Better Therapeutics Receives FDA Authorization for AspyreRx™ to Treat Adults with Type 2 Diabetes

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First prescription digital behavioral therapeutic device delivering novel form of cognitive behavioral therapy via smartphone

In a randomized controlled trial AspyreRx demonstrated clinically meaningful and statistically significant durable reductions in A1c

Company to host conference call and webcast on July 11 at 8:30 a.m. ET

SAN FRANCISCO--(BUSINESS WIRE)--Jul. 10, 2023-- Better Therapeutics, Inc. (NASDAQ: BTTX), a pioneer in developing software to treat cardiometabolic diseases, today announced that the Food and Drug Administration (FDA) authorized AspyreRx™ (formerly BT-001), a prescription-only digital therapeutic (PDT) treatment indicated to provide cognitive behavioral therapy to patients 18 years or older with type 2 diabetes (T2D). AspyreRx was reviewed through the FDA's De Novo pathway and its authorization creates a new class of diabetes digital behavioral therapeutic devices. AspyreRx is expected to launch commercially in Q4 2023.

"AspyreRx is a game-changer as we now have an evidence-based intervention to help clinicians and people living with type 2 diabetes address the underlying factors that contribute to disease progression and achieve treatment outcomes beyond glucose management alone," said David Kerr MBChB, DM, FRCP, FRCPE, Director of Digital Health at the Diabetes Technology Society. "The cornerstone of modern diabetes care is helping to improve self-efficacy and AspyreRx now provides a prescription tool for physicians that seamlessly integrates with existing disease management programs to help patients make and sustain meaningful changes to improve their overall health."

"This regulatory milestone signals a promising future where technology, psychology, and medicine converge to address for the first time the behavioral causes of disease for the 37 million patients living with T2D in the U.S.," said Frank Karbe, Chief Executive Officer at Better Therapeutics. "This De Novo authorization also provides a foundation for potential future growth opportunities. Given cardiometabolic diseases share common underlying factors that contribute to their development and progression, we intend to expand our PDT platform to multiple related conditions in the future."

AspyreRx was granted marketing authorization based on efficacy and safety data from a randomized controlled trial involving 668 participants, demonstrating clinically meaningful results, which were published in Diabetes Care.

Summary of Clinical Trial Results

- The trial met its primary ($p<0.0001$) and secondary ($p=0.01$) endpoints showing statistically significant decreases in HbA1c levels when compared to a control group receiving standard of care and a control app. The results were sustained and improved between day 90 and day 180 of the trial, demonstrating that BT-001 has the potential to deliver meaningful, durable reductions in blood sugar for a complex range of patients with T2D.
- 1 in 2 people achieved a mean A1c reduction of 1.3% after 180 days of use.
- On average, subjects who used BT-001 also experienced a host of cardiometabolic improvements including improved fasting blood glucose, reduced systolic blood pressure, reduced weight, improved mood, improved quality of life scores, lower medication utilization and fewer diabetes related risks compared to subjects who did not use BT-001.
- A clear dose-response between greater engagement in CBT and greater reductions in HbA1c was found, supporting CBT as a mechanism of action to generate positive clinical outcomes.
- Patient engagement and adherence was excellent with 94% of the participants using the intervention at day 90 and 81% still engaged at day 180.

The majority of patients with T2D progress in their disease, despite advances in pharmacotherapy. Treatment guidelines emphasize lifestyle behavior change as the cornerstone in the prevention and treatment of disease; however, given the constraints of delivering in-person therapy there has been limited advancement in helping patients make and sustain behavior change in a way that is standardized, convenient and scalable. AspyreRx is designed to address these barriers, leveraging technology to deliver an evidence-based therapeutic intervention to patients. The involvement of healthcare providers adds an important layer of expertise and oversight, ensuring seamless coordination between AspyreRx and other aspects of treatment.

"Our team has dedicated eight years to developing this treatment and we are grateful for the thousands of patients who have used our platform and for the many clinicians who have guided us to this point," said Mark Berman, MD, Chief Medical Officer at Better Therapeutics. "We are immensely proud of this milestone and believe AspyreRx holds the promise to enhance access to care for the diversity of the patient population, empowering individuals to live healthier lives."

Better Therapeutics Conference Call and Webcast

Better Therapeutics will hold a conference call on July 11 at 8:30 a.m. Eastern Time / 5:30 a.m. Pacific Time to discuss the FDA authorization of AspyreRx. Investors and the general public may access a live webcast of the call by visiting https://edge.media-server.com/mmc/p/adggoags

About Type 2 Diabetes

Type 2 diabetes (T2D) is a widespread chronic disease in the U.S. According to the Centers for Disease Control and Prevention (CDC), around 35 million people in the U.S. have T2D. About half of the T2D patients have uncontrolled blood sugars despite being on multiple medications. The prevalence of T2D has been steadily increasing over the years, primarily due to factors such as sedentary lifestyles, poor dietary habits, and an aging

population. T2D disproportionately affects certain populations, particularly racial and ethnic minority groups, and those from lower socioeconomic backgrounds. Factors like limited access to healthcare, health disparities, cultural differences, and social determinants of health contribute to these disparities. Addressing health inequities, slowing down disease progression and preventing costly complications, without overuse of high-cost therapies, is a major unmet need in T2D.

About AspyreRx

AspyreRx (formerly BT-001) is Better Therapeutics' clinically validated prescription digital therapy for the treatment of T2D. Using proven techniques that target the underlying psychological, behavioral and cognitive factors that sustain or worsen T2D, AspyreRx is a self-paced, engaging experience that patients can access anytime/anywhere. It is prescribed by a healthcare provider in 90-day increments, with proprietary CBT delivered digitally in a weekly step-by-step process. Through interactive therapy lessons, skill-building modules, weekly goal setting and tracking, patients connect changes in behavior to improvements in blood sugar and other biometrics. Each step in the experience builds on the prior to enable and reinforce cognitive restructuring, building the emotional resilience and acceptance needed to make enduring changes. AspyreRx is backed by robust data demonstrating clinically meaningful and sustained reduction in HbA1c when used up to 180 days.

Indications for Use

BT-001 is a prescription-only digital therapeutic device intended to provide cognitive behavioral therapy to patients 18 years or older with type 2 diabetes. The device targets behavior to aid in the management of type 2 diabetes in patients who are under the care of a healthcare provider. BT-001 provides cognitive behavioral therapy as a treatment that should be used adjunctively with standard of care.

About Better Therapeutics

Better Therapeutics is a prescription digital therapeutics company developing a novel form of cognitive behavioral therapy to address underlying factors that sustain or worsen cardiometabolic diseases. The Company has developed a proprietary platform for the development of FDA-regulated, software-based solutions for T2D, 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 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 Better Therapeutics' plans and expectations regarding FDA submissions, plans related to the potential commercial launch of AspyreRx (formerly BT-001) for the treatment of T2D, expectations related to the efficacy and potential benefits of BT-001 and CBT and their potential treatment applications, the potential of AspyreRx to address barriers and enhance access to care, Better Therapeutics' plans regarding the research and advancement of its product candidates for additional treatments, expectations related to pricing research and results and the interest of healthcare providers and payers in PDTs, Better Therapeutics' plans regarding publications, and statements related to its long-term plans and expectations, 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, including AspyreRx, 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 Better Therapeutics' 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 March 31, 2023 filed with the Securities and Exchange Commission (SEC) on May 11, 2023, and those that are included in any of Better Therapeutics' subsequent filings with the SEC.

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Investor Relations:
Mark Heinen
IR@bettertx.com

Media Inquiries:
Emma Williams
emma.williams@bettertx.com

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