

October 6, 2015



# **Boston Therapeutics Completes Enrollment for BTI-320 Clinical Trial**

## **Trial to Include Chinese Subjects With Pre-Diabetes**

MANCHESTER, NH -- (Marketwired) -- 10/06/15 -- Boston Therapeutics, Inc. (OTCQB: BTHE) today announced that its Hong Kong affiliate, Advance Pharmaceutical Company, Ltd. (APC), completed enrollment for the clinical trial at The Chinese University of Hong Kong (CUHK) to evaluate BTI-320 in subjects who are pre-diabetic. The clinical trial had 60 pre-diabetic patients.

This key developmental trial, being conducted in Hong Kong and the associated endpoints are pivotal for concluding the BTI-320 registration in mainland China. This clinical trial is supplemental to an on-going separate clinical trial, being conducted in mainland China. It is expected to be completed by year end and the overall dossier for approval is targeted to be submitted in January 2016 for pending country wide approval in the first half of 2016. BTI-320 is planned to address and benefit a population of 495,000,000 pre-diabetic people in China (*JAMA. 2013 Sep 4;310(9):948-59*) and 50% of the entire population in the USA, who are pre-diabetic and diabetic (*JAMA. 2015;314(10):1021-1029*) and could make a significant contribution to controlling healthcare costs.

Enrollment in the CUHK first trial was completed ahead of schedule and is expected to confirm the assessment of prevention biomarker parameters associated with postprandial glucose (PPG) spikes measured with Continuous Glucose Monitoring (CGM) device, Fructose accumulation (Fructosamine blood testing) and HbA1c (Glycated Hemoglobin). PPG maximum amplitude peaking and Fructosamines appears to be a major detriment and predicament to lowering HbA1c and forestalling the onset and the advancement of Type 2 Diabetes without the hypoglycemic threat possible with many of the compounds presently associated with diabetes treatment.

The Chinese FDA process is a major focus of APC's alliance partnership in Asia, where they are piloting clinical marketing education programs, specifically in Korea, Hong Kong, Singapore, and most recently Japan. APC has under license from Boston Therapeutics Inc. 15 countries in South East Asia.

David Platt, Ph.D., CEO of Boston Therapeutics, said, "BTI-320 is the only drug candidate in development to safely block Glucose, Fructose and other sugars simultaneously with a single molecular structure. With over 150 patients treated to date, there are no Serious Adverse Effects (SAE) observed. We are fortunate to have APC as a financial partner to conduct and fund these and other studies and look forward to commercializing BTI-320 where we may help many people to manage this world health mandate to manage blood

sugar."

Boston Therapeutics developed BTI-320 and markets it through APC in Asia. BTI-320 is a non-systemic compound (working only in the intestine not in blood), designed to block the increase of post-meal elevation of blood Glucose, Fructose and other key Sugars. BTI-320 is 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 Fructose and other sugars for absorption into the bloodstream.

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

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

Advance Pharmaceutical Company is a leading Hong Kong-based pharmaceutical company. Advance Pharmaceutical Company currently sells more than 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, a non-systemic chewable therapeutic compound designed to reduce post-meal glucose elevation, and IPOXYN, an injectable anti-necrosis drug designed initially to treat lower limb ischemia associated with diabetes. More information is available at [www.bostonti.com](http://www.bostonti.com) and [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

### ***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 are subject to factors beyond our control. We can provide no assurance that we or our commercial partners will be able to generate market demand

for BTI-320, and thus we may not be able to generate revenue from 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, 2014, 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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