

TABLE 8
PN 200-110 STUDY #301
SUMMARY OF BACKGROUND DATA
ALL CENTERS
VALID AND PARTIALLY VALID PATIENTS

VARIABLE /		TREATMENT					
CATEGORY STATISTIC		5 MG.	10 MG.	15 MG.	20 MG.	PLACEBO	TOTAL
AGE (YEARS)							
N		39	38	39	41	41	198
MEDIAN		53.0	53.5	53.0	53.0	49.0	53.0
MEAN		52.9	51.3	51.2	52.2	49.8	51.5
STD		10.58	12.07	10.50	8.88	17.05	10.90
MIN		34.0	22.0	24.0	31.0	27.0	22.0
MAX		73.0	74.0	69.0	68.0	77.0	77.0
F(4,193) = 0.490, PROB > F = 0.7438							
SEX							
MALE		29 (74%)	26 (68%)	29 (74%)	29 (71%)	30 (73%)	143 (72%)
FEMALE		10 (26%)	12 (32%)	10 (26%)	12 (29%)	11 (27%)	55 (28%)
TOTAL		39	38	39	41	41	198
CHI-SQUARE (4 DF) = 0.515 PROB > CHI = 0.9720							
RACE							
CAUCASIAN		17 (44%)	17 (42%)	16 (41%)	20 (49%)	14 (34%)	83 (42%)
NEGRO		22 (56%)	22 (58%)	23 (59%)	20 (49%)	27 (66%)	114 (58%)
AMER. INDIAN		0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
ORIENTAL		0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
OTHER		0 (0%)	0 (0%)	0 (0%)	1 (2%)	0 (0%)	1 (1%)
TOTAL		39	38	39	41	41	198
CHI-SQUARE (8 DF) = 5.976 PROB > CHI = 0.6499							
HEIGHT (INCHES)							
N		39	38	39	41	41	198
MEDIAN		68.0	67.5	68.0	68.0	69.0	68.0
MEAN		67.8	68.1	68.0	67.6	68.5	68.0
STD		3.08	3.74	3.88	3.83	3.51	3.60
MIN		62.0	62.0	61.0	60.0	62.0	60.0
MAX		73.0	76.0	76.0	76.0	77.0	77.0
F(4,193) = 0.360, PROB > F = 0.8358							

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TABLE 6

TABLE 7
PN 200-110 STUDY NO. 301

MEAN DAILY DOSE (IN MG)
VALID PATIENTS

	PN 200-110 Randomized Treatment Group			
	5 mg	10 mg	15 mg	20 mg
Week 1				
N	35	34	33	41
Mean	4.94	4.95	4.92	9.88
S.D.	0.37	0.37	0.45	0.88
Min	4.29	3.93	3.93	6.50
Max	6.07	5.71	6.25	12.86
Week 2				
N	35	34	38	41
Mean	5.00	9.85	9.39	13.46
S.D.	0.20	1.21	1.47	3.49
Min	4.29	5.00	4.29	4.69
Max	5.42	12.86	10.71	16.88
Week 3				
N	35	34	38	41
Mean	4.87	9.38	13.53	17.50
S.D.	0.24	1.35	3.14	5.37
Min	4.06	5.00	5.00	4.29
Max	5.00	10.71	16.50	25.71
Week 4				
N	35	34	38	41
Mean	4.90	9.26	14.33	17.17
S.D.	0.34	1.57	3.94	5.03
Min	3.57	5.00	4.64	4.79
Max	5.71	10.83	30.00	21.43
Week 5				
N	35	34	37 ⁺	41
Mean	4.88	9.45	13.88	17.07
S.D.	0.22	1.60	3.41	5.22
Min	4.29	4.77	4.64	3.21
Max	5.00	11.67	24.64	22.86

⁺Patient No. 254 failed to return the medication bottle for Week 5 so his average daily dose could not be determined for this interval.

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TABLE 8
PN 200-110 STUDY NO. 301

MEAN DAILY DOSE (IN MG)
VALID AND PARTIALLY VALID PATIENTS

	PN 200-110 Randomized Treatment Group			
	5 mg	10 mg	15 mg	20 mg
Week 1				
N	39	38	39	41
Mean	4.92	4.90	4.91	9.88
S.D.	0.42	0.40	0.44	0.86
Min	3.89	3.93	3.93	6.50
Max	6.07	5.71	6.25	12.86
Week 2				
N	38	37	39	41
Mean	4.97	9.06	9.41	13.46
S.D.	0.22	1.16	1.46	3.49
Min	4.29	5.00	4.29	4.69
Max	5.42	12.86	10.71	16.88
Week 3				
N	38	34	39	41
Mean	4.86	9.38	13.57	17.50
S.D.	0.25	1.35	3.11	5.37
Min	4.06	5.00	5.00	4.29
Max	5.00	10.71	16.50	25.71
Week 4				
N	37	34	38	41
Mean	4.86	9.26	14.33	17.17
S.D.	0.39	1.57	3.94	5.03
Min	3.57	5.00	4.64	4.79
Max	5.71	10.83	30.00	21.43
Week 5				
N	35	34	37	41
Mean	4.88	9.45	13.88	17.07
S.D.	0.22	1.60	3.41	5.22
Min	4.29	4.77	4.64	3.21
Max	5.00	11.67	24.64	22.86

*Patient No. 254 failed to return the medication bottle for Week 5 and his average daily dose could not be determined for this interval.

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SPONTANEOUS BLOOD PRESSURE RESPONSE TO TREATMENT WITH AN INVESTIGATOR, INVESTIGATOR INTERACTIONS FOR THE PLATEAU PERIOD - VALID PATIENTS

Variables	Investigator	Baseline Means (Sample Size)					Mean Change From Baseline					Treatment x Investigator Interaction	Treatment x Time Interaction	Treatment x Time x Investigator Interaction
		PN 200-110				Placebo	PN 200-110				Placebo	P-Value	P-Value	P-Value
		5 mg	10 mg	15 mg	20 mg		5 mg	10 mg	15 mg	20 mg				
Supine Systolic B.P. (mm Hg)	A	138.2 (6)	167.2 (3)	169.7 (7)	160.0 (6)	154.0 (6)	-18.33	-26.97	-24.67	-26.58	-0.11	.8132	.6467	.9682
	B	151.2 (5)	162.4 (5)	149.3 (6)	152.2 (6)	150.7 (6)	-9.87	-20.27	-12.78	-18.00	-2.78			
	C	134.5 (6)	147.7 (7)	150.3 (9)	152.0 (9)	145.9 (9)	-15.78	-17.62	-21.30	-22.37	-3.81			
	D	163.6 (8)	165.0 (7)	161.0 (7)	152.4 (9)	149.4 (7)	-18.50	-24.19	-20.43	-20.78	-2.19			
	E	149.5 (5)	170.9 (4)	161.4 (4)	154.3 (5)	155.8 (5)	-9.27	-29.29	-25.75	-12.47	-1.27			
	F	160.4 (5)	155.5 (6)	163.6 (5)	155.2 (6)	156.0 (6)	-23.13	-17.17	-32.47	-20.50	-9.67			
Supine Diastolic B.P. (mm Hg)	A	104.3 (6)	103.8 (5)	104.9 (7)	104.8 (6)	106.2 (6)	-12.33	-11.73	-14.57	-15.50	-3.20	.9495	.7384	.8528
	B	102.0 (5)	103.2 (5)	102.8 (6)	102.0 (6)	102.8 (6)	-11.20	-15.60	-17.72	-18.06	-4.50			
	C	104.5 (6)	103.0 (7)	102.1 (9)	102.7 (9)	102.3 (9)	-14.89	-17.71	-20.70	-20.44	-9.15			
	D	104.4 (8)	105.6 (7)	105.3 (7)	106.0 (9)	104.1 (7)	-15.96	-20.10	-17.67	-17.74	-9.24			
	E	105.1 (5)	106.0 (4)	102.5 (4)	102.6 (5)	105.6 (5)	-9.27	-19.62	-13.04	-14.67	-4.63			
	F	104.8 (5)	104.3 (6)	103.4 (5)	102.3 (6)	103.7 (6)	-18.53	-16.89	-16.93	-16.89	-7.61			
Supine Pulse (beats/min)	A	74.3 (6)	70.0 (5)	69.4 (7)	73.8 (6)	71.0 (6)	1.67	5.07	1.29	1.83	-1.89	.6295	.9982	.5844
	B	72.6 (5)	77.0 (5)	70.7 (6)	71.7 (6)	75.3 (6)	4.37	0.80	6.39	3.83	1.67			
	C	80.8 (6)	74.9 (7)	80.6 (9)	78.1 (9)	76.6 (9)	-3.06	4.48	1.07	4.41	-1.37			
	D	80.4 (8)	76.4 (7)	76.7 (7)	76.4 (9)	79.1 (7)	4.96	6.57	9.71	4.20	-0.21			
	E	82.8 (5)	71.0 (4)	68.3 (4)	75.6 (5)	74.2 (5)	-0.07	8.42	6.17	0.80	-3.20			
	F	78.4 (5)	77.3 (6)	79.0 (4)	78.0 (6)	76.8 (6)	0.13	1.56	-0.75	-1.22	1.61			
Standing Systolic B.P. (mm Hg)	A	148.0 (6)	161.6 (5)	154.9 (7)	144.2 (6)	136.5 (6)	-17.44	-24.23	-21.90	-26.22	2.83	.9246	.5619	.9467
	B	150.0 (5)	155.4 (5)	153.2 (6)	150.8 (6)	152.7 (6)	-8.00	-11.00	-17.00	-17.22	-4.61			
	C	150.2 (6)	147.3 (7)	150.1 (9)	148.1 (9)	143.3 (9)	-10.67	-13.67	-24.24	-16.67	1.07			
	D	161.1 (8)	156.3 (7)	158.9 (7)	149.4 (9)	143.1 (7)	-18.21	-20.95	-23.86	-20.04	4.33			
	E	150.8 (5)	164.6 (4)	155.5 (5)	146.6 (5)	155.2 (5)	-12.80	-19.98	-18.28	-6.87	-4.83			
	F	156.8 (5)	156.8 (6)	158.4 (5)	151.5 (6)	151.7 (6)	-20.00	-23.61	-27.47	-20.28	-8.64			
Standing Diastolic B.P. (mm Hg)	A	99.5 (6)	105.4 (5)	99.9 (7)	99.3 (6)	92.2 (6)	-12.06	-14.50	-15.76	-16.11	1.61	.9898	.6212	.4763
	B	101.8 (5)	106.6 (5)	104.3 (6)	105.2 (6)	102.0 (6)	-7.67	-15.47	-18.00	-18.22	-1.56			
	C	105.3 (6)	103.9 (7)	102.2 (9)	102.4 (9)	101.3 (9)	-13.11	-15.10	-18.67	-17.52	-3.89			
	D	102.8 (8)	103.9 (7)	106.4 (7)	108.7 (9)	101.9 (7)	-10.12	-16.09	-16.52	-17.04	-1.71			
	E	108.4 (5)	113.9 (4)	115.3 (5)	105.9 (5)	113.9 (5)	-7.97	-20.04	-17.00	-13.63	-4.40			
	F	104.8 (5)	105.0 (6)	105.6 (5)	107.0 (6)	105.5 (6)	-13.07	-17.72	-15.47	-18.17	-6.56			
Standing Pulse (beats/min)	A	80.0 (6)	80.4 (5)	79 (7)	86.0 (6)	79.7 (6)	3.94	7.07	-0.71	2.11	-5.33	.5728	.9456	.9398
	B	86.6 (5)	88.2 (5)	79.5 (6)	84.8 (6)	83.3 (6)	1.60	0.20	8.28	4.72	1.33			
	C	84.8 (6)	80.0 (7)	83.8 (9)	80.7 (9)	80.4 (9)	-2.94	5.62	0.74	0.27	-1.41			
	D	89.4 (8)	90.1 (7)	86.7 (7)	84.6 (9)	85.4 (7)	5.60	2.57	7.02	5.76	0.33			
	E	93.6 (5)	80.5 (4)	86.3 (5)	78.8 (5)	84.0 (5)	-0.20	7.92	4.72	0.40	-2.53			
	F	84.8 (5)	82.0 (6)	85.6 (5)	80.5 (6)	85.7 (6)	-2.27	5.89	3.93	7.28	1.17			

