Better Therapeutics Completes Pivotal Trial of BT-001 for Type 2 Diabetes and Announces Positive Secondary Endpoint Results Following the Earlier Announcement of Positive Primary Endpoint Results

July 28, 2022

Data demonstrates BT-001 was durable with A1c reductions continuing to improve after 180 days of treatment

On track to submit a de novo classification request with FDA for BT-001 in third quarter of 2022

Company to host conference call and webcast today at 8:30 a.m. ET

SAN FRANCISCO--(BUSINESS WIRE)--Jul. 28, 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 the completion of the pivotal clinical trial for BT-001, an investigational first-in-class prescription digital therapeutic that is designed to use nCBT to treat type 2 diabetes (T2D).

With the positive data reported by this pivotal clinical trial, Better Therapeutics intends to submit a *de novo* classification request to the U.S. Food and Drug Administration (FDA) in the third quarter of 2022, seeking marketing authorization for BT-001 for the treatment of patients with T2D. If granted, BT-001 would become the first prescription digital therapeutic for the treatment of T2D.

“Today’s announcement is a moment to celebrate – not just for the team at Better Therapeutics – but for the patients and health care providers who know all too well that the way we treat T2D today simply isn’t good enough given the magnitude of this epidemic disease,” said Frank Karbe, president and CEO of Better Therapeutics. “We believe the data from this trial is remarkable, given we enrolled a diverse patient population with advanced disease already on rigorous blood sugar lowering regimens and who could self-select their dose of BT-001, unlike in traditional new drug pivotal trials. The positive data from this trial serves as an important stepping stone towards our goal of bringing BT-001 to patients and physicians in need of new therapies, and entering the next phase of our growth as a commercial-stage company.”

This data follows the announcement in March that the trial had met its primary endpoint at day 90 with a p-value of < 0.0001. The secondary endpoint data assessed at day 180 continued this trend, showing statistically significant decreases in A1c levels when compared to a control group receiving standard of care (p-value = 0.01). The results achieved were sustainable and improved between day 90 and day 180 of the trial, demonstrating that BT-001 has the potential to deliver meaningful, durable improvements in blood sugar control for a complex range of patients with T2D already on standard of care blood sugar lowering medications. In addition, exploratory data revealed a host of cardiometabolic improvements as well as lower medication utilization compared to the control group, supporting the potential for BT-001 to improve the overall health of patients with T2D and potentially reduce the usage of increasingly costly T2D medications associated with the progression of the disease.

“As a physician focused on cardiometabolic conditions, it’s a rare and important moment to see an entirely new treatment paradigm emerge for patients with T2D, but that’s what we potentially have with this digital therapeutic approach,” said Mark Berman, MD, Chief Medical Officer of Better Therapeutics. “For too long, the treatment options available to people with T2D have largely been prescription medications that help reduce symptoms but do little to address the underlying causes of disease. This pivotal trial of digitally delivered nCBT in a complex patient population with advanced and difficult to treat disease generated results that were durable and a notable improvement over the current standard of care. The results also suggest that BT-001 has the potential to reduce the need for medications and lower healthcare utilization.”

Among the encouraging results shown were:

- Sustained and improved A1c levels in patients using BT-001, with average absolute A1c reduction improving from 0.3% at day 90 to 0.4% at day 180, supporting that the treatment effects of BT-001 were durable.
- The difference in A1c levels after 180 days of treatment between BT-001 treated patients and Standard of Care (SOC) control group patients receiving standard of care remained statistically significant (p=0.01) even as more SOC patients increased blood sugar lowering medications.
- Half of patients using BT-001 experienced clinically meaningful A1c reductions with a mean reduction of 1.3% in this subgroup at 180 days (SD 0.8%).
- Results indicated that patients who did not use BT-001 were more likely to be placed on additional medications to improve A1c control. After the day 180 A1c draw, 1.7 times more SOC control patients increased their medications compared to BT-001 patients.
- BT-001 demonstrated reassuring safety, with significantly fewer adverse (p<0.001) and serious adverse events (p=0.01) as compared to the SOC control group.
- A clear dose-response between greater engagement in nCBT and greater reductions in A1c was found, supporting nCBT as a mechanism of action.

The open label, randomized, controlled, parallel group trial enrolled a nationally representative group of 668 adults with T2D and mean baseline A1c of 8.1%. Participants in the trial had long standing T2D (mean 11 years), multiple comorbidities, and were already on multiple diabetes medications, representing a difficult to treat patient population. 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 trial was designed with a high bar to pass and to avoid artificial designs that could produce large outcomes that do not apply to all patients. This includes not constraining

patients to a specific medication profile and not incentivizing patients to use the BT-001 therapy.

“The results of this trial are not just encouraging for patients with T2D mellitus but mark the start of a potential sea change in how we approach treatment of cardiometabolic diseases and their root causes,” said Marc Bonaca, MD, MPH, professor of medicine and director of vascular research, University of Colorado. “If we can deliver a scalable, sustainable and clinically validated way to make important and durable improvements in cardiometabolic disease, we can empower patients to take back control of their health from these costly, common chronic diseases.”

Conference Call and Webcast

Better Therapeutics will host a conference call and webcast today, July 28, 2022, at 8:30 a.m. ET to review the results from the pivotal clinical trial of BT-001 after 180 days of treatment for T2D. The live conference call may be accessed by dialing (800) 715-9871 (domestic) or (646) 307-1963 (international) and referring to conference ID: 4326594. All participants are encouraged to dial-in 10 minutes prior to the start time. The live webcast may be accessed by visiting the event page here. A replay of the webcast may be accessed from the Presentations & Events page in the Investors section of the Better Therapeutics corporate website: www.bettertx.com.

About BT-001

BT-001 is Better Therapeutics’ investigational prescription digital therapy for the treatment of T2D. The investigational therapy is delivered via software that provides a tailored experience to patients designed to help them address the underlying causes of T2D by making meaningful, sustainable behavioral changes. The BT-001 investigational therapy is rooted in the well-studied, gold standard of behavioral modification therapies, cognitive behavioral therapy (CBT). While CBT has been used for T2D and other cardiometabolic conditions before, until now the approach has not been scalable due to the need to deliver the therapy via a therapist. If authorized by FDA, BT-001 would be the first validated, prescription solution for delivering this therapeutic approach to T2D patients at scale, from their digital devices.

About the Better Therapeutics nCBT Platform

Better Therapeutics digital therapeutic platform is designed to delivers a novel form of CBT - nutritional CBT (nCBT) - to help people with cardiometabolic diseases potentially improve key measures related to T2D, nonalcoholic fatty liver disease, nonalcoholic steatohepatitis, 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 affect eating habits and other behavioral factors associated with cardiometabolic diseases.

About Better Therapeutics

Better Therapeutics is a prescription digital therapeutics (PDT) company developing a novel form of cognitive behavioral therapy (CBT) 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 CBT 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, if authorized for marketing, 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 clinical trial of BT-001 in patients with type 2 diabetes, Better Therapeutics’ plans regarding FDA submissions, plans and expectations regarding the commercialization of BT-001, if authorized, 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, and expectations related to the interest of healthcare providers and payers in PDTs, including BT-001, 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, including BT-001, for commercial distribution and insurance companies to reimburse their use, market acceptance of PDTs, including BT-001, 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 Better Therapeutics’ annual report on Form 10-K for the year ended December 31, 2021 filed with the Securities and Exchange Commission (“SEC”) on March 28, 2022, and those that are included in any of the Company's future filings with the SEC.

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Investor Relations:
Mark Heinen
IR@bettertx.com

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

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