Exhibit 10

At the present time, there is only one nonprescription nutraceutical product that is currently under investigation (Pharmachem Laboratory, Phase II) and is approved by the US Food and Drug Administration, with a quali ed health claim for assistance in weight control and a structure-function claim for its mechanism, which is that it blocks starch absorption by means of an

experience using chlorogenic acids in a human study of the decrease in postprandial glucose.

Study design

This was a randomized, double-blind, 22-week study that implemented a crossover design to compare a low-dose green coffee extract, a high-dose green coffee extract, and a placebo. Subjects were randomly assigned to a high-dose/low-dose/placebo sequence ($n = 6$), low-dose/placebo/high-dose sequence ($n = 4$), or placebo/high-dose/low-dose sequence ($n = 6$). Subjects stayed on a treatment for a period of 6 weeks, followed by a 2-week washout period, before the next treatment period began.

Subjects were examined at weeks 0, 6, 8, 14, 16, and 22 of the study. Subjects were examined individually at Trinity Hospital, Bangalore, India. During each visit, the following measurements were taken: body weight to nearest 0.01 kg, height to nearest 0.01 m, and a body fat percentage analysis using a SFB7 Bioimpedance device. BMI was determined using the formula of BMI = weight in kg divided by the square of the height in meters. All subjects were counseled for diet and exercise compliance at every visit, with the initial interview to establish diet details at the start of the study done by the site nutritionist. Data gathered included daily calorie intake, nutrient composition, micronutrient intake, and incidence of binge eating (see Table 3 for average diet intake information). The same procedure was repeated at the beginning of each cycle to reflect the diet during the previous cycle, and subjects underwent pre- and post-assessment systolic and diastolic blood pressure and heart rate measurements, at every visit. Blood pressure was measured in the right forearm of the subject in a sitting position after a 10-minute rest using a standard mercury sphygmomanometer.

Statistical analysis

The primary measures in this study were weight, BMI, and body fat percentage; however, heart rate and blood pressure taken at each visit were also analyzed. Statistical analyses were carried out with a repeated-measures analysis of variance and post hoc t-tests. Factors for the analysis of variance were sequence (high-dose/low-dose/placebo versus low-dose/placebo/high-dose versus placebo/high-dose/low-dose), treatment arm (first versus second versus third treatment), and time (two evaluations per treatment arm). For the time factor, the first evaluation within each treatment arm (weeks 0, 8, 16) was considered a pretreatment evaluation, and the second evaluation within each treatment arm (weeks 6, 14, 22) was a post-treatment evaluation. A statistically significant time × arm interaction indicates drug effects, ie, individually for the high-dose, low-dose, or placebo conditions. A significant sequence × arm × time interaction would indicate significant differences between the drug effects. Finding these interactions significant in the omnibus analysis of variance would validate the comparisons made between the beginning and end data.

Results

The statistical analyses report the test statistic and P value. From the mean data reported in Table 1, there were statistically significant reductions in weight, BMI, percent body fat, and heart rate after consuming GCA for two-thirds of the 22-week crossover study, but there was no overall significant change in systolic or diastolic blood pressure. The mean values on all measures at the beginning and end of each treatment arm (high-dose, low-dose, placebo) assessed for all 16 subjects, are displayed in Table 2. The data show a reduction in weight, BMI, and percent body fat in the high-dose and low-dose arms, but not the placebo arm, and a reduction in heart rate in the high-dose arm, but not the low-dose and placebo arms. Figure 1 shows the mean weight change across the 22-week study for each of the three groups, and Figure 2 shows the mean change in BMI. A three-way repeated-measures analysis of variance (factor 1: sequence [high-dose/low-dose/placebo versus low-dose/placebo/high-dose versus placebo/high-dose/low-dose]; arm [first versus second versus third treatment]; and time [two evaluations]) and the data from all 16 subjects who were randomized into the crossover design was conducted on each of the primary outcome measures (weight, BMI, and percent body fat), as well as diastolic blood pressure, systolic blood pressure, and heart rate.

Primary outcome measures

There was a significant treatment arm effect for weight ($P < 0.001$), BMI ($P < 0.001$), and percent body fat ($P < 0.001$), showing an improvement in each measure over the course of the study. There was a significant time effect for weight ($P < 0.001$), BMI ($P < 0.001$), and percent body fat ($P < 0.001$), showing an improvement between the beginning and end for each arm. There was no significant difference between the three sequences ($P = 0.373$).

There was a significant sequence × arm interaction was significant for weight ($P = 0.004$), BMI ($P = 0.004$), and percent body fat ($P = 0.002$), indicating an overall difference in the arms across the three sequences, ie, a differential influence of each arm on each sequence. The × time interaction was

signi cant for weight (P 0.001), BMI (P 0.001), and percent body fat (P 0.03), indicating overall drug effects. This can be seen in Table 2, where there were improvements in weight, BMI, and percent body fat in the high-dose and low-dose arms, but not the placebo arm. For weight, the 2.04± 2.20kg decrease in the high-dose arm was signi cant (P 0.003), as was the 1.54± 1.74kg decrease in the low-dose arm (P 0.005); but the -0.34± 1.41kg change in the placebo arm was not signi cant (P= 0.355). For BMI, the 0.74± 0.80kg/m^2 decrease in the high-dose arm was signi cant (P 0.003), as was the 0.58± 0.62kg/m^2 decrease in the low-dose arm (P 0.004); but the -0.12± 0.51kg/m^2 change in the placebo arm was not signi cant (P= 0.384). For percent body fat, the 1.19%± 1.22% decrease in the high-dose arm was signi cant (P 0.002), as was the 1.06%± 1.12% decrease in the low-dose arm (P= 0.003); surprisingly, the decrease was also signi cant in the placebo arm 0.88%± 1.26% (P= 0.015). The sequence × time interaction was marginally nonsigni cant for weight, (P= 0.08), was marginally signi cant for BMI (P= 0.049), and was signi cant for percent body fat (P 0.001).

Most importantly, the triple interaction was signi cant for weight (P 0.001) and BMI (P 0.001), but not for percent body fat (P= 0.239). For weight, the 2.04± 2.20kg decrease in the high-dose arm was greater than the -0.34± 1.41kg increase in the placebo arm (P 0.013), and the 1.54± 1.74kg decrease in the low-dose arm was greater than the -0.34± 1.41kg increase in the placebo arm (P 0.001). The change in weight in the high-dose arm was not different from the change in weight in the low-dose arm (P= 0.544). For BMI, the 0.74± 0.80kg/m^2 decrease

pressure, diastolic blood pressure). For heart rate, there was a marginally nonsigni cant sequence effect (P=0.065), and arm× time interaction (P= 0.083). The only signi cant result was a time effect (P 0.007), re ecting an improvement between the beginning and end for each arm. No other effect was signi cant (P 0.165). There were no signi cant results

activated receptor. This is one of the key regulators of lipids and glucose.[20]

There have been a few human studies with green coffee extract. Thom investigated the efficacy and tolerability of a green coffee extract (Svetol®) added to instant coffee and compared within a randomized, placebo-controlled, double-blind study.[21] The product reduces the absorption of different types of sugar from the gastrointestinal tract.