		Median	118.0	-5.5	-3.0	123.5	0.5	5.0	119.5	-2.5	0.0
		Max	146	18	13	165	20	20	165	20	20

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Systolic Blood Pressure (mmHg)	Visit 6 - Day 29±1	N	20	20		19	19		39	39	
		Mean	124.5	-1.7		120.1	-2.5		122.3	-2.1	
		SD	14.4	12.7		10.6	14.7		12.7	13.6	
		CV%	11.5	-771.2		8.8	-582.9		10.4	-652.9	
		Min	102	-25		89	-29		89	-29	
		Median	122.5	0.0		122.0	-2.0		122.0	-2.0	
		Max	155	21		141	28		155	28	
Systolic Blood Pressure (mmHg)	Final Visit - Day 56±4/ETV	N	20	20		20	20		40	40	
		Mean	122.0	-4.2		125.0	2.0		123.5	-1.1	
		SD	12.0	9.3		15.3	13.9		13.7	12.1	
		CV%	9.8	-221.8		12.3	711.5		11.1	-1073.1	
		Min	100	-20		97	-29		97	-29	
		Median	121.0	-1.0		122.5	0.5		121.0	-1.0	
		Max	141	15		152	31		152	31	
Diastolic Blood Pressure (mmHg)	Screening - Day -15/-1	N	20			20			40		
		Mean	78.5			75.7			77.1		
		SD	8.5			10.0			9.3		

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			Value	Change from Baseline	Change from Pre-dose	Value	Change from Baseline	Change from Pre-dose	Value	Change from Baseline	Change from Pre-dose
Diastolic Blood Pressure (mmHg)	Visit 2 - Day 1 - Pre-dose	CV%	10.9			13.2			12.0		
		Min	67			54			54		
		Median	76.0			77.5			77.0		
		Max	97			92			97		
		N	20	20		20	20		40	40	
		Mean	76.9	-1.6		77.5	1.8		77.2	0.1	
		SD	9.4	6.6		10.4	6.9		9.8	6.9	
Diastolic Blood Pressure (mmHg)	Visit 2 - Day 1 - Post-dose	CV%	12.2	-412.8		13.4	385.2		12.7	6901.5	
		Min	58	-11		62	-10		58	-11	
		Median	76.0	-0.5		76.5	2.5		76.0	0.5	
		Max	92	14		105	17		105	17	
		N	20	20	20	20	20	20	40	40	40
		Mean	75.6	-2.9	-1.3	76.0	0.3	-1.5	75.8	-1.3	-1.4
		SD	8.4	5.6	6.4	10.8	6.4	6.0	9.6	6.1	6.1
Diastolic Blood Pressure (mmHg)	Visit 2 - Day 1 - Post-dose	CV%	11.2	-192.1	-491.7	14.2	2133.3	-397.4	12.6	-472.3	-435.8
		Min	66	-14	-14	60	-13	-16	60	-14	-16
		Median	73.0	-4.0	-0.5	71.5	0.5	-1.0	72.0	-0.5	-1.0
		Max	93	7	8	101	11	9	101	11	9

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Diastolic Blood Pressure (mmHg)	Visit 3 - Day 8±1 - Pre-dose	N	19	19		20	20		39	39	
		Mean	76.6	-2.3		74.0	-1.7		75.3	-2.0	
		SD	11.8	8.8		9.8	7.8		10.8	8.2	
		CV%	15.4	-381.4		13.2	-470.0		14.3	-415.0	
		Min	53	-20		51	-17		51	-20	
		Median	75.0	-2.0		76.0	-3.0		75.0	-3.0	
		Max	106	10		90	11		106	11	
Diastolic Blood Pressure (mmHg)	Visit 3 - Day 8±1 - Post-dose	N	20	20	19	20	20	20	40	40	39
		Mean	74.9	-3.6	-1.2	76.1	0.4	2.1	75.5	-1.6	0.5
		SD	9.9	7.7	6.0	9.8	7.0	5.2	9.7	7.5	5.8
		CV%	13.2	-213.7	-520.8	12.9	1740.4	252.5	12.9	-470.0	1183.7
		Min	61	-19	-16	53	-12	-7	53	-19	-16
		Median	74.0	-4.0	-1.0	77.5	2.0	2.0	75.0	-2.0	1.0
		Max	95	11	12	90	9	14	95	11	14
Diastolic Blood Pressure (mmHg)	Visit 6 - Day 29±1	N	20	20		19	19		39	39	
		Mean	75.1	-3.4		74.3	-1.4		74.7	-2.4	
		SD	8.8	8.3		10.1	7.3		9.4	7.8	

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Diastolic Blood Pressure (mmHg)	Final Visit - Day 56±4/ETV	CV%	11.8	-247.3		13.7	-533.8		12.6	-326.5	
		Min	62	-18		53	-11		53	-18	
		Median	73.0	-3.5		72.0	1.0		73.0	-2.0	
		Max	88	10		96	16		96	16	
		N	20	20		20	20		40	40	
		Mean	76.7	-1.8		75.8	0.1		76.2	-0.9	
		SD	7.4	7.5		10.9	7.4		9.2	7.4	
Pulse Rate (beats/min)	Screening - Day -15/-1	CV%	9.7	-416.4		14.3	7397.7		12.1	-872.1	
		Min	66	-14		55	-15		55	-15	
		Median	77.0	-1.0		76.5	1.0		77.0	1.0	
		Max	89	9		94	11		94	11	
		N	20			20			40		
		Mean	71.5			76.1			73.8		
		SD	7.4			11.0			9.6		
		CV%	10.4			14.5			13.0		
		Min	58			61			58		
		Median	71.5			74.5			73.5		
		Max	87			102			102		
		N	20			20			40		
		Mean	71.5			76.1			73.8		
		SD	7.4			11.0			9.6		