TABLE 9

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TABLE 10
PN 200-110 STUDY NO. 301

SUMMARY COMPARATIVE RESULTS FOR BLOOD PRESSURE AND PULSE
WEEK 1 - VALID AND PARTIALLY VALID PATIENTS

Variable	Randomized Treatment Group	No. of Patients	Baseline		Mean Change	S.D.	Adjusted Mean Change††	Treatment Period	
			Mean	S.D.				Mean	S.D.
Supine Systolic B.P. (mm Hg)	PN 5 mg	39	157.9	17.14	-10.4***	13.99	-9.6	147.3	13.62
	PN 10 mg	38	159.0	14.47	-11.5***	11.66	-10.3	147.5	12.04
	PN 15 mg	39	158.6	20.45	-12.7***	17.53	-11.7	145.8	17.37
	PN 20 mg	41	154.0	13.52	-15.1***	11.41	-16.0	138.9	12.60
	Placebo	41	151.5	14.40	-0.9	10.60	-2.9	150.7	15.29
Supine Diastolic B.P. (mm Hg)	PN 5 mg	39	104.2	4.47	-10.0***	7.74		94.2	9.05
	PN 10 mg	38	104.0	4.18	-10.1***	7.09		93.9	7.72
	PN 15 mg	39	103.6	3.64	-8.6***	9.04		95.0	8.12
	PN 20 mg	41	103.5	3.95	-14.4***	6.64		85.1	5.28
	Placebo	41	103.9	4.36	-4.5***	3.68		99.4	5.77
Supine Pulse (per min.)	PN 5 mg	39	78.4	10.41	2.7(*)	9.15	3.5	81.1	11.02
	PN 10 mg	38	75.5	9.06	3.8***	9.12	5.6	81.3	11.88
	PN 15 mg	38	74.7	9.24	2.5(*)	8.57	2.1	77.2	9.24
	PN 20 mg	41	75.6	8.22	4.5***	7.51	4.4	80.1	9.25
	Placebo	41	75.7	9.25	-0.8	9.25	-0.8	75.0	10.26
Standing Systolic B.P. (mm Hg)	PN 5 mg	39	154.2	17.45	-11.4***	12.33	-10.3	142.8	14.67
	PN 10 mg	38	155.3	12.77	-10.0***	13.20	-8.5	145.3	14.32
	PN 15 mg	38	154.8	14.24	-12.4***	15.65	-11.1	142.4	15.56
	PN 20 mg	41	148.5	12.48	-14.9***	13.75	-16.3	133.7	13.13
	Placebo	41	146.9	17.08	0.9	11.28	-1.4	147.7	15.27
Standing Diastolic B.P. (mm Hg)	PN 5 mg	39	103.8	6.83	-8.8***	6.96	-8.9	95.0	10.25
	PN 10 mg	38	105.4	7.61	-8.2***	7.25	-7.8	97.2	7.51
	PN 15 mg	38	104.6	6.12	-6.1***	7.97	-6.0	98.5	8.85
	PN 20 mg	41	104.8	5.78	-12.8***	9.53	-12.6	92.1	9.87
	Placebo	41	102.0	9.06	-1.8	7.00	-2.4	100.3	8.08
Standing Pulse (per min.)	PN 5 mg	39	86.4	10.53	2.1	10.12	2.9	88.5	12.77
	PN 10 mg	38	84.0	10.12	3.9**	11.03	3.9	89.8	12.62
	PN 15 mg	38	83.3	6.35	1.8	9.65	1.7	85.1	10.47
	PN 20 mg	41	82.7	9.74	4.9***	7.69	4.5	87.6	10.09
	Placebo	41	83.1	9.39	-1.8	10.37	-2.0	91.3	11.40

(*) p<.10, **p<.05, ***p<.01, ****p<.001

†Results are presented according to randomized treatment group and not dose of PN 200-110 prescribed for Week 1.

††Presented only when analysis of covariance assumptions are met.

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TABLE 11
PN 200-110 STUDY NO. 301

SUMMARY COMPARATIVE RESULTS FOR BLOOD PRESSURE AND PULSE
WEEK 1 ANALYSIS - EVALUATION ACCORDING TO PRESCRIBED DOSE ADMINISTERED
VALID AND PARTIALLY VALID PATIENTS

Variable	Total Daily Prescribed Dose	No. of Patients	Baseline		Mean Change	S.D.	Adjusted Mean Change†	Treatment Period	
			Mean	S.D.				Mean	S.D.
Supine Systolic B.P. (mm Hg)	PN 5 mg	116	158.5	17.40	-11.6***	14.52		146.9	14.51
	PN 10 mg	41	154.0	13.52	-13.1***	11.41		138.9	12.60
	Placebo	41	151.5	14.40	-0.9	10.60		150.7	15.29
Supine Diastolic B.P. (mm Hg)	PN 5 mg	116	104.0	8.89	-9.6***	7.97	-9.5	94.2	8.26
	PN 10 mg	41	103.5	3.95	-14.4***	8.64	-14.3	89.1	5.20
	Placebo	41	103.9	4.36	-4.5***	5.68	-4.3	99.4	5.77
Supine Pulse (per. min.)	PN 5 mg	115	76.2	9.65	3.7***	9.00	3.7	79.9	10.84
	PN 10 mg	41	75.6	8.22	4.5***	7.51	4.4	80.1	9.25
	Placebo	41	75.7	9.25	-0.8	9.25	-0.8	75.0	10.26
Standing Systolic B.P. (mm Hg)	PN 5 mg	115	154.8	14.85	-11.3***	13.70	-10.0	143.5	14.12
	PN 10 mg	41	148.5	12.48	-14.9*	13.75	-16.3	132.7	13.13
	Placebo	41	146.9	17.08	0.9	11.28	-1.3	147.3	15.23
Standing Diastolic B.P. (mm Hg)	PN 5 mg	115	104.6	6.85	-7.7***	7.43	-7.6	96.9	5.99
	PN 10 mg	41	104.8	5.78	-12.6***	9.53	-12.6	92.1	9.87
	Placebo	41	105.0	9.06	-1.8	7.00	-2.4	100.3	8.98
Standing Pulse (per. min.)	PN 5 mg	115	84.6	9.23	3.3***	10.36	3.3	87.8	10.07
	PN 10 mg	41	82.7	9.74	4.9***	7.69	4.3	87.6	10.09
	Placebo	41	83.1	9.39	-1.6	10.37	-2.0	81.3	10.40

(*) p<.10, **p<.05, ***p<.01, ****p<.001

When appropriate, treatment groups receiving the same prescribed dose of PN 200-110 were pooled.

†Represented only when analysis of covariance assumptions are met.

