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Boston Therapeutics Initiates New Exploratory and Adaptive Multicenter Clinical Study of BTI320 On Type 2 Diabetics Currently on Metformin and or Sulfonylureas in the United States

LAWRENCE, Mass., Sept. 24, 2018 (GLOBE NEWSWIRE) -- Boston Therapeutics Inc. (the "**Company**" or "**BTI**") (OTCQB:BTHE), an innovator in the design, development and commercialization of novel therapeutics as an adjunct therapy for diabetes, announces the start of a new double-blind, placebo-controlled study that will confirm the potential of the newly patented (EU) investigative material to support and possibly enhance current anti-diabetic regimen of glycemic control in subjects with type diabetes. First subject in the multicenter trial was consented on September 18, 2018. The objective of this confirmatory, proof of concept adaptive study is to assess appropriate efficacy of clinical benefit and contribute to the growing safety of BTI320. This will be compared to placebo and will also have the addition of metformin and/or sulfonylureas on critical glycemic control over a 12-week duration in a diseased population. BTI320 has been shown to significantly decrease postprandial glucose excursions, a key immediate impactful influence on red cell protein glycation which then persists for months (BMC Endocrine Disorders, https://bmcendocrdisord.biomedcentral.com/track/pdf/10.1186/s12902-018-0288-5). It is hypothesized that BTI320, through this simple immediate post-meal effect on blood sugar, may help stall or delay the progression of diabetes and other related complications. BTI320 is designed to reduce glycemic variabilities, as shown by indices captured through the rapidly emerging continuous glucose monitoring systems (CGMS). CGMS is an innovative way to limit "finger sticking "for blood sampling, and replace it with a system that provides reliable immediate understanding of the direct effect of the food and drinks that are being consumed.

The current multicenter clinical study is designed to confirm the appropriate outcome effects of BTI320 on specific postprandial glucose excursions and possibility of better control of variability in type 2 diabetics. We have employed the innovative, "Big Data" approach through the use of the Abbott Freestyle Libre Pro, which will be used to collect glycemic parameters hourly for several days and over the variable meal programs of each individual. This commercially available CGMS is factory-calibrated, and thereby eliminates subject finger prick calibration. It also assures a high degree of data integrity and reduces both the trial time to assessment and the time to expand and complete the registration trials.

CEO, Carl W. Rausch, commented: "Boston Therapeutics has been extremely fortunate in garnering the financial support from our Asian license holder and collaborator. We are extremely pleased with this progress as we have set new directions and will position this important trial with the FDA and EMA to be used as a basis for adapting endpoints and

expanding to the larger trial planned in our clinical pipeline. With the incidence of diabetes on the rise, there is an immediate need for the development of novel safe (non-systemic) drugs to provide safe, convenient and cost-effective new treatment modalities to help individuals with pre-diabetes and diabetes thereby improving their diabetes management options and compliance."

A total of 4 clinical sites have been qualified and selected to participate in the study (Protocol: BTI320-SG02). Eligible subjects first phase (n=60) enrolled in the study will have the opportunity to get a detailed assessment of their glycemic and metabolic profiles to help identify ways to improve their condition. It is proposed that those randomized in the treatment arm may benefit from a lower blood glucose through identification of the "time out of range" or any spike postprandially that appears to have a lasting effect not previously measured or understood.

About Boston Therapeutics, Inc. **www.bostonti.com**
Boston Therapeutics, headquartered in Lawrence, MA (OTCQB: BTHE) and with an office in Albuquerque, NM is an innovator in design, development and commercialization of novel compounds to treat diabetes and diabetes related complications. The company has proprietary compounds based on glucose chemistry, peptide chemistry and protein conjugates.

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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