Research Milestones

Below is a brief summary of research studies on amylase inhibitors in general, and Satial (Phase 2)™ in particular. The Phase 2 research studies summarized below are included in their entirety in the following pages of this science dossier.

2013 -- A study was conducted in two phases to demonstrate the safety and efficacy of Satial (Phase 2) (IQP-PV-101) in weight management in obese and overweight Caucasian adults. The weight loss phase was a 12-week randomized, double-blind, placebo-controlled study where all subjects followed a strict diet plan; the second phase was the weight maintenance study over 24 weeks, where the subjects' energy intake was ad libitum. Results showed that those subjects taking Phase 2 lost significantly more weight than those on placebo after 12 weeks. In the weight management phase, 73.5% of participants successfully maintained their body weight after 24 weeks. ("Weight Reduction and Maintenance with IQP-PV-101: A 12-Week Randomized Controlled Study with a 24-Week Open Label Period," Barbara Grube, Wen-Fen Chong,
Pee-Win Chong and Linda Riede, Obesity, published online 2013).

2011 --

A review of over a dozen separate studies confirmed that Satial (Phase 2) Carb Controller™ demonstrated the ability to cause weight loss with doses of 500 to 3000 mg per day, in either a single dose, or in divided doses. The studies also showed that the ingredient has the ability to reduce the post-prandial spike in blood glucose levels. ("A proprietary alpha-amylase inhibitor from white bean [Phaseolus vulgaris]:
A review of clinical studies on weight loss and glycemic control," Marilyn L. Barrett, Pharmacognosy
2008 -- Consulting, Jay K. Udani, MD, Medicus Research LLC, Nutrition Journal, March 2011).

Although obesity and diabetes are on the increase worldwide, based on research developments discussed, the common bean (P. vulgarius) alpha-amylase inhibitor has potential to serve as a widely used
remedy against these conditions. ("The Nutraceutical role of Phaseolus vulgaris alpha-amylase inhibitor,"
-- Wokadala Cuthbert Obiro, Tao Zhang, Bo Jiang; State Key Laboratory of Food Science & Technology, Southern Yangtze University, Jiangsu, China; British Journal of Nutrition, 2008, 100, 1-12.

A two-year, randomized study showed that a low-carb diet helped people lose more weight than a Mediterranean-style diet and the traditional low-fat diet. ("Weight Loss with a Low-Carbohydrate,
-- Mediterranean, or Low-Fat Diet," Michael, Stumvoll, M.D., and Meir J. Stampfer, M.D., Dr. P.H., et al, The Dietary Intervention Randomized Controlled Trial (DIRECT) Group, The New England Journal of Medicine, July, 2008, Vol. 359, No. 3, pages 229-41.

-- ("Alternations in Hepatic Glucose and Energy Metabolism as a Result of Calorie and Carbohydrate Restriction," Jeffrey D. Browning, Brian Weis, Jeannie Davis, Santhosh Satapati, Matthew Merritt, Craig R. Malloy and Shawn C. Burgess," Hepatology, November, 2008.

A randomized, double-blind, placebo-controlled study of 101 subjects showed that those receiving Phaseolus vulgaris extract (Satial Phase 2) had clinical and significantly greater average reduction of body weight and waist circumference, but essentially no difference in average hip circumference.
2007 -- ("Enhanced weight loss from a Dietary Supplement Containing Standardized Phaseolus Vulgaris Extract in Overweight Men and Women," Jianguo Shen, M.D., Xiaofeng Xu, M.S., Allesandro D'Amore, M.D., Harry Preuss, M.D., MACN, CNS.

A scientific study was conducted to determine the stability of Satial (Phase 2) in processed foods and develop a method for monitoring its alpha-amylase inhibiting activity. The study showed that the
-- alpha-amylase inhibiting action of Phase 2 was not affected during preparation of instant mashed potatoes. It also showed that exposure of alpha-amylase to Phase 2 for 30 minutes resulted in significant inhibition. (Yesu Das, Ph.D., ISSI Laboratories, Inc., Piscataway, NJ).

A study was conduced to assess the efficacy of Satial (Phase 2) in inhibiting the human salivary alpha
-- amylase in chewing gum. The study showed that alpha amylase was significantly inhibited by Phase 2 and the inhibiting action of Phase 2 was not affect by the processing/ manufacturing of the chewing gum. (Yesu Das, Ph.D., ISSI Laboratories, Inc., Piscataway, NJ).