TABLE 12
PN 200-110 STUDY -OL 301

SUMMARY COMPARATIVE RESULTS FOR BLOOD PRESSURE AND PULSE
WEEK 2 - VALID AND PARTIALLY VALID PATIENTS

Variable	Randomized Treatment Group	No. of Patients	Baseline		Mean Change	S.D.	Adjusted Mean Change†	Treatment Period	
			Mean	S.D.				Mean	S.D.
Supine Systolic B.P. (mm Hg)	PN 5 mg	38	138.3	17.17	-11.4***	11.25		144.0	14.36
	PN 10 mg	37	139.4	14.48	-19.2***	12.14		140.1	11.13
	PN 15 mg	39	138.6	20.65	-15.2***	16.98		142.6	13.03
	PN 20 mg	41	134.0	13.52	-19.2***	13.04		134.8	14.00
	Placebo	41	131.5	14.40	-1.4	13.12		150.2	17.74
Supine Diastolic B.P. (mm Hg)	PN 5 mg	38	104.3	4.21	-11.4***	7.07		92.9	9.17
	PN 10 mg	37	104.1	4.19	-14.6***	6.61		89.5	7.93
	PN 15 mg	39	103.6	3.64	-12.1***	8.05		91.5	7.16
	PN 20 mg	41	103.5	3.95	-16.0***	6.22		87.5	7.35
	Placebo	41	103.9	4.36	-5.3***	6.98		98.6	7.98
Supine Pulse (per. min.)	PN 5 mg	38	78.6	10.50	3.3*	8.17	3.9	81.9	10.70
	PN 10 mg	37	75.6	9.17	3.8**	8.56	3.7	79.4	10.89
	PN 15 mg	38	74.7	9.24	5.4***	7.52	5.0	80.1	11.19
	PN 20 mg	41	75.6	8.22	4.7**	9.22	4.6	80.3	9.86
	Placebo	41	75.7	9.25	-0.5	8.66	-0.6	75.2	11.18
Standing Systolic B.P. (mm Hg)	PN 5 mg	38	134.5	17.68	-13.2***	13.31	-12.1	141.1	13.05
	PN 10 mg	37	135.6	12.87	-17.6***	5.07	-15.9	138.0	13.72
	PN 15 mg	38	134.8	14.24	-14.7***	17.32	-13.3	140.1	14.76
	PN 20 mg	41	148.5	12.48	-14.3***	15.62	-17.8	134.2	13.48
	Placebo	41	146.9	17.08	-0.4	11.36	-2.7	146.5	17.12
Standing Diastolic B.P. (mm Hg)	PN 5 mg	38	103.7	6.88	-9.2***	7.43	-9.3	94.5	10.18
	PN 10 mg	37	103.4	7.71	-13.3***	7.17	-12.8	92.2	8.92
	PN 15 mg	38	104.6	6.32	-11.7***	11.08	-11.5	93.0	10.44
	PN 20 mg	41	104.8	5.78	-15.1***	7.88	-14.9	89.7	8.42
	Placebo	41	102.0	9.06	-1.6	7.83	-2.3	100.4	9.26
Standing Pulse (per. min.)	PN 5 mg	38	86.6	10.56	3.1*	7.88	4.2	89.7	10.64
	PN 10 mg	37	84.2	10.18	3.6(*)	11.11	3.7	87.7	11.88
	PN 15 mg	38	83.3	6.35	4.3**	9.19	4.1	87.6	9.76
	PN 20 mg	41	82.7	9.74	4.2*	11.39	3.7	85.9	11.03
	Placebo	41	83.1	9.39	-1.2	9.08	-1.5	81.9	10.50

(*) p<.10, *p<.05, **p<.01, ***p<.001

†Results are presented according to randomized treatment group and not dose of PN 200-110 prescribed for Week 2.
‡Presented only when analysis of covariance assumptions are met.

0122

07-02288

TABLE 13
PM 200-110 STUDY NO. 301

SUMMARY COMPARATIVE RESULTS FOR BLOOD PRESSURE AND PULSE
WEEK 2 ANALYSIS - EVALUATION ACCORDING TO PRESCRIBED DOSE ADMINISTERED
VALID AND PARTIALLY VALID PATIENTS

Variable	Total Daily Prescribed Dose	No. of Patients	Baseline		Mean Change	S.D.	Adjusted Mean Change†	Treatment Period	
			Mean	S.D.				Mean	S.D.
Supine Systolic B.P. (mm Hg)	PM 5 mg	38	158.3	17.17	-14.3***	11.23		144.0	14.56
	PM 10 mg	76	159.0	17.48	-17.6***	14.82		141.4	11.30
	PM 15 mg	41	154.0	13.52	-19.2***	13.04		136.8	14.00
	Placebo	41	151.5	14.40	-1.4	13.12		150.2	17.72
Supine Diastolic B.P. (mm Hg)	PM 5 mg	38	104.3	4.51	-11.4***	7.07		92.9	9.17
	PM 10 mg	76	103.9	3.90	-13.3***	7.45		90.5	7.56
Supine Pulse (per. min.)	PM 15 mg	41	103.5	3.95	-16.0***	6.22		87.5	7.33
	Placebo	41	103.5	4.36	-5.3***	6.98		98.6	7.98
	PM 5 mg	38	78.6	10.50	3.3*	8.17	3.5	81.9	10.70
	PM 10 mg	75	75.1	9.16	4.6***	8.03	4.4	79.8	10.57
Supine Systolic B.P. (mm Hg)	PM 15 mg	41	75.6	8.22	4.7**	9.22	4.6	80.4	9.86
	Placebo	41	75.7	9.25	-0.5	8.66	-0.6	75.2	11.18
	PM 5 mg	38	154.3	17.68	-13.2***	13.31		141.1	15.05
	PM 10 mg	75	155.2	13.50	-16.1***	16.20		139.1	14.20
Standing Diastolic B.P. (mm Hg)	PM 15 mg	41	148.5	12.48	-14.3***	15.62		134.2	15.48
	Placebo	41	146.9	17.08	-0.4	11.96		146.5	17.12
	PM 5 mg	38	103.7	6.88	-9.2***	7.43	-9.3	94.5	10.18
	PM 10 mg	75	105.0	6.91	-12.5***	9.33	-12.2	92.6	9.66
Standing Pulse (per. min.)	PM 15 mg	41	104.8	5.78	-15.1***	7.88	-14.9	89.7	8.41
	Placebo	41	102.0	9.06	-1.6	7.83	-2.3	100.4	9.26
	PM 5 mg	38	86.6	10.56	3.1*	7.88	4.2	89.7	10.64
	PM 10 mg	75	83.7	8.41	4.0**	10.12	3.9	87.7	10.78
Standing Systolic B.P. (mm Hg)	PM 15 mg	41	82.7	9.74	4.2*	11.39	3.7	86.9	11.03
	Placebo	41	83.1	9.39	-1.2	9.08	-1.5	81.9	10.50

(*) p<.10, **p<.05, ***p<.01, ****p<.001

When appropriate, treatment groups receiving the same prescribed dose of PM 200-110 were pooled.

0123
07-02289

TABLE 14
PW 200-110 STUDY NO. 301

SUMMARY COMPARATIVE RESULTS FOR BLOOD PRESSURE AND PULSE
MEAN OVER PLATEAU PERIOD (WEEKS 3-5) - VALID PATIENTS ONLY

Table	Randomized Treatment Group	No. of Patients	Baseline		Mean Change	S.D.	Adjusted Mean Change†	Treatment Period	
			Mean	S.D.				Mean	S.D.
Supine Systolic B.P. (mm Hg)	PN 5 mg	35	156.9	16.48	-16.1***	10.51		140.8	9.95
	PN 10 mg	34	160.4	14.32	-22.0***	13.78		138.4	9.53
	PN 15 mg	38	158.6	20.75	-22.4***	17.70		136.3	14.23
	PN 20 mg	41	154.0	13.52	-20.5***	12.45		133.5	12.02
	Placebo	39	151.1	13.69	-3.4*	9.17		147.7	13.19
Supine Diastolic B.P. (mm Hg)	PN 5 mg	35	104.2	4.48	-13.9***	6.20	-13.7	90.3	6.96
	PN 10 mg	34	104.3	4.35	-17.1***	6.89	-16.9	87.2	6.72
	PN 15 mg	38	103.5	3.68	-17.9***	7.95	-17.4	86.3	7.32
Supine Pulse (per. min.)	PN 20 mg	41	103.5	3.95	-17.3***	5.87	-17.4	86.2	6.32
	Placebo	39	103.9	4.44	-7.0***	6.45	-7.0	96.9	6.97
	PN 5 mg	35	78.4	10.22	1.5	7.00	2.2	79.9	10.27
	PN 10 mg	34	74.8	8.55	4.4**	7.37	4.1	79.2	8.17
	PN 15 mg	37	74.6	9.36	4.0**	7.40	3.6	78.6	10.27
Standing Systolic B.P. (mm Hg)	PN 20 mg	41	75.6	8.22	2.6**	5.59	2.6	78.2	8.04
	Placebo	39	75.7	8.91	-0.6	6.87	-0.6	75.2	9.03
	PN 5 mg	35	153.3	17.56	-14.9***	10.89	-14.0	138.4	11.13
	PN 10 mg	34	156.2	15.24	-18.8***	15.15	-16.2	137.4	13.01
	PN 15 mg	37	154.7	14.42	-22.9***	17.16	-21.1	131.8	13.91
Standing Diastolic B.P. (mm Hg)	PN 20 mg	41	148.5	12.48	-18.2***	13.36	-20.0	130.3	12.98
	Placebo	39	146.5	14.83	-1.2	11.98	-4.1	145.3	12.85
	PN 5 mg	35	103.6	6.97	-10.7***	5.11	-10.9	92.9	8.36
	PN 10 mg	34	109.9	7.89	-16.3***	6.86	-15.7	89.6	7.59
	PN 15 mg	37	104.4	6.08	-17.0***	9.96	-17.0	87.4	9.08
Standing Pulse (per. min.)	PN 20 mg	41	104.8	5.78	-16.9***	7.13	-16.7	87.9	7.93
	Placebo	39	102.4	8.79	-2.8*	6.60	-3.4	99.6	7.90
	PN 5 mg	35	86.6	9.55	1.3	7.74	2.2	87.9	11.07
	PN 10 mg	34	83.6	9.87	4.7**	8.25	4.7	88.5	9.18
	PN 15 mg	37	83.3	6.42	3.8**	7.73	3.6	87.1	9.91
	PN 20 mg	41	82.7	9.74	4.8***	8.30	4.4	87.4	9.33
	Placebo	39	82.9	9.25	-1.0	8.07	-1.3	81.9	9.77

*p<.10, **p<.05, ***p<.01, ****p<.001

†Results are presented according to pre-determined randomized treatment group pooling together all patients randomized to the treatment group.

