SYNOPSIS

Final Clinical Study Report for Study MB121008

TITLE OF STUDY: A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Phase 2B Trial to Evaluate the Safety and Efficacy of BMS-823778 in Overweight and Obese Subjects with Inadequately Controlled Hypertension.

PURPOSE: The research hypothesis of this study was that there will be a positive trend among doses of BMS-823778 administered orally for 12 weeks in lowering mean 24-hour ambulatory systolic and diastolic blood pressure in subjects with a body mass index ≥ 27 kg/m^2 and inadequately controlled mild to moderate hypertension (seated diastolic blood pressure ≥ 90 and ≤ 105 mm Hg and seated systolic blood pressure ≤ 155 mm Hg and a 24-hour mean ambulatory blood pressure ≥ 85 mm Hg). Because this study was stopped prior to completion the protocol-specified research hypothesis was not assessed as planned, and no formal statistical analyses were performed for this study.

The purpose of this study was to evaluate the safety and efficacy of BMS-823778, following 2, 6, or 15 mg of daily oral doses of BMS-823778 for 12 weeks, in overweight and obese subjects with inadequately controlled hypertension. However, as stated above, during the course of the study, Bristol-Myers Squibb (BMS) decided to discontinue the clinical development of this compound and the study was stopped prior to its completion. Therefore, a synoptic clinical study report has been prepared.

NUMBER OF SUBJECTS: Approximately 272 subjects were planned, only 7 subjects were randomized at the time of study termination**.**

DISPOSITION, DEMOGRAPHICS AND OTHER PERTINENT BASELINE CHARACTERISTICS:

Disposition information is presented in Table 1. Demographic characteristics are presented in Table 2.

Table 1: Subject Disposition[a]

Number	Placebo	BMS-823778 Multiple Oral Doses			All Subjects
		2 mg	6 mg	15 mg	
Subjects Treated	3	0	2	2	7
Subjects Discontinued	3	0	2	2	7
Subjects Completing the Study	0	0	0	0	0

[a] Total number of subjects randomized = 7

Table 2: Demographic Characteristics[a]

Number	Placebo (N = 3)	BMS-823778 Multiple Oral Doses 2 mg (N = 0)	6 mg (N = 2)	15 mg (N = 2)	All Subjects (N = 7)
Age, years					
Mean	52.7	NA	62.5	51.5	55.1
Min, Max	48, 61	NA	61, 64	43, 60	43, 64
Gender, N					
Male	1	NA	2	2	5
Female	2	NA	0	0	2
Race, N					
White	1	NA	2	0	3
Black/African American	2	NA	0	2	4

[a] Total number of subjects randomized = 7

N = number; Min = minimum; Max = maximum

SUMMARY OF SAFETY RESULTS:

- Since the study was terminated prior to its completion, safety data are available for only 3 placebo and 4 drug treated subjects.
- There were no deaths, serious adverse events (SAEs), or discontinuations due to AEs during the study. None of the subjects had clinical laboratory marked abnormalities.
- Key safety information is presented in Table 3.

Table 3: Key Safety Information[a]

Number (%)	Placebo N=3	BMS-823778 Multiple Oral Doses 2 mg (N = 0)	6 mg (N = 2)	15 mg (N = 2)	All Subjects (N = 7)
Deaths	0	NA	0	0	0
SAEs	0	NA	0	0	0
AEs Leading to Discontinuation	0	NA	0	0	0
Total Subjects with AEs	1 (33.3)	NA	2 (100)	0	3

[a] Total number of treated subjects = 7

- Three (42.9%) subjects had mild AEs during the study, 2 (100%) of whom received 6-mg BMS-823778 and 1 (33.3%) of who received placebo. Back pain was reported for the placebo-treated subject, while psychomotor activity, noncardiac chest pain, and respiratory chest congestion were reported with subjects receiving 6-mg BMS-823778. All AEs were mild, unrelated to treatment, and did not require any action or treatment. There were no ECG or vital sign related AEs.

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