Better Therapeutics Announces Publication of the Rationale, Design and Baseline Characteristics Manuscript for Type 2 Diabetes Pivotal Trial of BT-001, a Novel Prescription Digital Therapy, in Clinical Cardiology

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SAN FRANCISCO--(BUSINESS WIRE)--Jul. 11, 2022-- Better Therapeutics, Inc. (NASDAQ: BTTX), a prescription digital therapeutics company developing nutritional cognitive behavioral therapy (nCBT) to address the root causes of cardiometabolic diseases, today announced the publication of a manuscript detailing the study design and methodology for its pivotal clinical trial of BT-001 in adult patients with type 2 diabetes (T2D) in the medical journal, Clinical Cardiology. The study represents a first-in-class randomized, controlled clinical trial of a prescription digital therapeutic (PDT) for the treatment of T2D and is expected to support the filing of a de novo classification request with the U.S. Food and Drug Administration (FDA) in the third quarter of 2022. The company announced positive primary endpoint data for this trial in March of this year and expects to release secondary data in the third quarter of this year.

The manuscript, titled, “Cognitive behavioral therapy delivered via digital mobile application for the treatment of type 2 diabetes: Rationale, design, and baseline characteristics of a randomized, controlled trial,” includes a detailed description of study design, efficacy and safety endpoints, the nCBT protocols embedded in BT-001, statistical considerations and baseline characteristics of the study population. BT-001 is an investigational digital therapeutic designed to provide nCBT via a T2D patient’s smartphone to support dietary change, physical activity and medication adherence for the reduction of A1c.

“This is one of the largest randomized trials of a digital therapeutic that includes a diverse population of patients that need more treatment options for their type 2 diabetes," said Dr. Marc Bonaca, Director of Vascular Research at the University of Colorado. “The data, to date, support a new approach to treating type 2 diabetes that does not simply address symptoms but instead tackles the behavioral causes of the disease. This technology is promising not just for patients with type 2 diabetes but potentially for those with a broader range of cardiometabolic diseases sharing common root causes.”

The open-label, randomized, controlled, parallel group trial evaluated the efficacy and safety of BT-001 and its ability to improve glycemic control among patients with T2D. Participants were randomized to receive standard of care with or without BT-001 and the primary efficacy endpoint was the difference in mean change from baseline in A1c after 90 days of treatment between the two groups. The secondary efficacy endpoint is the change from baseline to Day 180. Exploratory endpoints include physical measures, biomarkers, healthcare utilization, and patient-reported outcomes (PRO). Patients receiving standard of care were on multiple anti-hyperglycemic meds at baseline and free to adjust meds as needed. In this way, the design parallels cardiovascular outcome trials of other medications. The clinical trial enrolled 669 adults with T2D and supported inclusion and exclusion criteria chosen to enroll a representative population of adult outpatients with T2D across population groups often underrepresented in biotech research, including women, minority groups and patients in low socioeconomic status neighborhoods.

The manuscript highlights key potential advantages of the digital therapeutic over in-person nCBT, which include its scalability, standardization of the intervention, and ease of access. The latter is particularly important for rural residents and patients with time, mobility or transportation limitations. In-clinic CBT is a long-standing and well-studied therapeutic approach, but broad utilization has been limited by inherent access and resource constraints. Prescription digital therapeutics that digitally deliver nCBT have the potential to overcome these obstacles by making behavioral therapy accessible and affordable to millions of patients in need.

About Better Therapeutics

Better Therapeutics is a prescription digital therapeutics (PDT) company developing a novel form of cognitive behavioral therapy to address the root causes of cardiometabolic diseases. The company has developed a proprietary platform for the development of FDA-regulated, prescription software-based solutions for type 2 diabetes, heart disease and other conditions. The nutritional cognitive behavioral therapy delivered by Better Therapeutics’ PDT is designed to enable changes in neural pathways of the brain so lasting changes in behavior become possible. Addressing the underlying causes of these diseases has the potential to dramatically improve patient health while lowering healthcare costs. Better Therapeutics clinically validated mobile applications are intended to be prescribed by physicians and reimbursed like traditional medicines.

For more information visit: bettertx.com

Forward-Looking Statements

Certain statements made in this press release are "forward-looking statements" within the meaning of the safe harbor provisions under the United States Private Securities Litigation Reform Act of 1995. Forward-looking statements are typically identified by words such as “plan,” “believe,” “expect,” “anticipate,”“ intend,” “outlook,” “ estimate,” “forecast,” “project,” “ continue,” “could,” “may,” “might,” “ possible,” “potential,” “predict,” “should,” “would” and other similar words and expressions, but the absence of these words does not mean that a statement is not forward-looking. The forward-looking statements in this press release include, but are not limited to, statements regarding the timing and results of the ongoing trial of BT-001 in patients with type 2 diabetes, Better Therapeutics’ plans regarding FDA submissions, expectations related to the potential benefits of BT-001 and CBT and their potential treatment applications, Better Therapeutics’ plans regarding the research and advancement of its product candidates for additional treatments, expectations related to the interest of healthcare providers and payers in PDTs and legislative developments affecting PDTs and the outcome of such developments, among others. These forward-looking statements are based on the current expectations of the management of Better Therapeutics and are inherently subject to uncertainties and changes in circumstances and their potential effects and speak only as of the date of such statement. There can be no assurance that future developments will be those that have been anticipated. These forward-looking statements involve a number of risks, uncertainties or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements including: risks related to Better Therapeutics’ business, such as the willingness of the FDA to authorize

PDTs for commercial distribution and insurance companies to reimburse their use, market acceptance of PDTs, the risk that the results of previously conducted studies will not be repeated or observed in ongoing or future studies involving our product candidates and other risks and uncertainties included under the header "Risk Factors" in the definitive proxy statement/prospectus filed by us on October 12, 2021.

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