Studies were conducted on Super Bows Diet Type B, a supplement in the Japanese marketplace that

contains Phase 2, to evaluate its effect on body weight, body fat and blood glucose levels. In an 8-week open test on 47 human subjects who took Super Bows Diet Type B, there was a significant decrease in the body weight and body fat percentage of test subjects after 8 weeks. In a double-blind cross-over test of 13 human subjects, those who took Super Bows Diet Type B had blood glucose and insulin levels 30 minutes after intake that were significantly lower than those on placebo. ("Effects of Combination of Functional Food Materials on Body Weight, Body Fat Percentage, Serum Triglycerides and Blood Glucose" Yamamoto Tetsuro, Yamaguchi Hideyo, TTC Co. Ltd.)

2006 -- An open-label 6-arm crossover study with 13 randomized subjects using standardized GI testing showed that the GI of Wonder Brand White Bread was significantly reduced by the addition of 3000mg of the Phase 2/StarchLite white bean extract in powder form with other dosages and formulations trending toward significance. ("A Novel Method of Lowering the Glycemic Index of White Bread Using a Proprietary White Bean Extract," Jay Udani, MD Medical Director, Medicus Research)

2005 -- An 8-week trial of 10 overweight subjects showed that those who took Phaseolamin™ 1600 diet reduced body weight, body fat ratio, body fat, abdomen fat ratio, BMI, waist-hip size and triglycerides in the blood serum at a statistically significant level. In addition, the basal metabolism quantity per weight (kg.) was increased at a statistically significant level. ("The Anti-Obesity Effect and the Safety of Taking Phaseolamin 1600 Diet," Takashi Koike, Yoshimitsu Koizumi, Liang Tang, Kyouko Takahara, Yasuhiro Saitou; J. New Rem & Clin, Vol. 54, No. 7; 2005)

-- A 30-day study of 50 overweight and obese subjects revealed that 98% of those completing the study (74%) obtained positive results by reducing their body weight with no special eating regimen and no additional exercise; no adverse reactions or gastrointestinal discomfort were reported. ("Random Multi-Center Evaluation to Test the Efficacy of Phaseolus Vulgaris [PreCarb/Phase 2] in Obese and Overweight Subjects; Lucilla Velasso Osorio, dietitian, Jorge Alberto Zavola Gamboa, Q.I."

-- A series of baked goods, including breads, pizza, muffins and coffee Cake, was developed containing Phase 2/StarchLite at the David Geffen Center for Human Nutrition, UCLA. The products were then subjected to a series of consumer taste tests comparing the Phase 2-containing (Test) baked goods to traditional baked goods (control). In all cases, the Phase 2 products were liked similarly to the control products suggesting the products are interchangeable. In addition, researchers concluded that Phase 2/StarchLite does not affect the taste or texture of foods. (Kanak Udani, Ph.D., and Tragon Corporation.)

2004 -- A double-blind, human pilot study found that those who ate the most carbohydrates and took a supplement containing Phase 2 Starch Neutralizer™, lost significantly more weight and inches from their waist than the placebo group. When stratified by total carbohydrate intake, the Phase 2 group lost an average of 8.7 lbs and 3.3 inches off their waists, while the placebo group lost an average of 1.7 lbs and 1.3 inches. The results were statistically significant. ("Blocking Carbohydrate Absorption and Weight Loss: A Clinical Trial Using a Proprietary Fractionated White Bean Extract" Jay Udani, MD, Medical Director, Integrative Medicine Program, Northridge Hospital Medical Center, Northridge, CA; Betsy Singh, Ph.D., Dean of Research, Southern California University of Health Sciences. Alternative Therapies in Health and Medicine, Jul/Aug 2007, Vol. 13, No.4.)

-- A randomized, double-blind, placebo-controlled, cross-over study of 54 overweight and obese subjects showed minor weight loss and favorable alterations of BMI in some of the stratified groups; several statistically significant favorable changes in blood pressure in the single arm prospective study; and statistically significant improvement in total cholesterol levels in all stratified groups. ("The Effect of TheraSlim [with Phase 2] on Weight, Body Composition, and Select Laboratory Parameters in Adults with Overweight and Mild-Moderate Obesity," Stuart I. Erner, M.D., bariatric physician and researcher, integrative medicine practice).