‡Presented only when analysis of covariance assumptions are met.

TABLE 13
PN 200-110 STUDY NO. 301

SUMMARY COMPARATIVE RESULTS FOR BLOOD PRESSURE AND PULSE
ENDPOINT ANALYSIS FOR THE PLATEAU PERIOD
VALID AND PARTIALLY VALID PATIENTS

Variable	Randomized Treatment Group	No. of Patients	Baseline		Mean Change	S.D.	Adjusted Mean Change†	Treatment Period	
			Mean	S.D.				Mean	S.D.
Supine Systolic B.P. (mm Hg)	PN 5 mg	30	158.3	17.17	-16.9***	14.68	-15.7	161.4	16.71
	PN 10 mg	34	160.4	14.32	-22.3***	14.96	-19.9	138.1	11.83
	PN 15 mg	39	158.6	20.45	-24.1***	18.12	-22.8	134.5	15.11
	PN 20 mg	41	156.0	13.32	-19.0***	14.10	-20.3	135.0	13.11
	Placebo	40	150.8	13.67	-3.8*	11.37	-6.5	167.0	17.66
Supine Diastolic B.P. (mm Hg)	PN 5 mg	30	104.3	4.51	-13.6***	8.42	-13.5	90.7	9.06
	PN 10 mg	34	104.3	4.35	-17.4***	8.21	-17.3	86.9	8.04
	PN 15 mg	39	103.6	3.64	-17.4***	7.89	-17.4	84.2	7.89
	PN 20 mg	41	103.5	3.93	-17.1***	8.07	-17.2	86.4	8.38
	Placebo	40	103.9	4.46	-6.5***	8.19	-6.3	97.4	8.47
Supine Pulse (per min.)	PN 5 mg	30	78.6	10.30	1.0	7.62	1.7	79.6	11.53
	PN 10 mg	34	74.8	8.33	3.9*	9.64	3.6	78.6	9.86
	PN 15 mg	38	74.7	9.24	3.9**	8.89	3.7	78.6	11.83
	PN 20 mg	41	73.4	8.22	2.1(*)	6.91	2.1	77.8	10.11
	Placebo	40	75.4	9.06	-1.6	7.92	-1.7	73.8	9.13
Standing Systolic B.P. (mm Hg)	PN 5 mg	30	154.3	17.68	-16.1***	15.00	-14.7	138.1	17.73
	PN 10 mg	34	156.2	13.24	-19.3***	16.39	-17.0	136.7	13.82
	PN 15 mg	38	154.8	14.24	-23.6***	19.60	-21.9	131.2	16.89
	PN 20 mg	41	148.5	12.48	-16.7***	16.42	-18.4	131.9	16.66
	Placebo	40	145.7	15.51	-1.2	15.62	-6.3	144.4	12.63
Standing Diastolic B.P. (mm Hg)	PN 5 mg	30	103.7	6.88	-10.9***	7.70		92.8	11.64
	PN 10 mg	34	103.9	7.89	-17.6***	7.99		88.3	8.70
	PN 15 mg	38	104.6	6.12	-16.8***	10.31		87.8	9.67
	PN 20 mg	41	104.8	5.78	-16.4***	9.00		88.4	9.16
	Placebo	40	101.9	9.15	-2.4	9.36		99.3	8.18
Standing Pulse (per min.)	PN 5 mg	30	86.6	10.36	1.4	9.33	2.3	88.0	10.38
	PN 10 mg	34	83.8	9.87	4.6*	10.13	4.6	88.4	9.58
	PN 15 mg	38	83.3	6.73	4.1*	9.32	3.9	87.3	11.34
	PN 20 mg	41	82.7	9.74	4.1*	10.08	3.8	86.8	10.94
	Placebo	40	82.8	9.28	-1.9	8.80	-2.3	80.8	10.30

(*) p<.10, **p<.05, ***p<.01, ****p<.001

†Results are presented according to pre-determined randomized treatment group pooling together all patients randomized to the treatment group.

‡Presented only when analysis of covariance assumptions are met.

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07-02291

TABLE 16

PN 200-110 STUDY NO. 301
SUMMARY OF PAIRWISE COMPARISONS BETWEEN
ACTIVE TREATMENT GROUP MEAN DIFFERENCES
VITAL SIGNS

WEEK 2
(DATA PRESENTED IN TABLE 13)

Variable	10 mg vs. 5 mg	15 mg vs. 5 mg	15 mg vs. 10 mg
+Supine Systolic B.P.			
+Supine Diastolic B.P.		**	(*)
Supine Pulse			
+Standing Systolic B.P.			
Standing Diastolic B.P.	(*)	**	(*)
Standing Pulse			

(*) $p < .10$, * $p < .05$, ** $p < .01$,

PLATEAU MEAN
(DATA PRESENTED IN TABLE 14)

Variable	Randomized Treatment Groups					
	10 mg vs. 5 mg	15 mg vs. 5 mg	20 mg vs. 5 mg	15 mg vs. 10 mg	20 mg vs. 10 mg	20 mg vs. 15 mg
+Supine Systolic B.P.	(*)	*				
Supine Diastolic B.P.	*	*	*			
Supine Pulse						
Standing Systolic B.P.		**	*	(*)		
Standing Diastolic B.P.	**	***	***			
Standing Pulse						

(*) $p < .10$, * $p < .05$, ** $p < .01$, *** $p < .001$

+Unadjusted means used where indicated since assumptions for analysis of covariance were not met.

0126

07-02292

TABLE 17
 PN 200-110 STUDY NO. 301
 SUMMARY COMPARATIVE RESULTS FOR BLOOD PRESSURE AND PULSE
 MEAN OVER PLATEAU PERIOD (WEEKS 3-5) - VALID PATIENTS ONLY
 EVALUATION ACCORDING TO ACTUAL DOSE TAKEN

Table	Actual Dose Taken	No. of Patients	Baseline		Mean Change	S.D.	Adjusted Mean Change†	Treatment Period	
			Mean	S.D.				Mean	S.D.
Systolic B.P. (mm Hg)	PN 5 mg	46	136.1	15.38	-15.3***	10.76		140.5	10.69
	PN 10 mg	33	160.0	14.51	-22.6***	13.90		137.4	9.10
	PN 15 mg	35	159.1	21.03	-23.1***	18.04		136.0	14.54
	PN 20 mg	34	154.6	14.22	-22.0***	11.70		132.6	11.06
	Placebo	39	151.1	13.69	-3.4*	9.17		147.7	13.19
Diastolic B.P. (mm Hg)	PN 5 mg	46	103.8	4.15	-14.1***	5.79	-14.1	89.7	6.35
	PN 10 mg	33	104.3	4.44	-16.8***	7.07	-16.6	87.3	6.98
Mean Pulse (per min.)	PN 15 mg	35	103.6	3.73	-17.9***	8.08	-18.1	85.6	7.24
	PN 20 mg	34	103.7	4.09	-17.6***	6.04	-17.7	86.1	6.86
	Placebo	39	103.1	4.44	-7.0***	6.45	-7.0	96.9	6.97
	PN 5 mg	46	77.2	11.03	1.7(*)	6.56	2.0	78.8	10.79
	PN 10 mg	33	74.1	8.33	4.3**	7.42	4.0	78.8	7.68
	PN 15 mg	34	76.2	8.33	3.1**	7.63	3.9	80.0	9.65
	PN 20 mg	34	74.9	7.72	3.2**	5.74	3.0	78.1	7.50
Standing Systolic B.P. (mm Hg)	Placebo	39	75.7	8.91	-0.6	6.87	-0.6	75.2	9.03
	PN 5 mg	45	152.8	16.33	-13.7***	11.07	-13.0	139.1	12.02
	PN 10 mg	33	155.6	13.88	-19.3***	14.82	-17.1	136.3	12.16
	PN 15 mg	35	155.1	14.12	-23.7***	17.34	-21.8	131.4	13.86
	PN 20 mg	34	148.6	12.95	-19.7***	13.27	-21.5	128.8	12.52
Standing Diastolic B.P. (mm Hg)	Placebo	39	146.5	14.83	-1.2	11.98	-4.1	145.3	12.85
	PN 5 mg	45	104.4	6.59	-11.2***	5.19		93.2	7.73
	PN 10 mg	33	105.8	8.22	-16.0***	7.06		89.8	8.71
	PN 15 mg	35	104.1	5.64	-17.7***	9.93		86.4	8.09
	PN 20 mg	34	104.6	6.14	-17.7***	7.26		86.9	8.12
Standing Pulse (per min.)	Placebo	39	102.4	8.79	-2.8*	6.60		99.6	7.50
	PN 5 mg	45	85.8	9.75	1.6	7.92		87.3	11.66
	PN 10 mg	33	83.4	9.31	5.1**	8.46		88.5	8.72
	PN 15 mg	35	84.3	6.82	3.6**	7.69		87.9	10.22
	PN 20 mg	34	82.0	9.68	5.1***	7.91		87.1	7.78
Placebo	Placebo	39	82.9	9.25	-1.0	8.07		81.9	9.77

10, *p<.05, **p<.01, ***p<.001

When appropriate, patients taking the same dose of PN 200-110 were pooled.
 Presented only when analysis of covariance assumptions are met.

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07-02202

TABLE 18

FN 200-110 STUDY NO. 301

SUMMARY OF PAIRWISE COMPARISONS BETWEEN ACTIVE
TREATMENT GROUP MEAN DIFFERENCES
VITAL SIGNS

PLATEAU MEAN
(DATA PRESENTED IN TABLE 17)

Variable	Actual Dose Taken					
	10 mg vs. 5 mg	15 mg vs. 5 mg	20 mg vs. 5 mg	15 mg vs. 10 mg	20 mg vs. 10 mg	20 mg vs. 15 mg
+Supine Systolic B.P.	*	**	*			
Supine Diastolic B.P.	(*)	..*	*			
Supine Pulse						
Standing Systolic B.P.		***	***	(*)		
+Standing Diastolic B.P.	**	***	***			
+Standing Pulse	(*)		(*)			

(*) $p < .10$, * $p < .05$, ** $p < .01$, *** $p < .001$

+Unadjusted means used where indicated since assumptions for analysis of covariance were not met.

