Better Therapeutics Announces Key Milestones and Updates for Ongoing Studies of its Digital Therapeutics Approach for Cardiometabolic Diseases

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First Study of Nutritional Cognitive Behavioral Therapy for Fatty Liver Disease and Expanded Real-World Evidence Studies for Type 2 Diabetes Follow Promising Primary Endpoint Clinical Trial Data

SAN FRANCISCO--(BUSINESS WIRE)--Apr. 6, 2022-- Better Therapeutics, Inc. (NASDAQ: BTTX), a prescription digital therapeutics (PDT) company developing nutritional cognitive behavioral therapy (nCBT) to address the root causes of cardiometabolic diseases, today announced several key research milestones designed to advance and further validate its therapeutic technologies, including the first ever study of nCBT as potential treatment for Nonalcoholic Fatty Liver Disease (NAFLD) and Nonalcoholic Steatohepatitis (NASH). This announcement arrives on the heels of positive primary endpoint data from the pivotal clinical trial of BT-001, the company's prescription digital therapeutic for type 2 diabetes.

Better Therapeutics digital therapeutic platform delivers a novel form of cognitive behavioral therapy to help people with cardiometabolic diseases potentially improve key measures related to type 2 diabetes, NAFLD, NASH, hypertension, hyperlipidemia and other cardiometabolic conditions. By adapting the principles and mechanisms of cognitive behavioral therapy, the digital therapeutic platform is designed to address and modify the cognitive patterns that drive eating habits and other behavioral factors associated with cardiometabolic diseases.

Better Therapeutics + Arizona Liver Health LivVita Study

Conducted in collaboration with Arizona Liver Health, a leading liver clinical research center, Better Therapeutics has commenced the LivVita study designed to evaluate the feasibility of its nCBT platform to reduce liver fat and improve liver disease biomarkers in NAFLD and NASH, and enrolled its first patients.

"With a quarter of American adults affected by NAFLD, including 70% of diabetes patients, fatty liver disease is a growing public health crisis made even more challenging by a lack of effective, FDA-approved therapeutics," said Mazen Noureddin, MD, director of Cedars Sinai Fatty Liver Program and who serves as the senior clinical advisor for the LivVita study. "We are hopeful that the nCBT approach offered by Better Therapeutics can prove effective in treating this condition and alleviating the pressure it places on our health system, including the $100 billion annual cost incurred as a direct result of this condition."

Better Therapeutics + Mass General Brigham BT-001 Real-World Evidence Study

Additionally, Better Therapeutics announced that it has expanded its real-world evidence study of BT-001, now including Mass General Brigham, and has begun enrolling patients with type 2 diabetes.

"The Digital Care Transformation program at Mass General Brigham is an ideal setting to evaluate BT-001's long-term durability of effect and cost of care impact in a diverse population treated in a remote, real-world clinical setting," said Benjamin Scirica, MD, MPH, director of quality initiatives at the cardiovascular division of Mass General Brigham. "We see great potential for a prescription digital therapeutic like BT-001, and how the patient data generated during the course of use could inform and improve the delivery and quality of care we provide our patients."

This study follows Better Therapeutics' release of primary endpoint data for BT-001 which demonstrated statistically significant and clinically meaningful reductions in A1c, a measure of blood sugar. After 90 days of treatment, 61% of patients lowered A1c (a measure of blood sugar); 43% reduced A1c by 0.4% or greater (mean 1.1%), while only 25% of the control group achieved the same reduction. The result was highly statistically significant with a p value of < .00001.

Better Therapeutics + Durham Veterans Administration BT-001 Real-World Evidence Study

Better Therapeutics also announced that the Durham Veterans Administration Medical Center has joined its real-world evidence study held in collaboration with the Colorado Prevention Center.

"Demonstrating the potential to improve and maintain glycemic control and reduce ongoing healthcare costs and medications within the veteran community is of critical importance," said Mark Berman, MD, chief medical officer of Better Therapeutics. "Veterans suffer disproportionately from type 2 diabetes, which is the largest driver of costs within the VA."

Studies like this are critical not only to the development of BT-001, but to establish the effectiveness of nCBT delivered by prescription digital therapeutics as a critical tool in the fight against cardiometabolic diseases.

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, software-based solutions for type 2 diabetes, heart disease and other conditions. The 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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Investor Relations:
Mark Heinen
IR@bettertx.com

Media:
Ryan McKenna at Real Chemistry
rmckenna@realchemistry.com

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