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QUALITY OF CARE AND OUTCOMES ASSESSMENT

EFFECTS ON MORTALITY AND MORBIDITY IN OVERWEIGHT/OBESE SUBJECTS: THE SIBUTRAMINE CARDIOVASCULAR OUTCOMES (SCOUT) TRIAL

ACC Poster Contributions
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Background: SCOUT is the first trial to assess the combined effects of a pharmacologic agent and weight management on cardiovascular outcomes in overweight/obese subjects at high-risk of cardiovascular events. Sibutramine hydrochloride monohydrate is indicated for weight management, amplifying weight loss and inducing weight loss maintenance but linked to rises in blood pressure and heart rate.

Methods: SCOUT is a randomized, double-blind, placebo-controlled, multi-national trial. Eligible subjects were aged ≥55years with BMI ≥27 to ≤45kg/m2, or BMI ≥25 to <27kg/m2 plus waist circumference ≥102 cm (M)/ ≥88 cm (F) with a history of CAD, stroke or PAOD and/or type 2 diabetes mellitus plus hypertension, dyslipidemia, current cigarette smoking or diabetic nephropathy. Assuming a 7% placebo annual event rate, it was estimated 9,000 subjects randomized 1:1 over a 2-year period and followed for a minimum of 3 years would accrue 2160 primary outcome events (first occurrence of nonfatal myocardial infarction, nonfatal stroke, resuscitated cardiac arrest, cardiovascular death) after 5 years which would provide 80% power to detect an 11.4% reduction in the hazard ratio versus placebo if 30% of sibutramine subjects discontinued study drug.

Results: 10,745 subjects were treated in a 6-week single-blind, lead-in period with sibutramine plus standard care for weight management to assess drug tolerability and compliance prior to randomization. Subjects who experienced sustained increases in blood pressure or pulse, increased blood pressure medication, gained ≥3kg, or were <85% compliant with study drug were not to be randomized. 9,805 (91%) were randomized to sibutramine 10 mg or placebo, both with weight management; mean age, BMI, percent males, mean SBP/DBP, and heart rate were 63 years, 33.5kg/m2, 58%, 133.5/76.4mmHg and 72.5bpm, respectively at randomization. Due to a lower than anticipated event rate, the study follow-up period was extended to a maximum of 6 years.

Conclusion: Formal presentation of the key SCOUT trial results will be made for the first time at the ACC meeting in March 2010.