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# Boston Therapeutics Reports Positive Topline Data From Proof of Concept Asia Trial

## Trial Demonstrates Drug Effect and Safety of BTI320

LAWRENCE, MA -- (Marketwired) -- 10/06/16 -- Boston Therapeutics, Inc. (OTCQB: BTHE) and its Asian partner Advance Pharmaceutical Company Limited, Hong Kong presented today the positive topline data on postprandial hyperglycemia in high risk pre-diabetic Chinese population from the proof of concept trial (Protocol Code: SG01) conducted at the Chinese University of Hong Kong (CUHK).

Dietary control to induce normal postprandial glycemic response (PPGR) is emerging to be critically important in the prevention and manifestation of metabolic syndromes (i.e. diabetes), and new portable, wearable continuous glucose monitoring devices (Dexcom Inc., US, Medtronic, Ireland, etc.) open a new, important self-management technique for better healthcare. Mr. Carl Rausch, CEO said, "We are pleased to be able to work with advanced technology, sensors, wearable devices, and in the future, mobile apps that have the potential to offer pharmaceutical sponsors access to patient data for unique real-time development of an investigative drug material that complement existing data and will provide a more complete view of safety and efficacy."

The investigative material from Boston Therapeutics, BTI320, has been in development for the past several years and, with operation partners in Asia, have advanced what is believed to be a new patented, effective investigative material for the benefit of safe blood glucose management.

**Positive Phase II Data Supports the Effect and Safety of BTI320** in a randomized, double-blind, placebo controlled clinical trial (<https://clinicaltrials.gov/ct2/show/NCT02358668>). With >95% overall compliance across study groups, the phase II proof of concept trial (Protocol Code: SG01) demonstrated that both low dose (4g) and high dose (8g) BTI320 are safe and effective in significantly reducing various continuous glucose monitor (CGMS) parameters when compared against placebo.

**The SG01 Clinical Study** was a 16-week double-blind randomized placebo-controlled study designed to investigate the effect of a low and a high dose of BTI320 compared with placebo in Chinese subjects at high risk of diabetes. A total of 60 prediabetic but otherwise healthy subjects were recruited into the study to assess the drug effect of BTI320 on serum fructosamine (primary objective), the area under the glucose

concentration-time curve for glucose level above 180mg/dL (AUC 180) or 10mmol/L and HbA1c level (secondary objectives). Our findings suggest that these subjects, while at high risk, were not expected to exhibit any change in the glycosylation of this serum glucose protein.

***The BTI320 planned key supplementary analyses reveals a better understanding of diabetes management and care in the prevention of IGT and other pre-diabetic conditions.*** To account for the glycemic variability among individual subjects on a day-to-day basis, CGMS analyses (with variability adjusted) were performed to appropriately reflect the drug effects of BTI320 on an individual level with no group data pooled.

***Supplementary Analyses Demonstrate Positive Effect of BTI320.*** Low dose BTI320 (4g) demonstrated significant treatment effects in the changes of AUC at 1, 2, 3 hours postprandial when compared to placebo (all  $p \leq 0.02$ ). A significant effect was also observed in Mean Postmeal Maximum Glucose (MPMG) reduction ( $p=0.03$ ) compared with placebo. According to results of adjusted analysis, low dose BTI320 demonstrated significant effects in MBG reductions of 0.32, 0.31 and 0.27 mmol/L at 1, 2 and 3 hr postprandial respectively. Previous studies have shown that reduction in MBG is significant and is associated with a reduction in HbA<sub>1c</sub> in diabetic patients.

***BTI320 is shown to be safe*** as no remarkable changes from baseline were observed in hematology and general biochemistry across BTI320 groups throughout visits in this 16-week study. BTI320 appears to be safe and well-tolerated among subjects, where similar frequencies of adverse events (AE) including flatulence, abdominal distension/discomfort and bowel movement were equally reported across the three groups in the initial month of the trial. Overall compliance for the study was reported to be greater than 95%. Only one serious adverse event of osteosarcoma was reported and was confirmed to be unrelated to the study drug.

The extensive dataset of the CUHK SG01 clinical study is currently under preparation for publication and will be posted on Clinicaltrials.gov in the near future. An abbreviated description of this clinical trial innovation was presented at the seminar for "Frontier Technologies with Impact in Public Health" at the Chinese University of Hong Kong sponsored by the Jockey Club School of Public Health and Primary Care on September 25<sup>th</sup> 2016, a key collaborator in this and future trials.

### ***SugarDown<sup>®</sup>***

The Company also developed and markets SugarDown<sup>®</sup>, a sugar blocker dietary food supplement designed to support glycemic health. More information is available at [www.bostonti.com](http://www.bostonti.com). SugarDown<sup>®</sup> in its present formulation is a natural sugar blocker dietary supplement product made entirely from a non-digestible sugar molecule that can help people maintain healthier weight levels and is the first chewable tablet of its kind. In a previous study, SugarDown<sup>®</sup> demonstrated significant reduction of glucose and insulin Area Under the Curve (AUC) when taken with Jasmine rice, a food with a glycemic index of about 90 compared to glucose, which is 100. More information can be found on [www.sugardown.com](http://www.sugardown.com)

**About Boston Therapeutics, Inc.**

Boston Therapeutics, headquartered in Lawrence MA, (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: BTI320, a non-systemic chewable therapeutic compound designed to regulate postprandial glucose level and ultimate reduction in HbA1C for diabetes management.

**Forward Looking Statement**

This press release includes forward-looking statements. These statements may be identified by words such as "feel," "believes," "expects," "estimates," "projects," "intends," "should," "is to be," or the negative of such terms, or other comparable terminology. Forward-looking statements are statements that are not historical facts. Such forward-looking statements are subject to risks and uncertainties, which could cause actual results to differ materially from the forward-looking statements contained herein. Factors that could cause actual results to differ materially include, but are not limited to: our limited operations and need to expand in the near future; risks associated with obtaining regulatory approval of our products; the ability to protect our intellectual property; the potential lack of market acceptance of our products; potential competition; our inability to retain key members of our management team; our inability to raise additional capital to fund our operations and business plan; our ability to continue as a going concern; our liquidity and other risks and uncertainties and other factors discussed from time to time in our filings with the Securities and Exchange Commission ("SEC"), including our annual report on Form 10-K filed with the SEC. Boston Therapeutics expressly disclaims any obligation to publicly update any forward-looking statements contained herein, whether as a result of new information, future events or otherwise, except as required by law.

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