Study Report Summary

RANDOMIZED, PARALLEL, DOUBLE-BLINDED, PLACEBO-CONTROLLED STUDY TO ASSESS THE EFFECTS OF CHRONIC CONSUMPTION OF [A DECAFFEINATED STANDARDIZED GREEN COFFEE (C. *canephora robusta*) EXTRACT] ON BODY WEIGHT AND BODY COMPOSITION (FINAL STUDY REPORT – OCT 19, 2010)

OBJECTIVE: To assess the effects of chronic consumption of [a decaffeinated standardized green coffee extract] on body weight and body composition in overweight men and women.

DESIGN AND SETTING: Fifty-six day (8 weeks) randomized, double-blinded, placebo-controlled, and parallel designed study.

VOLUNTEERS: A total of 100 sedentary, healthy, overweight men and women were selected for the trial (ages 21-60 years, BMI 27.0 to 36.0 kg/m²). Ninety volunteers completed the trial.

INTERVENTIONS: Volunteers were randomly assigned into two groups to receive a decaffeinated green coffee extract (n=50) or placebo (n=50) at 400 mg/day, with two 200 mg doses taken approximately 30 to 60 minutes before their two main (largest) meals. Volunteers were instructed to follow a healthy calorie-reduced diet consisting of three meals per day, in between meals or after dinner. Volunteers were also asked to follow a moderate exercise program daily. The subjects were also monitored to ensure compliance with the dietary and exercise parameters of the study.

RESULTS: Of the 100 selected volunteers, 90 completed the study (45 subjects using decaffeinated green coffee, 45 subjects using placebo). Only the volunteers who completed the study were included in the statistical analysis. Compared to placebo, subjects using the decaffeinated green coffee extract in combination with a calorie-reduced diet and moderate exercise, showed a statistically significant effect on weight loss (3.7 lbs vs. 1.25 lbs), BMI reduction (-0.65 kg/m² vs. -0.22 kg/m²) and percentage of fat mass reduction (-0.76% vs -0.27%). No adverse events were reported, and supplementation was well tolerated.

CONCLUSIONS: In this study, supplementation of a specialized decaffeinated green coffee extract, standardized to 45% chlorogenic acids for 8 weeks, was shown to be a safe and effective means of supporting statistically significant weight loss compared to placebo, in healthy overweight subjects, when used as part of a calorie-reduced diet and moderate exercise program.

The study was conducted in full conformance with the principles of the Declaration of Helsinki (52nd WMA General Assembly, Edinburgh, Scotland, October 2000), and applicable laws and regulations. The study protocol was approved by the International Ethical Committee of Fortis Hospital.