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TABLE 19
PN 200-110 STUDY NO. 301

SUMMARY COMPARATIVE RESULTS FOR BLOOD PRESSURE AND PULSE
ENDPOINT ANALYSIS - VALID AND PARTIALLY VALID PATIENTS

Variable	Randomized Treatment Group	No. of Patients	Baseline		Mean Change	S.D.	Adjusted Mean Change††	Treatment Period	
			Mean	S.D.				Mean	S.D.
Supine Systolic B.P. (mm Hg)	PN 5 mg	39	157.9	17.14	-16.9***	14.49	-15.9	141.0	14.81
	PN 10 mg	38	159.0	14.47	-20.8***	15.23	-19.2	138.2	11.25
	PN 15 mg	39	158.5	20.45	-24.1***	18.12	-22.7	134.5	12.11
	PN 20 mg	41	154.0	13.52	-19.0***	14.10	-20.2	133.0	12.11
	Placebo	41	151.5	14.40	-3.3(*)	11.76	-3.9	148.2	14.74
Supine Diastolic B.P. (mm Hg)	PN 5 mg	39	104.2	4.47	-13.6***	8.33	-13.4	90.7	8.94
	PN 10 mg	38	104.0	4.18	-16.8***	8.43	-16.7	87.3	8.54
	PN 15 mg	39	103.6	3.64	-17.4***	7.89	-17.5	86.2	7.89
	PN 20 mg	41	103.5	3.95	-17.1***	8.07	-17.2	86.4	8.58
	Placebo	41	103.9	4.36	-6.1***	8.39	-6.1	97.8	8.74
Supine Pulse (per min.)	PN 5 mg	39	78.4	10.41	1.0	7.32	1.6	79.4	11.40
	PN 10 mg	38	75.5	9.06	4.4**	9.39	4.3	79.9	10.30
	PN 15 mg	38	74.7	9.24	3.9**	8.69	3.7	78.6	11.85
	PN 20 mg	41	75.6	8.22	2.1(*)	6.91	2.1	77.8	10.11
	Placebo	41	75.7	9.25	-1.5	7.86	-1.5	74.3	9.55
Standing Systolic B.P. (mm Hg)	PN 5 mg	39	154.2	17.45	-16.4***	14.89	-15.2	137.8	17.42
	PN 10 mg	38	155.3	12.77	-18.8***	15.65	-17.0	136.5	14.57
	PN 15 mg	38	154.8	14.24	-23.6***	19.60	-22.0	131.2	16.89
	PN 20 mg	41	148.5	12.48	-16.7***	16.42	-18.4	131.9	16.46
	Placebo	41	140.9	17.08	-1.2	15.43	-3.8	145.6	14.48
Standing Diastolic B.P. (mm Hg)	PN 5 mg	39	103.8	6.83	-11.0***	7.60		92.8	11.49
	PN 10 mg	38	103.4	7.61	-16.4***	8.29		89.0	8.51
	PN 15 mg	38	104.6	6.12	-16.8***	10.51		87.8	9.67
	PN 20 mg	41	104.8	5.78	-16.4***	9.08		88.4	9.16
	Placebo	41	102.0	7.06	-2.1	9.47		99.9	8.53
Standing Pulse (per min.)	PN 5 mg	39	86.4	10.53	1.2	9.25	2.0	87.5	12.44
	PN 10 mg	38	84.0	10.12	5.3**	10.18	5.5	89.4	10.46
	PN 15 mg	38	85.3	6.35	4.1*	9.32	3.9	87.7	11.34
	PN 20 mg	41	82.7	9.74	4.1*	10.08	3.8	86.8	10.94
	Placebo	41	83.1	9.39	-1.9	8.69	-2.1	81.2	10.46

*) p<.10, **) p<.05, ***) p<.01, ****) p<.001

Results are presented according to pre-determined randomized treatment group pooling together all patients randomized to the treatment group.

†) Presented only when analysis of covariance assumptions are met.

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TABLE 20
PN 200-110 STUDY NO. 301

SUMMARY COMPARATIVE RESULTS FOR BLOOD PRESSURE AND PULSE
ENDPOINT ANALYSIS: ALL PATIENTS

Table	Randomized Treatment Group	No. of Patient	Baseline		Mean Change	S.D.	Adjusted Mean Change ¹⁾	Treatment Period	
			Mean	S.D.				Mean	S.D.
Supine Systolic B.P. (mm Hg)	PN 5 mg	40	138.2	17.04	-17.0***	14.30	-15.7	141.3	14.72
	PN 10 mg	39	139.0	14.28	-20.3***	15.75	-18.6	138.8	11.41
	PN 15 mg	41	157.6	20.40	-23.2***	18.12	-22.3	134.4	14.73
	PN 20 mg	41	154.0	13.52	-19.0***	14.10	-20.2	135.0	13.11
	Placebo	41	151.5	14.40	-3.3(*)	11.76	-5.9	148.2	14.74
Supine Diastolic B.P. (mm Hg)	PN 5 mg	40	104.7	4.42	-13.4***	8.28	-13.3	90.8	8.05
	PN 10 mg	39	104.1	4.14	-15.8***	8.92	-15.7	88.3	8.53
	PN 15 mg	41	103.5	3.82	-17.2***	7.95	-17.3	86.3	7.72
	Placebo	41	103.9	4.36	-6.1***	8.39	-6.1	97.8	8.76
Supine Pulse (per. min.)	PN 5 mg	40	78.7	10.67	1.0	7.42	1.6	79.7	11.40
	PN 10 mg	39	75.7	9.00	3.7*	5.34	3.7	79.4	9.93
	PN 15 mg	40	74.5	9.04	3.8**	8.49	2.5	78.3	11.64
	PN 20 mg	41	75.6	8.22	2.1(*)	6.91	2.0	77.8	10.11
	Placebo	41	75.7	9.25	-1.5	7.86	-1.5	74.3	9.55
Standing Systolic B.P. (mm Hg)	PN 5 mg	40	154.6	17.43	-16.3***	14.72	-14.9	138.3	17.74
	PN 10 mg	39	155.1	12.66	-17.0***	17.63	-15.3	138.2	16.15
	PN 15 mg	40	154.8	13.92	-23.3***	19.15	-21.7	131.6	16.25
	PN 20 mg	41	148.5	12.48	-16.7***	16.42	-16.5	131.9	16.66
	Placebo	41	146.9	17.08	-1.2	15.43	-3.9	145.6	14.68
Standing Diastolic B.P. (mm Hg)	PN 5 mg	40	104.0	6.79	-11.0***	7.51		93.0	11.35
	PN 10 mg	39	103.7	7.72	-15.2***	9.96		90.4	10.30
	PN 15 mg	40	103.0	6.33	-17.2***	10.37		87.9	9.45
	PN 20 mg	41	104.8	5.78	-16.4***	9.08		88.4	9.16
	Placebo	41	102.0	9.06	-2.1	9.47		99.9	8.53
Standing Pulse (per. min.)	PN 5 mg	40	86.6	10.48	1.1	9.15	2.0	87.7	12.50
	PN 10 mg	39	84.1	10.04	4.9**	9.68	3.0	89.0	10.05
	PN 15 mg	40	82.8	6.62	4.2**	9.13	3.8	86.9	11.27
	PN 20 mg	41	82.7	9.74	4.1	10.08	3.8	86.8	10.94
	Placebo	41	83.1	9.39	-1.9	8.69	-2.1	81.2	10.66

*) p<.10, **) p<.05, ***) p<.01, ****) p<.001

Results are presented according to pre-determined randomized treatment group pooling together all patients randomized to the treatment group.

Presented only when analysis of covariance assumptions are met.

0130
07-02295

TABLE 22
PN 200-11C STUDY NO. 301

PHYSICAL EXAMINATION
NEWLY-OCCURRING ABNORMALITIES*

Treatment Group	Type	Patient Number	Specific Abnormalities
PN 5 mg	Ears, Nose, Throat	554	Slight Nasal Cong. S. In
		153	Grade 2/6 Systolic Ejection Murmur, Grade 1/6 Diastolic
	Extremities	157	Atrial Gallop
		157	Trace to 1+ Pretibial Edema
PN 10 mg	Skin	61311	Edema
		411	Rash
	Ears, Nose, Throat	655	Contact Dermatitis on Forearms
		359	Pharyngeal Infection 2+ Upper Respiratory Tract Infection
PN 15 mg	Heart	617	Nasal Congestion
		101	Atrial Gallop, LV Lift, Extra Systoles
	Abdomen	218	Tachycardia
		108	Liver Edge Felt
	Extremities	218	2+ Pedal Edema
		509	Trace Distal Leg Edema
	General Appearance	602	Trace Edema
		403	Periorbital Edema
	Skin	322	Large Ecchymosis Below RUM
		403	Dry; Scar and Bunions
	Eyes (Funduscopy)	116	Cataract Right Eye, Eccentric Pupil Left Eye
		403	Periorbital Edema
	Ears, Nose, Throat	452	Nasal Congestion
		508	Nasal Congestion
	Heart	607	Nasal Congestion
		620	2+ Nose Congestion
PN 20 mg	Extremities	151	Systolic Flow Ejection Murmur Left LSB
		162	1+ Pretibial Edema
	Skin	403	Right Knee Swollen
		512	Trace Ankle Edema
	Heart	351	Flushing - Face and Back
		410	Erythematous Puritic Rash - Lower Extremities
	Extremities	105	LV Lift, A-Wave, LVH
		107	LVH, Atrial Gallop, Irregular A-Wave, LVE, LV Lift
	Abdomen	107	1-2+ Pretibial Edema
		351	1+ Bilateral Ankle Edema
Placebo	Extremities	410	2+ Bilateral Red Edema
		114	Liver Slightly Enlarged Below Right Costal Margin
	Ears, Nose, Throat	152	Trace Pretibial Edema
		113	Tympanic Membrane - Fluid R, Erythema L-Pharynx Red
		515	Slight Tenderness in R Lower Pre- Molar No Cavities

*Defined as an abnormality at the final visit that is not present at the initial visit.

