

# Boston Therapeutics Initiates Phase IIb Study to Assess the Efficacy and Safety of SUGARDOWN(R) for Type 2 Diabetes

# Company Seeks to Enroll 24 Patients in Five-Week Double-Blinded Study

MANCHESTER, NH -- (Marketwired) -- 05/29/14 -- Boston Therapeutics, Inc. (OTCQB: BTHE), a leading developer of compounds that address diabetes using complex carbohydrate chemistry, has initiated a Phase IIb clinical study to assess the efficacy and safety of SUGARDOWN<sup>®</sup> in 24 patients with Type 2 diabetes taking metformin. The study, SD-002, is being conducted by Accumed Research Associates in Garden City, NY under the direction of Principal Investigator Mitchell D. Efros, MD, FACS.

SUGARDOWN<sup>®</sup> is Boston Therapeutics' (BTI) currently marketed dietary supplement that is intended to support healthy blood sugar. Previous clinical studies have indicated that SUGARDOWN<sup>®</sup> can maintain healthy glucose levels even after meals when sugar tends to spike.

The five-week, randomized, double-blind Phase IIb study is designed to assess the safety and efficacy of SUGARDOWN<sup>®</sup> in two different doses versus placebo on serum glucose levels after meals in 24 subjects with Type 2 diabetes treated with metformin alone. The primary endpoint of the study is postprandial serum glucose area under the curve; secondary endpoints are peak postprandial serum glucose, time to peak postprandial serum glucose, and peak blood serum excursion at two hours from baseline.

David Platt, Ph.D., Chief Executive Officer of Boston Therapeutics, said, "We are looking forward to enrolling and conducting this new study on the safety and efficacy of SUGARDOWN<sup>®</sup>, in order to corroborate the previous clinical findings we have obtained. We expect this study will strengthen the existing body of evidence that SUGARDOWN<sup>®</sup> can play a useful role in supporting healthy blood sugar levels. Having recently signed a strategic marketing agreement for SUGARDOWN<sup>®</sup> with Benchworks SD, a leading branding and marketing agency, we look forward to having the results of this clinical study help support our marketing and sales initiatives."

Individuals with Type 2 diabetes currently taking metformin who are interested in participating in the trial should visit <a href="http://www.clinicaltrials.gov/ct2/show/NCT02135549?">http://www.clinicaltrials.gov/ct2/show/NCT02135549?</a> term=SD-002&rank=1.

## **About Study SD-002**

Subjects will undergo a screening visit, baseline visit and three treatment visits. Subjects will

all receive placebo tablets at the baseline visit, eat a standard rice meal, and then serum glucose levels will be measured in frequent intervals over four hours immediately following the meal. Subjects will be randomized to one of six treatment sequences. Subjects will take in an unknown order one week of placebo, one week of 4 g dose and one week of 8 g dose of SUGARDOWN<sup>®</sup> immediately before breakfast, lunch and dinner meals. Subjects will continue their usual metformin regimen during the trial period.

#### 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 (formerly PAZ320), 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. The company also produces and sells SUGARDOWN<sup>®</sup>, a non-systemic complex carbohydrate-based dietary food supplement designed to support healthy blood glucose. More information is available at <a href="https://www.bostonti.com">www.bostonti.com</a>.

## **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 the clinical trials are subject to factors beyond our control and provide no assurance of FDA approval of any of our future drug development plans. Our clinical trials may not produce positive results in a timely fashion, if at all, and any necessary changes during the course of the trial could prove time consuming and costly. We may have difficulty in enrolling candidates for testing, which would affect our estimates regarding timing, and we may not be able to achieve the desired results. Any significant delays or unanticipated costs in any subsequent drug trial could delay obtaining meaningful results from Phase II studies and/or preparing for Phase III studies with the current cash on hand.

Upon receipt of FDA approval, we may face competition with other drugs and treatments that are currently approved or those that are currently in development, which could have an adverse effect on our ability to achieve revenues from our approved products. Plans regarding development, approval and marketing of any of our compounds, including BTI-320, are subject to change at any time based on the changing needs of our company as determined by management and regulatory agencies. We have incurred operating losses since our inception, and our ability to successfully develop and market drugs 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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