Better Therapeutics Announces Positive Primary Endpoint Data From Pivotal Clinical Trial of BT-001, a Prescription Digital Therapeutic (PDT) for Patients With Uncontrolled Type 2 Diabetes

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Data Demonstrates Clinically Meaningful and Statistically Significant Results, Improving Glycemic Control by Reducing A1c 0.4% Versus the Control Group Receiving Standard of Care

SAN FRANCISCO--(BUSINESS WIRE)--Mar. 15, 2022-- Better Therapeutics, Inc. ("Better Therapeutics", NASDAQ: BTTX), a prescription digital therapeutics company developing nutritional cognitive behavioral therapy (nCBT) to address the root causes of cardiometabolic diseases, today announced primary endpoint data from its pivotal trial of BT-001, a first-in-class investigational PDT platform that is designed to use digitally delivered nCBT to treat type 2 diabetes.

The open label, randomized, controlled, parallel group trial enrolled 669 adults with type 2 diabetes and mean baseline A1c of 8.1%. 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. Following is an overview of key takeaways from the 90-day data:

- The clinical trial included a diverse, nationally representative patient population including participants from minority groups often underrepresented in diabetes studies. 40.2% of participants were non-white; 15.7% were Hispanic or Latin American.
- Participants had long-standing type 2 diabetes, high cardiovascular risk, multiple comorbidities with use of multiple medications.
- The primary efficacy endpoint (n=602) showed highly statistically significant improvement in A1c between the intervention and control groups (-0.4%, p <0.001).
- Clinically meaningful changes (A1c reductions of 0.4% or more) occurred in 42.7% of the group receiving standard of care and BT-001 vs. 25.4% in the group receiving standard of care alone (difference of 17.3%, p <0.001); we believe this demonstrates use of BT-001 significantly improved A1c compared to standard of care alone.
- There was a clear dose-response between greater engagement in nCBT and greater reductions in A1c, supporting nCBT as a mechanism of action.
- Measures of patient engagement, adherence, persistence, and satisfaction were all positive.
- No meaningful differences in safety events were observed between groups.

The six-month trial is ongoing and is expected to be completed in Q2 2022. Given the compelling benefit-to-risk profile of BT-001 and highly statistically significant 0.4% reduction in A1c, Better Therapeutics intends to file a De Novo classification request with the FDA upon completion of the study.

"The data we're unveiling today is a critical step in our journey to reimagine how cardiometabolic diseases are treated. By demonstrating that BT-001 can improve glycemic control at 90 days by addressing the behaviors that are root causes of type 2 diabetes, even in a very sick, poorly controlled population with long-standing diabetes, we not only open a new avenue of potential treatment, but a new horizon for non-pharmaceutical approaches to care," said Dr. Mark Berman, chief medical officer of Better Therapeutics. "If these positive trends continue, we see the potential to advance PDTs to improve health and reduce reliance on medications."

"The existing treatment paradigm for type 2 diabetes relies almost exclusively on the use of traditional medications to address the symptoms of the disease, while doing very little about the behaviors that are the underlying causes. We created nutritional CBT delivered as a prescription digital therapeutic to fill a known gap in clinical care," said Kevin Appelbaum, co-founder and CEO of Better Therapeutics. "This primary endpoint data for BT-001 suggests that we are not only on the right track for creating a safe and effective treatment for type 2 diabetes, but that nutritional CBT may offer potential across a broad range of cardiometabolic conditions."

Better Therapeutics intends to advance its product pipeline candidates BT-002 and BT-003, for the treatment of hypertension and hyperlipidemia, respectively, to pivotal trials after the completion of its pivotal trial in type 2 diabetes. The company will soon begin clinical research in fatty liver disease to understand the potential of nCBT as a potential treatment.

BT-001 is part of a new class of PDTs that are increasingly garnering interest from health care providers and payers. The Center for Medicare and Medicaid Services recently established new codes aimed at making it easier for providers to adopt and integrate these innovative therapies into their care regimens. And just last week, the bipartisan, bicameral *Access to Prescription Digital Therapeutics Act of 2022* was introduced in Congress. If passed, this legislation would create a new benefit category within Medicare to cover and reimburse PDTs. Type 2 diabetes is the largest cost driver among government payers, including Medicare, Medicaid, and the Veterans Health Administration, with 40% of type 2 diabetes patients obtaining their insurance through Medicare. Medicare coverage would represent upside to the company's financial projections.

Investor Conference Call and Webcast

Better Therapeutics management will host an investor conference call and webcast today, March 15 at 8:30 a.m. ET to discuss the BT-001 data announcement and related corporate updates. The conference call may be accessed by dialing +1 (833) 945-2463 and entering the conference ID: 7299550. The live webcast may be accessed by visiting the event link at: https://edge.media-server.com/mmc/p/u4w9dpwb. Following the webcast, a replay of the webcast may be accessed from the Investor Relations section of the Better Therapeutics corporate website at: investors.bettertx.com.

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 investigational mobile applications are intended, if authorized for marketing, 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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