**Physical exam was performed 7 weeks after last dose.

0131

07-02-37

TABLE 23

PM 200-110 STUDY NO. 301

CARDIOVASCULAR EXAMINATION
NEWLY-OCCURRING ABNORMALITIES†

Abnormality	Patient Number					# of Patients With Newly Occurring Abnormalities (%)				
	PM 200-110				Placebo	PM 200-110				Placebo
	5 mg Group	10 mg Group	15 mg Group	20 mg Group		5 mg Group	10 mg Group	15 mg Group	20 mg Group	
Chest Pain - Exertional:		601	403	631	152	0 (0)	1 (3)	1 (2)	1 (2)	1 (2)
Chest Pain at Rest:	463 606	601 617 658	403 627	631 622 615	161	2 (5)	3 (8)	2 (5)	2 (5)	1 (2)
Dyspnea on Exertion:		158 658	403	631	152 304	0 (0)	2 (5)	1 (2)	1 (2)	2 (5)
Dyspnea Sitting:					152	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Dyspnea Supine:					152	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Dyspnea Paroxysmal Nocturnal:										
Cough:	606 354 613†	617 655		311 301 311 609	113 314 307 353 356 619 453	1 (3) 2 (5)	0 (0) 2 (5)	0 (0) 0 (0)	0 (0) 4 (10)	0 (0) 7 (17)
Syncope:	153				152	1 (3)	0 (0)	0 (0)	0 (0)	1 (2)
Palpitations:	323 654	601 655	607 652	410 615 616 657	152	2 (5)	2 (5)	2 (5)	4 (10)	1 (2)
General Appearance:			302 353 403	311 351		0 (0)	0 (0)	3 (7)	2 (5)	0 (0)
ECG Exam:	618		152		161	1 (3)	0 (0)	1 (2)	0 (0)	1 (2)
ECG Findings:					353	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)
Heart Exam:	153 157 323	101 218 213	152 162	105 107 351 613	152 152	3 (8) 3 (8)	3 (8) 3 (8)	2 (5)	4 (10)	2 (5)
Physical Exam:				114		0 (0)	0 (0)	0 (0)	1 (2)	0 (0)
Arteries:	153 157 613† 639	101 108 153 218 313 610 622 635 658	102 152 116 162 403 467 512	107 351 410 465 616 631	152 404 310 619	4 (10)	8 (21)	7 (17)	6 (15)	4 (10)
NYHA Functional Class				631		0 (0)	1 (3)	0 (0)	1 (2)	0 (0)
Total Number of Patients with at Least One Newly-Occurring Abnormality/No. of Patients†††	10/40 (25)	13/39 (33)	12/41 (29)	16/41 (39)	13/41 (32)					

†Defined as an abnormality reported during the double-blind phase that was not present during the placebo washout or an abnormality (reported during the placebo washout) that worsened during the double-blind phase of the trial.

††Cardiovascular exam was performed 7 weeks after last dose.

†††Only includes patients who have at least one evaluation done during the double-blind phase of the trial.

0132

02-02213

TABLE 24
PN 200-110 STUDY NO. 301
CARDIOVASCULAR EXAMINATION
NEWLY-OCCURRING ABNORMALITIES*

Treatment Group	Type	Patient Number	Weeks	Specific Abnormalities
PN 5 mg	Chest Pain at Rest	463	1	
		606	3	Transient rt. chest pain - skeletal
	Dyspnea Paroxysmal	613	5	Wheezes
	Nocturnal			
	Cough	554	1	Cough with a cold
		613††	4	
			(follow up)	
	Syncope	153	1	Dizziness while standing
	Palpitations	323	1	With chest pain and dizziness
N 10 mg		654	3	Fast heart on exertion
	Neck Examination	618	3,5	Small rt. thyroid nodule
	Heart Examination	153	5	Grade 2/6 SEM, grade 1/6 diastolic murmur
		157	5	Atrial gallop
		323	1	Irregular pulse
	Extremities	153	1,2	Skin lesion
		157	5	Trace to 1+ pretibial edema
		613††	4	2+ edema
			(follow up)	
		659	4	1-2+ edema
	Chest Pain at Rest	601	4	
		617	4	Rt. chest wall pain with cough
		658	1	
	Chest Pain Exertional	601	4	
	Dyspnea on Exertion	158	1,3,5	SOB at work, HR slightly up
		658	5	Chest tightness when walking
	Cough	617	4,5	2° Cedar allergy with rhinitis
		655	1	Nasal congestion
	Palpitations	601	3	Inc. pulse
		655	1	Tachypalpitations 6-8 beats
	Heart Examination	101	5	Atrial gallop, LV lift, extra systole
		218	2	Tachycardia
		313	5	Irreg. pulse, multiple PVC's
	Extremities	101	2	Trace pretibial edema
		108	4	Trace - 1+ pretibial edema
		155	1,2	Trace left leg edema
		218	2	2+ pedal edema
		513	5	Trace distal leg edema
		610	1	Trace 1+ edema
		622	5	Trace edema
		655	2,4	1-2+ edema

*Defined as an abnormality reported during the double-blind period that was not present during the placebo washout or an abnormality (reported during the placebo washout) that occurred during the treatment period.

††Cardiovascular exam was performed 7 weeks after last dose

0133

07-0228

TABLE 24 (Continued)
 PN 200-110 STUDY NO. 301
 CARDIOVASCULAR EXAMINATION
 NEWLY-OCCURRING ABNORMALITIES*

Treatment Group	Type	Patient Number	Weeks	Specific Abnormalities
PN 10 mg (cont.)	NYHA Functional Class	658	5	Change from Class 1 to Class 2
PN 15 mg	Chest Pain at Rest	403	2,3,4,5	
		607	5	Pain radiates to back
	Chest Pain Exertional	403	1	Substantial stabbing pain
PN 20 mg	Dyspnea on Exertion	403	1,2,3,4,5	
	Palpitations	607	5	
		652	2,3,4,5	Fast heart after taking med.
	Overall Appearance	322	1,5	Mildly flushed face; obese
		353	2	Flushed face; obese
		403	5	Periorbital edema
	Neck Exam	112	3,4	Inc. jugular A wave
	Heart Examination	151	1,2,5	PMI>MCU; systolic murmur
		162	5	LV lift; double thrust sl. LVE
	Extremities	107	5	Trace pretibial edema
		112	1	Left foot swollen - gout
		116	4	1+ pretibial edema
		162	5	1+ pretibial edema
		403	1,3,5	Bunions; rt. knee swelling and pain
	Chest Pain at Rest	467	4	Swollen left hand
		512	5	Trace ankle edema
		422	3,4	Chest wall pain (an inc. resp.)
	Chest Pain Exertional	615	2	Chest wall tenderness
		651	1,3	Chest tightness on walking
		651	1	SOB on walking
		311	4	Virus
		501	4	Nasal congestion
		511	3	Slight non-productive cough which is decreasing
		609	3,5	Upper resp. infection, laryngitis
	Palpitations	410	1	After taking drug
		615	1	
		616	2,3	Tachypalpitations after dose
		657	2,4,5	After taking drug
	Overall Appearance	311	4	Left cheek swollen, abscess on molar
		351	3,4,5	Flushed face and back; 2° vasodilation

*Defined as an abnormality reported during the double-blind period that was not present during the placebo washout or an abnormality (reported during the placebo washout) that occurred during the treatment period.

0134

07-02303

TABLE 24 (Continued)
 PM 200-110 STUDY NO. 30:
 CARDIOVASCULAR EXAMINATION
 NEWLY-OCCURRING ABNORMALITIES*

Treatment Group	Type	Patient Number	Weeks	Specific Abnormalities
PM 20 mg (cont.)	Heart Examination	105	5	Possible LVE
		107	5	LVM - irreg. A-wave, atrial gallop, LVE, LV lift
		351	3,4	Atrial gallop, mid-systolic click, sinus tachycardia
	Extremities	413	4	Atrial gallop
		107	2,5	1-2+ pretibial edema
		351	3,4,5	1+ bilateral ankle edema
placebo		410	2,3,4,5	Slight pedal edema, lower leg rash
		455	1	Swelling feet and legs
		416	2,3,4,5	1+ edema - lower extremities
		651	1,4,5	1-2+ peripheral edema
		114	5	Liver sl. enlarged; 1 finger below right costal margin-smooth, non-tender
	NYHA Functional Class	651	1	Change from Class 1 to Class 2
	Chest Pain at Rest	161	3	Pain on left side of chest
	Chest Pain Exertional	152	3	
		152	1,2,3,4	
	Dyspnea on Exertion	304	3	
		152	1	
	Dyspnea Sitting	152	1	
		113	5	URI with cough, nasal congestion
	Cough	314	2,3,4,5	Associated COPD
		453		Chest cold
		503	3	with chills, fever and headache
		553	3,4	Due to a cold
		556	1,2,3,4	From post-nasal drip
		619	1	

* defined as an abnormality reported during the double-blind period that was not present during the placebo washout or an abnormality (reported during the placebo washout) that worsened during the treatment period.

0135

07-02302

TABLE 24 (Continued)
 PM 200-110 STUDY NO. 301
 CARDIOVASCULAR EXAMINATION
 NEWLY-OCCURRING ABNORMALITIES*

Treatment Group	Type	Patient Number	Weeks	Specific Abnormalities
Placebo (cont.)	Syncope	152	1	
	Palpitations	152	1	
	Pulmonary Findings	553	3,4	Few dry rhonchi in lungs
	Neck Exam	161	5	Neck pain/arthritis
	Heart Examination	109	3	LVE, LV lift, inc. A-wave, atrial gallop
		161	2	Occasional irregular heart rate
	Extremities	152	5	Trace pretibial edema
		404	3,4	Skin on wrists peeling
		510	3,4	Trace ankle edema
		619	2	2+ edema

*Defined as an abnormality reported during the double-blind period that was not present during the placebo washout or an abnormality (reported during the placebo washout) that worsened during the treatment period.