2003 -- A double-blind, placebo-controlled study of 27 subjects showed that those taking Phase 2 lost nearly a half pound per week (3.8 lbs. over eight weeks), on average, or 129% more than those on placebo. Those on placebo lost 1.65 lbs. Patients on the starch neutralizer also lost 1.47 inches around their waists, on average, or 36% more than those on placebo. Those on placebo lost 1.07 inches. ("Blocking Carbohydrate Absorption and Weight Loss: A Clinical Trial Using Phase 2 Brand Proprietary Fractionated Bean Extract," Jay Udani, MD, Mary Hardy, MD, and Damian C. Madsen, B.A., Alternative Medicine Review, Volume 9, Number 2, March 2004).

-- A double-blind, placebo-controlled study involving 60 overweight subjects showed that those taking StarchAway (Phase 2 chews) experienced significantly more weight loss than their placebo counterparts. ("Reduction in Body Weight with a Starch Blocking Diet Aid: StarchAway Comparison with Placebo," Dana Rothacker, Ph.D., Leiner Health Products; 2003.

2002 -- A double-blind, placebo-controlled, cross-over pilot study of 11 adult human subjects showed that starch absorption averaged 66% less in the group taking Phase 2. (Joe A. Vinson, Ph.D., and Donna M. Shuta, B.S., Department of Chemistry, University of Scranton, April 24, 2002).

-- After critical independent evaluation of the available safety and clinical information, the undersigned experts conferred and, anticipating imminent publication of the 28-day rodent study manuscript, concluded that Phase 2 may be Generally Recognized as Safe (GRAS) by scientific procedures providing an upper limit of aggregate intake of 6 g of Phase 2 per day from supplement and qualified food use applications," (Evaluation of the Generally Recognized as Safe (GRAS) Status of Phase 2 White Bean (Phaseolus Vulgaris) Extract, Robert Nicolosi, Ph.D., Donald Hughes, Ph.D., and David Bechtel, Ph.D.)

2001 -- A double-blind, placebo-controlled study of 60 human subjects who took Phase 2 lost an average of 6.45 lbs. in 30 days, compared to those on placebo, who lost less than 1 lb., on average. Those participants on Phase 2 also lost, on average, over 10% of body fat mass, and more than 3% in waist circumference. There was no loss of lean body mass. (Dr. Licia Tiberi, EVIC Italia. "A Dietary Supplement Containing Standardized Phaseolus Vulgaris Extract Influences Body Composition of Overweight Men and Women." Celleno L, Tolaini MV, D'Amore A, Perricone NV, Preuss HG. Int. J. Med. Sci., 2007; 4:45-52. http://www.medsci.org/v04p0045.htm)

1999 -- A double-blind, placebo-controlled study of 40 overweight human subjects showed that those who took a supplement containing Phase 2 several times a day for 12 weeks experienced statistically significant weight loss and BMI reduction. The Phase 2 supplement had a significantly greater effect on body weight than did the placebo (weight loss of 3.5 kg vs. 1.2 kg). In addition, body mass analyses show that the weight loss in the active group consisted mainly of fat loss as >85% of the weight loss was accounted for by fat. (Dr. E. Thom, Parexel Medstat AS, Lillestrom, Norway. "A Randomized, Double-Blind, Placebo-Controlled Trial of a New Weight-Reducing Agent of Natural Origin" Journal of Int'l Medical Research 2000; 28: 229-233)

1984-88 -- Mayo clinic begins a series of studies. Major findings, include:

"Commercial amylase inhibitors failed to decrease starch digestion in vivo mainly because they have insufficient anti-amylase activity."

"Partially purified inhibitor, prepared by simple extraction of crude bean powder, has much more specific anti-amylase and less agglutinating activity compared with commercial preparations."

"[Partially purified inhibitor] causes dose-dependent intraluminal amylase inactivation in the human intestine, and decreases in vitro digestion of both cooked and raw dietary solid starches."

1982 -- Food and Drug Administration suspends sale of crude bean amylase inhibitors (marketed as starch blockers) based on clinical studies showing that the products failed to influence fecal calorie excretion; postprandial concentrations of plasma glucose or breath hydrogen; and metabolism of C-labeled starch.

1980 -- First crude bean amylase inhibitor preparations are commercially advertised and sold as weight control remedies.

1974 -- J. John Marshall and Carmen M. Lauda purify a proteinaceous inhibitor of alpha-amylase from kidney beans (Phaseolus vulgaris), which they name Phaseolamin.

The researchers perform the first in-vitro research on phaseolamin and conclude it is a specific alpha-amylase inhibitor.

1940's -- Specific inhibitors of animal alpha-amylases were found in plants, particularly wheat and beans.