PHN-06

Form A101: Eligibility

INSTRUCTIONS: This form must be completed for all potentially eligible trial subjects with an aortic root z-score > 2.5 and meet at least one of the major Ghent criteria.

Section A: KEY IDENTIFYING INFORMATION

A1.	Study Identification Number	·
A2.	Study visit	BASELINE
	a. What number screening is this?	
A3.	Date of form completion	$-\underline{M} \ \underline{M} \ \underline{M} \ \underline{D} \ \underline{D} \ \underline{D} \ \underline{V} \ \underline{Y} \ \underline{Y} \ \underline{Y} \ \underline{Y} \ \underline{Y} $
A4.	Name of person completing form	PRINT FULL NAME INITIALS

Section B: INCLUSION/EXCLUSION CRITERIA

		YES	NO	UNKNOWN
B1.	Is subject between 6 months and < 26 years old?	1	2	-8
B2.	Based on the retrospective echo data reported on the A100 form, is the subject's aortic root Z-score > 3.0?	1	2	-8
B3.	Has the subject had prior aortic surgery?	1	2	-8
B4.	Based on the retrospective echo data reported on the A100 form, Is the subject's maximum aortic root dimension at the sinuses of Valsalva > 5 cm?	1	2	-8
B5.	Is aortic surgery planned within 6 months of enrollment?	1	2	-8
B6.	Has the subject had an aortic dissection?	1	2	-8
B7.	Is ACE inhibitor, BB or calcium channel blockers being used therapeutically (e.g. for arrhythmia, ventricular dysfunction or valve regurgitation) rather than as a prophylactic medication?	1	2	-8
B8.	Does the subject have a history of angioedema while taking an ACE inhibitor or BB?	1	2	-8
B9.	Has the subject experienced intolerance to losartan or other ARB that resulted in termination of therapy?	1	2	-8
B10.	Has the subject experienced intolerance to atenolol or other BB that resulted in termination of therapy?	1	2	-8
B11.	Is the subject currently being treated for renal dysfunction/renal failure (Creatinine > upper limit of age- related normal values)?	1	2	-8

EligibilityForm A101Version B: 01-30-07Page 1 of 2Revised:03-19-08

		YES	NO	UNKNOWN
B12.	Does the subject have asthma of sufficient severity to preclude the use of a BB, defined as chronic use of steroids and/or beta-adrenergic agents with exacerbations of asthma that are frequent (averaging three or more per year) or severe (requiring hospitalization)?	1	2	-8
B13.	Does the subject have a diagnosis of diabetes mellitus?	1	2	-8
B14.	Is the subject currently pregnant or planning to become pregnant within 36 months of enrollment?	1	2	-8
B15.	Inability to complete study procedures including history of poor acoustic windows (inability to obtain accurate measurement of aortic root)?	1	2 (B16)	-8 (B16)
	a. Specify inability to completestudy procedures			

If NO to B1 or B2 OR YES to any B3-B15, then subject is NOT eligible for the Trial. End Baseline Screening. Any UNKNOWN in this section should be resolved at the screening visit. Any UNKNOWN in this section will render the subject ineligible for randomization.

- B16. Is the subject eligible to proceed with screening?

Section C: AGREE TO SCREENING VISIT

C1. Has subject agreed to come in for a screening visit?

YES 1

NO......2

If NO to C1, the subject is NOT eligible for the Trial. Go to Z1 and end Baseline Screening.

Section Z: TIME TO COMPLETE FORM

How long did it take to complete this form? Z1.

END OF FORM

Eligibility	Form A101	Version B: 01-30-07	Page 2 of 2
		Revised: 03-19-08	

YES 1

minutes