0136

07-02302

TABLE 26
 PN 200-110 STUDY NO. 301
 CHEST X-RAY
 NEWLY-OCCURRING ABNORMALITIES*

Treatment Group	Chest X-Ray Findings	Patient Number	Specific Abnormalities
PN 5 mg	Chest X-Ray Findings	103	Aorta uncoiled with calcification in arch, degenerative change in thoracic spine
PN 10 mg	Chest X-Ray Findings	406	Increased interstitial markings; abdominal vascular calcifications
PN 15 mg	Chest X-Ray Findings	361	Cardiomegaly with left ventricular enlargement and ectatic aorta
Placebo	Chest X-Ray Findings	318	Mild cardiomegaly
		452	Cardiac silhouette 1+ enlarged, Ctr 19.5 x 31 cm; accentuated by a moderate inspiratory effort. Minimal blunting of posterior costophrenic sulci bilaterally
		352	Sternotomy suture, heart size at upper limit of normal LVH config.
		318	Thin layer of pleural thickening along both lateral chest walls
		352	Moderate dextroscapular scoliosis of the lower thoracic spine

*Defined as an abnormality at the final visit that was not present at the initial visit or an abnormality (reported at the initial visit) that worsened during the double-blind phase of the study.

0137

87-0530

TABLE 28
PN 200-110 STUDY NO. 301

ECG EXAMINATION
NEWLY-OCCURRING ABNORMALITIES*

Treatment Group	Type	Patient Number	Weeks	Specific Abnormalities
PN 5 mg	Rhythm	323	1	Probable Atrial Fibrillation
		506	2,5	Sinus Tachycardia (Rates = 90, 92)
		554	4	Occasional PVC*
PN 10 mg	Interpretation of ECG	165	2,5	Intraatrial Blocks
			4	Wandering Baseline
		306	1	Non-Specific ST-T Changes
		326	4,5	Left Axis Deviation
		317	1	U-waves
		454	1-5	Old Myocardial Infarction
		468	1-5	LVH by Voltage Criteria
		613	1,2	Q-waves Leads II, III, F
	Rhythm	101	5	6/Min Unifocal PVB's*
		111	1	Occasional APB's**
		158	1,5	Sinus Tachycardia (Rates = 112, 92)
		313	1,2,4,5	PVB*
		316	2	Occasional PVC*
		355	2,3	Occasional PVC*
		459	5	Irregular Sinus Rhythm
		555	2	Occasional PVC*
		658	4	Sinus Bradycardia (Rate = 58)
	Interpretation of ECG	101	1-5	Left Atrial Enlargement
			2-4	Non-Specific ST Changes
			2	APB**
		111	2,5	Intraatrial Block
		155	1-4	Intraatrial Block
			2-5	Left Axis Deviation; Probable Left Atrial Abnormality
			4,5	Left Atrial Enlargement
			5	LVH
		158	1,2	Non-Specific ST-Wave Changes
			2	Intraatrial Block

*Defined as an abnormality reported during the double-blind period that was not present during the placebo washout or an abnormality (reported during the placebo washout) that occurred during the treatment period.

*PVC (PVE) - Premature Ventricular Contraction

PB - Atrial Premature Beats

TABLE 28 (Continued)
PN: 200-110 STUDY NO. 301

ECG EXAMINATION
NEWLY-OCCURRING ABNORMALITIES*

Treatment Group	Type	Patient Number	Weeks	Specific Abnormalities
PN 10 mg (cont'd)	Interpretation of ECG	302	1	Slow QT Prolongation
		307	1	Q-Wave More Prominent in Lead III
		313	3	Cannot Rule Out Old MI
		324	2-4	Left Atrial Abnormality
PN 15 mg	Rhythm	329	1	Non-Specific ST-T Changes
		459	1	Increased QT
			3,4	Intraventricular Conduction Delay
			5	LBBB; Positive U-Wave V3-V6
			1	Non-Specific ST wave Changes
		112	5	Probable Aberrantly Conducted APB**
		303	4	Bradycardia (Rate = 58)
		322	2	One APB**
		330	3	Tachycardia (Rate = 102)
		605	1	Single PVC*
	Interpretation of ECG	110	1	Non-Specific ST-wave Changes
		112	2,4,5	Ischemia
			5	Intraventricular Conduction Delay
		151	1	Non-Specific T wave Changes V4-V6
		159	1,2	Pericarditis
			2,3	Increased Intracardiac Deflection
		162	1,3	Increased Voltage Limb Lead
		315	1,3,5	Borderline 1° AV Block
		317	5	Intraventricular Conduction Delay
		330	4	Borderline Voltage for LVH
		333	1	Cannot Rule Out Old MI
		403	5	Inverted T Waves Leads V1-V6;
				Non-Specific ST-T Changes
		467	1	Inverted T Waves
			4	PVC's*; LVH by Voltage Criteria

*Defined as an abnormality reported during the double-blind period that was not present during the placebo washout or an abnormality (reported during the placebo washout) that worsened during the treatment period.

*PVC (PVB) - Premature Ventricular Contraction

**APB - Atrial Premature Beats

TABLE 28 (Continued)
PN 200-110 STUDY NO. 101

ECG EXAMINATION
NEWLY-OCCURRING ABNORMALITIES*

Treatment Group	Type	Patient Number	Weeks	Specific Abnormalities
PN 20 mg	Rhythm	105	5	One PVB ⁺
		154	2	Sinus Tachycardia (Rate = 104)
		216	5	Sinus Bradycardia (Rate = 52)
		321	2	APB ⁺⁺ ; PVB's ⁺
		351	5	PVB's ⁺
	Interpretation of ECG	358	2	PVC ⁺
		469	2	Sinus Bradycardia (Rate = 54)
		107	2	Left Atrial Enlargement; Intraatrial Block; Non-Specific ST-Wave Changes Artifact Present
		150	2-5	Non-Specific ST-Wave Changes
		163	1	Non-Specific ST-Wave Changes
			4	Electrical and Muscle Artifact
		301	1-5	Non-Specific ST-Wave Changes
			1,2	Left Atrial Abnormality
		320	1,3,4,5	Left Axis Deviation
			2-4	Non-Specific ST-T Changes
		321	4	Poor R-Wave Progression
		127	2	Non-Specific ST-T Changes; Increased QT Interval
		351	4	Low Voltage in Limb Leads
		113	1	Left Axis Deviation
Placebo	Rhythm	465	2,5	LvH by Voltage Criteria
		469	2,5	Prolonged QT
		161	2	Marked Sinus Arrhythmia
		304	2-5	Frequent APB's ⁺⁺
		325	3,5	Possible Ectopic Atrial
		331	1	Occasional PVC ⁺
		352	5	Rare PVC ⁺

*Defined as an abnormality reported during the double-blind period that was not present during the placebo washout or an abnormality (reported during the placebo washout) that worsened during the treatment period.

⁺PVC (PVB) - Premature Ventricular Contraction

⁺⁺APB - Atrial Premature Beats

0140

07-0230C

TABLE 28 (Continued)
PN 270-110 STUDY NO. 301

ECG EXAMINATION
NEWLY-OCCURRING ABNORMALITIES*

Treatment Group	Type	Patient Number	Weeks	Specific Abnormalities
Placebo (cont'd)	Rhythm	404	1	Sinus Bradycardia (Rate = 55)
		421	1	Sinus Bradycardia (Rate = 57)
		461	3	Irregular Sinus Rhythm
	Interpretation of ECG	109	1-3	Left Atrial Enlargement
		113	1,2	QT Prolongation
		117	5	Left Axis Deviation
		304	1-5	Voltage Criteria for LVH
			2-5	Left Axis Abnormality
			2	Q-Waves in V1 and V2
		310	1,4,5	Non-Specific ST-T Changes
			3,4	Borderline Voltage for LVH
		314	5	1° AV Block; Minor Non-Specific ST-T Changes
		325	2-4	Non-Specific ST Abnormalities
		326	5	Voltage Criteria for LDH
		331	1,3	Borderline Voltage for LVH
		412	4,5	Q-Waves Leads II, III; 1° Heart Block
			5	Left Axis Deviation
		418	3	Non-Specific ST-T Changes
		461	1	Non-Specific ST-T Changes

*Defined as an abnormality reported during the double-blind period that was not present during the placebo washout or an abnormality (reported during the placebo washout) that worsened during the treatment period.

