Positive Results from Pivotal Trial of Better Therapeutics' Investigational BT-001 Prescription Digital Therapy for Type 2 Diabetes Published in Diabetes Care

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ADA-published, peer-reviewed journal article highlights positive primary endpoint data from trial evaluating digitally delivered approach to diabetes management

SAN FRANCISCO--(BUSINESS WIRE)--Oct. 4, 2022-- Better Therapeutics, Inc. (NASDAQ: BTTX), a prescription digital therapeutics (PDT) company developing a novel form of cognitive behavioral therapy (CBT) to address the root causes of cardiometabolic diseases, today announced that the positive 90 day results from its pivotal trial for BT-001, a potentially first-of-its-kind digital therapeutic platform that is designed to use CBT to treat type 2 diabetes (T2D) in patients 18 years and older, have been published in the American Diabetes Association (ADA)-produced, peer reviewed journal *Diabetes Care*.

The article published in the latest edition of *Diabetes Care* details data from the first 90 days of the pivotal trial, which looked at a group of adults with T2D receiving the current standard of care randomized to BT-001 or a control group. This trial was the largest randomized, controlled study conducted to date looking at use of digitally delivered CBT to improve glycemic control in T2D. Patients using BT-001 saw A1c lowered on average by 0.4% compared to the control group after 90 days, with a greater reduction among patients who completed more modules of the therapy. The article concludes that "delivery of a cognitive behavioral intervention via smartphone app can provide a scalable option for improving glycemic control."

In addition to publication in *Diabetes Care,* the pivotal trial results were recently presented on October 1, 2022 by Dr. Marc Bonaca, Professor of Medicine at the University of Colorado School of Medicine and Executive Director of CPC Clinical Research as part of the Society for Vascular Medicine's Annual Scientific Sessions.

"When we saw the complete results from this trial at both the 90- and 180-day endpoints, we were encouraged by the real and tangible potential of using our investigational, digitally-delivered CBT to help people with type 2 diabetes gain more control over their condition," said Dr. Mark Berman, Chief Medical Officer of Better Therapeutics. "We are excited for this data to be featured in such a well-regarded and widely-cited publication as *Diabetes Care*."

The results featured in *Diabetes Care* – as well as the topline 180-day results announced earlier this summer – helped support the recent submission of a *de novo* classification request for BT-001 to the U.S. Food and Drug Administration (FDA), which, if authorized, would make BT-001 the first prescription digital therapeutic delivering CBT available for adults with T2D. The pivotal trial data showed that patients using BT-001 saw encouraging improvement over the current standard of care, with significant and durable A1c reductions at both 90 and 180 days. Exploratory data revealed cardiometabolic improvements as well as lower medication utilization compared to the control group.

"When it comes to cardiometabolic diseases like type 2 diabetes, available treatments have been focused on improving biomarkers alone, like glucose, rather than helping to address the underlying behaviors which lead to the onset and inevitable progression of disease," said Dr. Marc P. Bonaca, a Cardiologist and Vascular Medicine Specialist at the University of Colorado School of Medicine and Executive Director of CPC Clinical Research and CPC Community Health, the senior author on the journal article. "While both are important, the foundation of treatment must include effective interventions for behavioral change. We are encouraged that digital solutions like BT-001 have the potential to be prescribed to help patients make sustainable changes that improve A1c and may also improve health outcomes, slow the progression of their disease and decrease the long-term cost of care."

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 in-person 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 CBT Platform

Better Therapeutics' investigational digital therapeutic platform is designed to deliver a novel form of CBT 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 CBT, 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 the results of the completed trial of BT-001 in patients with type 2 diabetes, Better Therapeutics’ plans and expectations regarding FDA submissions and the potential for marketing authorizations, 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, 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 interpreted favorably by the FDA or repeated or observed in ongoing or future studies involving our product candidates and other risks and uncertainties included under the header “Risk Factors” in Better Therapeutics’ quarterly report on Form 10-Q for the quarter ended June 30, 2022 filed with the Securities and Exchange Commission (SEC) on August 11, 2022, and those that are included in any of Better Therapeutics’ subsequent filings with the SEC.

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