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# **Boston Therapeutics' Affiliate Advanced Pharmaceutical Initiates SUGARDOWN(R) Clinical Trial in Hong Kong**

## **Advance Pharmaceutical Company to Evaluate the Effect of SUGARDOWN(R) on Post-Prandial Hyperglycemia in Chinese Subjects With Pre-Diabetes**

MANCHESTER, NH -- (Marketwired) -- 03/25/15 -- Boston Therapeutics, Inc. (OTCQB: BTHE), affiliate in Hong Kong, Advance Pharmaceutical Company, Ltd. (APC), initiated enrollment of the first subjects in a clinical trial at The Chinese University of Hong Kong to evaluate the effects of SUGARDOWN® who are pre-diabetic. (Trial posted on ClinicalTrials.gov)

David Platt, Ph.D., CEO of Boston Therapeutics, said, "We are moving forward in our key strategic development demonstrating the effects of SUGARDOWN® on individuals who are pre-diabetic and of higher body mass index. We expect these study results to confirm the test results of our two Sydney University Australia trials, where post prandial reductions in both insulin response and glucose response were reported in all of the participants. We are pleased to have the support of APC for this study, and look forward to reporting the results. In mainland China, it is estimated that approximately 11 percent of adults have diabetes and 30 percent are pre-diabetic.

The single-center, 16-week, randomized, *double-blind*, placebo-controlled, three-treatment arm pilot trial, is funded by APC, and is designed to evaluate the proof of concept for post prandial glucose management, safety and efficacy of SUGARDOWN® in high-risk Chinese subjects with pre-diabetic conditions. The primary endpoint is change in serum fructosamine (indication of glycation of serum proteins) in subjects treated with a variable-dose of SUGARDOWN® compared with placebo from baseline to Week 4. The secondary endpoints include changes in Area Under the Curve\_180 (with continuous monitoring) and HbA1c in subjects from baseline to Week 4 and Week 16, and changes in HbA1c in subjects compared with placebo from baseline to Week 16. A total of 60 subjects are expected to be recruited for the trial.

Dr. Andria Luk and Dr. Juliana CN Chan, PRCP are the lead principal investigators and the lead clinical site which is the Department of Medicine, The Chinese University of Hong Kong, Prince of Wales Hospital.

### ***Obesity and Fructose/ Serum Fructosamine***

Obesity is a major epidemic and excessive consumption of high-fructose corn syrup (HFCS) in beverages as well as many food stuffs plays a role in the immediate post prandial increases in blood glucose levels. The consumption of HFCS and the processing food to

remove fiber have permitted high immediate post consumption of easily absorbed sugar. This has created a dramatic increase in the daily easy and convenient consumption of excess glucose and fructose. Today, HFCS and fast convenience foods represent a significant portion of caloric intake from foods and beverages. Primarily the caloric sweetener used in soft drinks and the fiberless source of sugar from otherwise healthy fruit juices. Sucrose is part glucose and part fructose. These are two "sugars", one the body uses for energy and the other is made into fat if not utilized and converted into glucose. The digestion, absorption, and metabolism of fructose differs from the metabolism of glucose. In addition, unlike glucose, fructose does not stimulate insulin secretion or enhance leptin production (the hormone that signals us to stop eating). Because insulin and leptin act as key afferent signals in the regulation of food intake and body weight, this suggests that fructose may contribute to increased energy intake and weight gain. Additionally increased insulin response signals the body to store sugars as fat. Furthermore, calorically sweetened beverages may enhance caloric overconsumption. Thus, the increase in consumption of HFCS has a temporal relation to the epidemic of obesity, and the overconsumption of HFCS in calorically sweetened beverages may play a role in the epidemic of obesity.

SUGARDOWN® will be administered as an oral chewable tablet containing either four grams of SUGARDOWN® or matching placebo. All subjects will be instructed to take two chewable tablets prior to meal ingestion. Low-dose SUGARDOWN® consists of one active chewable tablet and one placebo chewable tablet; high-dose SUGARDOWN® consists of two active chewable tablets.

### ***About SUGARDOWN®***

SUGARDOWN® is a non-systemic chewable complex carbohydrate-based compound designed to reduce post-meal elevation of blood glucose. It also has been indicated in a reduction of insulin response in high body mass index individuals. SUGARDOWN® is a proprietary polysaccharide to be taken before meals and works in the gastrointestinal tract to block the action of carbohydrate-hydrolyzing enzymes that break down complex carbohydrates into simple sugars, reducing the availability of glucose for absorption into the bloodstream. SUGARDOWN® is the dietary supplement version of BTI-320.

### ***About Advance Pharmaceutical Company, Ltd.***

Advance Pharmaceutical Company is a leading Hong Kong-based pharmaceutical company. Advance Pharmaceutical Company currently sells over 400 types of licensed pharmaceutical products, consisting of prescription and over the counter products to local dispensaries, medicine shops, clinics and hospitals, as well as chain stores, such as 7-11, Wellcome, Park-N-Shop, Mannings and Watson's. Outside of Hong Kong, Advance Pharmaceutical Company has been building and maintaining its marketing network in Macau since 1983 and has many years of experience in exporting and distributing pharmaceutical products to China. Currently, Advance Pharmaceutical Company's products penetrate 90% of dispensaries and drug stores in Macau. Additional information is available at <http://www.apc.com.hk/aboutus.php>.

### ***About Boston Therapeutics, Inc.***

Boston Therapeutics, headquartered in Manchester, NH, (OTCQB: BTHE) is an innovator in designing compounds using complex carbohydrate chemistry. The company's product

pipeline is focused on developing and commercializing therapeutic molecules that address diabetes and inflammatory diseases, including: BTI-320 and SUGARDOWN®, non-systemic chewable therapeutic compounds designed to reduce post-meal glucose elevation, and IPOXYN, an injectable anti-necrosis drug designed initially to treat lower limb ischemia associated with diabetes. The company also developed and markets SUGARDOWN®, a non-systemic complex carbohydrate-based dietary food supplement designed to support healthy blood glucose. More information is available at [www.bostonti.com](http://www.bostonti.com).

### ***Cautionary Note Regarding Forward Looking Statements***

This press release contains, in addition to historical information, forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements relate to future events or future financial performance, and use words such as "May," "estimate," "could," "expect" and others. They are based on our current expectations and are subject to factors and uncertainties which could cause actual results to differ materially from those described in the statements. Factors that could cause our actual performance to differ materially from those discussed in the forward-looking statements include, among others, that our plans, expectations and goals regarding our clinical development of BTI-320 and SUGARDOWN® are subject to factors beyond our control. We can provide no assurance we or our commercial partner will be able to generate market demand for SUGARDOWN®, and thus we may not be able to generate revenue from SUGARDOWN® sales.

Moreover, we have incurred operating losses since our inception, and our ability to successfully develop, market, manufacture, distribute and sell drugs or over-the-counter products may be affected by our ability to manage costs and finance our continuing operations. For a discussion of additional risk and other factors affecting our business, see our Annual Report on Form 10-K for the year ended December 31, 2013, and our subsequent filings with the SEC.

You should not place undue reliance on forward-looking statements, and actual results may differ materially from the results anticipated in our forward-looking statements. Although subsequent events may cause our views to change, we disclaim any obligation to update forward-looking statements.

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