*PVC (PVB) - Premature Ventricular Contraction

*APB - Atrial Premature Beats

0141

37-52309

Variable	Treatment Group	Completers Only										No. of Patients	All Patients			
		No. of Patients	Baseline		Week 1		Week 2		Plateau Mean		Baseline		Endpoint			
			Mean	S.D.	Mean Change	S.D.	Mean Change	S.D.	Mean Change	S.D.	Mean		S.D.	Mean Change	S.D.	
Ventricular Rate* (per min.)	PN 5 mg	32	74.13	10.26	4.84**	8.13	6.94***	9.02	3.72**	6.53	40	74.33	10.16	3.53**	11.71	
	PN 10 mg	32	69.97	8.97	6.50**	10.15	7.09***	9.42	6.39***	7.14	39	71.23	9.65	6.44***	9.14	
	PN 15 mg	39	71.49	10.64	3.03*	8.65	5.82***	9.60	5.92***	7.94	40	71.53	10.51	1.53**	9.66	
	PN 20 mg	37	73.16	12.89	3.76*	10.64	3.68*	10.27	2.66(*)	9.72	41	72.73	13.00	2.20	9.67	
	Placebo	35	74.91	2.57	-3.60**	7.81	-2.74(*)	8.63	-1.30	6.27	40	75.00	12.34	-1.98	8.48	
-R Interval (sec.)	PN 5 mg	32	0.160	0.019	-0.001	0.016	0.002	0.015	-0.002	0.010	39	0.161	0.019	-0.004	0.013	
	PN 10 mg	32	0.170	0.025	-0.003**	0.017	-0.008*	0.019	-0.007*	0.014	39	0.166	0.025	-0.003	0.018	
	PN 15 mg	39	0.174	0.022	-0.003	0.017	-0.008**	0.014	-0.004(*)	0.011	40	0.173	0.022	-0.003	0.017	
	PN 20 mg	37	0.168	0.019	-0.003**	0.013	-0.001	0.018	-0.001	0.012	41	0.168	0.019	-0.002	0.015	
	Placebo	34	0.162	0.023	0.001	0.006	-0.004	0.020	-0.001	0.013	40	0.165	0.023	0.002	0.018	
RS Duration (sec.)	PN 5 mg	32	0.081	0.010	0.002	0.012	0.000	0.010	0.001	0.009	40	0.080	0.010	-0.001	0.011	
	PN 10 mg	32	0.082	0.006	-0.001	0.009	0.001	0.009	0.001	0.010	39	0.083	0.008	0.001	0.013	
	PN 15 mg	37	0.079	0.012	0.001	0.011	0.001	0.012	0.002	0.009	39	0.079	0.012	-0.004	0.012	
	PN 20 mg	37	0.082	0.010	-0.002	0.011	0.000	0.010	0.001	0.007	41	0.082	0.010	0.001	0.009	
	Placebo	35	0.080	0.010	-0.001	0.009	0.001	0.009	-0.001	0.008	41	0.080	0.011	0.003	0.009	
-T Interval* (sec.)	PN 5 mg	32	0.376	0.025	-0.001	0.025	-0.002	0.020	-0.003	0.025	40	0.376	0.026	-0.005	0.033	
	PN 10 mg	31	0.306	0.030	-0.012*	0.029	-0.014*	0.030	-0.012*	0.024	39	0.303	0.030	-0.013**	0.027	
	PN 15 mg	37	0.307	0.025	-0.005	0.025	-0.014*	0.026	-0.010*	0.025	39	0.308	0.026	-0.015**	0.029	
	PN 20 mg	37	0.377	0.028	-0.002	0.027	0.001	0.024	-0.001	0.020	41	0.378	0.028	-0.003	0.024	
	Placebo	36	0.350	0.046	0.014	0.033	0.011	0.041	0.012(*)	0.010	41	0.353	0.045	0.010	0.040	

p<0.10, *p<0.05, **p<0.01, ***p<0.001
 by the ventricular rate was analyzed. The study was equal to the ventricular rate.

Variable (Normal Range)	Treatment Group	No. of Patients	Week 3								No. of Patients	All Patients			
			Baseline		Mean Change		S.D.		Mean Change			Baseline		Endpoint	
			Mean	S.D.	Mean Change	S.D.	Mean Change	S.D.	Mean	S.D.		Mean Change	S.D.		
Hemoglobin gm% (11.9-17.6)	PN 5 mg	31	14.38	1.47	-0.22	0.86	0.18	0.74	38	14.60	1.43	0.13	2.91		
	PN 10 mg	27	14.56	1.42	0.77	0.71	-0.16	0.74	35	14.68	1.51	-0.17	0.73		
	PN 15 mg	33	14.35	1.32	0.15	0.81	-0.17	0.92	40	14.49	1.47	-0.16	0.90		
	PN 20 mg	34	14.57	1.47	-0.01	0.63	-0.15	0.67	37	14.53	1.43	-0.02	0.66		
	Placebo	32	14.30	1.52	0.18	1.23	0.22	0.76	39	14.14	1.47	0.18	0.73		
Leucocyte % (27-54)	PN 5 mg	31	44.47	4.78	0.10	2.60	-0.08	2.85	38	45.20	4.72	-0.25	2.85		
	PN 10 mg	27	44.50	4.20	3.03	2.73	-0.66	2.13	35	45.17	4.57	-0.60	2.36		
	PN 15 mg	33	44.24	3.55	0.35	2.84	-0.71	2.70	40	44.58	3.97	-0.62	2.74		
	PN 20 mg	34	45.73	3.85	-0.37	2.10	-0.35	2.33	37	44.58	3.85	-0.01	2.47		
	Placebo	32	44.35	4.17		4.17	0.33	2.91	39	43.84	4.26	0.21	2.81		
WBC $\times 10^3/\text{cu mm}$ (3.5-11.4)	PN 5 mg	31	6.13	1.61	0.05	1.03	0.08	1.05	38	6.17	1.56	0.06	1.01		
	PN 10 mg	27	6.62	2.01	-0.30	1.59	-0.31	1.57	35	6.71	2.63	-0.33	2.10		
	PN 15 mg	33	6.22	1.76	0.46	1.15	0.49	0.96	40	6.48	1.76	0.32(*)	1.03		
	PN 20 mg	34	6.52	1.59	0.21	1.27	0.15	1.30	39	6.52	1.62	0.22	1.24		
	Placebo	32	6.62	1.97	-0.10	1.28	-0.12	1.05	39	6.33	1.67	-0.09	0.98		
Neutrophils % (57-61)	PN 5 mg	31	62.16	6.57	-0.71	7.50	-1.73	4.83	38	61.87	6.94	-1.42(*)	4.87		
	PN 10 mg	27	65.07	8.47	-0.82	6.60	-0.63	7.98	35	59.17	8.75	0.26	8.69		
	PN 15 mg	34	60.68	7.15	-0.06	5.21	1.35	7.25	40	60.78	8.68	0.65	7.21		
	PN 20 mg	34	59.24	8.57	1.35	9.52	1.59	8.34	40	59.63	8.76	1.40	7.74		
	Placebo	30	59.93	7.87	0.30	7.80	-0.33	7.04	39	58.28	9.52	-1.26	8.02		
Sed's % (0-5)	PN 5 mg	9	0.65	0.53	-0.23(*)	0.50	-0.11	0.78	27	0.26	0.43	-0.04	0.63		
	PN 10 mg	11	0.09	0.30	0.00	0.43	-0.09	0.30	25	0.24	0.6	0.12	0.88		
	PN 15 mg	8	0.38	0.52	-0.25	0.46	0.50	2.00	21	0.49	0.40	0.38	1.24		
	PN 20 mg	17	0.47	1.18	-0.27	1.31	-0.33	1.27	23	0.30	1.00	-0.16	1.14		
	Placebo	14	0.50	1.33	-0.29	1.49	-0.36	1.43	28	0.37	0.98	-0.18	1.07		

(*)p<0.10, **p<0.05, ***p<0.01, ****p<0.001

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PN 233-3
SUMMARY OF THERAPEUTIC RESULTS
FOR IMMUNOLOGY DATA

Variable (Normal Range)	Treatment Group	Completers Only							No. of Patients	All Patients			
		No. of Patients	Baseline		Week 3		Week 5			Baseline		Endpoint	
			Mean	S.D.	Mean	S.D.	Mean Change	S.D.		Mean	S.D.	Mean Change	S.D.
Lymphocytes % (10-47)	PN 5 mg	31	27.97	6.17	1.36	5.89	1.81*	4.44	38	28.21	6.34	2.08*	4.96
	PN 10 mg	27	29.70	7.26	1.85	5.90	0.89	6.13	35	10.74	7.40	-0.20	6.73
	PN 15 mg	34	28.94	8.60	0.44	4.05	-1.56	6.28	40	29.03	8.21	-1.05	6.89
	PN 20 mg	34	31.35	8.22	-1.50	8.64	-1.12	7.34	40	31.00	7.94	-1.18	6.99
	Placebo	30	31.03	9.11	-0.27	7.41	0.27	8.14	39	32.67	10.88	1.26	8.78
Monocytes % (0-10)	PN 5 mg	31	7.45	1.73	-0.48	2.84	-0.45	2.62	38	7.53	1.67	-0.55	2.61
	PN 10 mg	27	7.59	3.03	-1.51	2.69	-0.11	2.65	35	7.43	2.93	-0.11	3.28
	PN 15 mg	34	7.50	1.64	-0.56	2.06	-0.12	2.37	40	7.35	1.66	0.00	2.31
	PN 20 mg	34	6.50	2.43	0.59	2.23	-0.18	2.33	40	6.53	2.30	0.50	2.31
	Placebo	30	6.67	2.85	-0.43	3.14	-0.03	2.50	39	6.62	2.74	-0.39	2.74
Eosinophils % (0-8)	PN 5 mg	31	1.81	1.20	0.07	0.71	0.03	0.91	38	1.84	1.37	0.05	0.99
	PN 10 mg	27	2.11	1.65	0.57	1.20	0.04	1.63	35	2.06	1.57	0.06	1.61
	PN 15 mg	34	2.44	1.53	0.09	0.90	0.44(*)	1.31	40	2.40	1.52	0.55**	1.28
	PN 20 mg	34	2.29	1.57	-0.27	2.04	-0.32	1.36	40	2.20	1.54	-0.33	1.31
	Placebo	30	1.90	1.42	0.57	0.71	-0.03	1.10	39	2.08	1.81	0.28	2.79
Basophils % (0-2)	PN 5 mg	31	0.52	0.63	0.26(*)	0.71	0.10	0.75	38	0.55	0.60	0.11	0.72
	PN 10 mg	27	0.63	0.74	0.26	0.90	0.04	0.71	35	0.60	0.70	0.00	0.64
	PN 15 mg	34	0.68	0.54	0.00	0.74	-0.15	0.82	40	0.70	0.52	-0.18	0.78
	PN 20 mg	34	0.63	0.63	-0.12	0.88	0.07	0.76	40	0.65	0.66	0.05	0.73
	Placebo	30	0.57	0.56	0.13	0.73	0.50***	0.63	39	0.56	0.54	0.36***	0.63

(*)p<0.10, **p<0.05, ***p<0.01, ****p<0.001

TABLE 31 (CONT'D)

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02-02333