NUTRACEUTICALS

VLADIMIR BADMAEV ¹ MUHAMMED MAJEED ANTHONY A. CONTE JOHN E. PARKER

Sabinsa Corporation 121 Ethel Road West, Unit 6 Piscataway, NJ 08854, USA

1. Tel +1 732 777-1111 Fax +1 732 777-1443 E-mail vebadmaev@attglobal.net

Diterpene Forskolin (*Coleus forskohlii, Benth.*): A possible new compound for reduction of body weight by increasing lean body mass

weight loss strategy for the following reasons:

- increase in lean body mass is proportionate to an increase in the body's thermogenic response to food and the basic metabolic rate (BMR);
- food induced thermogenesis controls body weight by an increase in catabolism of body fat (thermogenesis is preferentially fueled by fatty acids derived from body fat and/or from food); and
- 3. enhanced thermogenesis contributes to a buildup of lean body mass.

An extract of *Coleus forskohlii* root, *Benth.* (Fam. Labiatae) standardized for diterpene forskolin was tested in an open-field study for weight loss and lean body mass increase. The study's hypothesis was based on the recognized role of diterpene forskolin as the plant derived compound which stimulates enzyme adenylate cyclase and subsequently cyclic AMP (3'5'adenosine monophosphate) (1,2). Cyclic AMP may release fatty acids from the adipose tissue depots which may result in enhanced thermogenesis (3), loss of body fat, and theoretically increased lean body mass.

Six overweight, but otherwise healthy, women were selected for the trial. Each participant was informed about the purpose of the study and was asked to sign an informed consent before entering the study. Each participant was examined by a physician at the inception and after 4 and 8 weeks of the study. The body composition was determined by bioelectrical impedance analysis. The forskolin formula was prepared in the form of two piece hard shell capsules. Each capsule contained 250 mg of the extract standardized for 10% forskolin, and each bottle contained 60 capsules. Participants were instructed to take one capsule in the morning and one in the evening, half an hour before a meal. Each participant was asked to maintain their previous daily physical exercise habits and eating habits. In addition, physical activity was monitored based on a questionnaire before and during the trial. The study was performed in an outpatient bariatric clinic at Hilton Head, S.C. and supervised by a physician specializing in bariatric medicine for over 30 years.

During the eight week trial the mean values for body weight, and fat content were significantly decreased, whereas lean body mass was significantly increased as compared to the baseline (Wilcoxon matched pairs test). Weight loss was statistically significant (p < 0.05) after 4 and 8 weeks, and the mean amounted to 4.3 and 9.17 lbs respectively. The body fat values expressed as % body fat were: 0 weeks 33.63 ± 3.02, 4 weeks 30.10 ± 4.34 (statistically not significant or n.s.), and 8 weeks 25.88 ± 4.77 (p<0.05). The lean body mass values expressed as % lean body mass were: 0 weeks 67.07 ± 3.02 , 4 weeks 69.90 ± 4.34 (n.s.), and 8 weeks 74.13 ± 4.77 (p<0.05).

The eight week therapy with 50 mg of forskolin per day did not adversely affect the systolic/diastolic blood pressure nor the pulse rate. A trend has been observed to lower the systolic/diastolic pressure in the course of treatment. Systolic pressure (mm Hg) was 0 weeks 113.67 ± 14.50 , 4 weeks 110.00 ± 18.93 (n.s.), and 8 weeks 104.50 ± 17.54 (n.s.). Diastolic

pressure (mmHg) was 0 weeks 71.00 \pm 12.76, 4 weeks 69.33 \pm 9.93 (n.s.), and 8 weeks 66.00 \pm 8.49(n.s.). Pulse rate (beats/min) was 0 weeks 66.33 \pm 8.02, 4 weeks 69.00 \pm 7.97(n.s.), and 8 weeks 74.67 \pm 11.55(n.s.).

This preliminary data obtained with 250 mg bid of a 10% extract of *Coleus forskohlii* indicate that this botanical bears promise as a safe and effective weight loss regimen. The effect of *Coleus forskohlii* is particularly valid in

the absence of change in frequency and intensity of physical exercise and without diet restrictions during the course of the trial. This study warrants a double-blind clinical trial evaluating effects of forskolin on body composition and its possible thermogenic mechanism.

REFERENCES

1) LEAMON, KB; PADGETT, W; DALY, JW. "Forskolin: Unique diterpene activator of adenylate cyclase in membrane and intact cells" Proc. Natl. Acad. Sci. USA 1981,78, 3363-67

- 2) DE SOUZA, NJ; DOHADWALLA, AN; REDEN, J; Forskolin, A. "Labdane Diterpenoid with Antihypertensive, Positive Inotropic, Platelet Aggregation Inhibitory, and Adenylate Cyclase Activating Properties" *Medicinal Research Reviews* **1983**, 3(2), 201-219
- 3) GIRARDIER, L. "Brown Fat: An Energy Dissipating Tissue"; In: *Mammalian Thermogenesis*; Girardier, L.; Sock M.J. Eds.; Chapman and Hall Ltd.:London New York, 1983, pp.50-98

