Better Therapeutics Announces New Data Highlighting Concurrent Use of AspyreRx and GLP-1 Receptor Agonists to Treat Type 2 Diabetes

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Pivotal trial established use of AspyreRx alongside standard of care demonstrating clinically meaningful and statistically significant reduction in HbA1c leading to FDA authorization

In a subgroup analysis, the use of AspyreRx and GLP-1 receptor agonists showed substantially greater A1c reductions than the previously reported results of the entire trial population

Recent draft guidance from the FDA indicates the intent to consider the combined effectiveness of pharmaceuticals and digital therapeutic solutions when making drug labeling decisions

SAN FRANCISCO--(BUSINESS WIRE)--Oct. 11, 2023-- Better Therapeutics, Inc. (NASDAQ: BTTX), a pioneer in developing prescription digital therapeutics (PDTs) to treat cardiometabolic diseases, today announced top-line findings from a recent subgroup analysis of AspyreRx (formerly BT-001) in its pivotal trial for type 2 diabetes (T2D). The analysis reveals that adjunctive use of AspyreRx with standard of care, including GLP-1 receptor agonists (GLP-1), leads to a substantially greater clinical improvement compared to control participants who did not incorporate AspyreRx into their regimen. The subgroup analysis, involving approximately 160 participants on GLP-1s randomized to the active and control arm of the study, exhibited an average reduction in HbA1c of 0.7% at 90 days, between the two groups. This exceeds the results of the entire BT-001 pivotal trial population, where AspyreRx outperformed the standard of care control arm by 0.4%. Both reductions were statistically significant when compared to the corresponding control group.

In addition to improvements in HbA1c at day 90, participants that were on both GLP-1 medications and AspyreRx also showed greater HbA1c reduction, greater weight loss, and utilized fewer medications at day 180 when compared to participants on GLP-1 medications without AspyreRx. The data for this subgroup analysis are being submitted for peer-reviewed publication.

“The findings from this subgroup analysis support that patients receiving GLP-1 derive additional additive benefit from intensive behavioral modification provided by AspyreRx. Despite the important benefits of GLP-1 agents, patients receiving them may continue to struggle to achieve glycemic control for multiple reasons including therapeutic inertia and side-effects associated with these drugs. This new data underscores the importance of recognizing that behavior modification is a critical foundational component of diabetes treatment, including for patients taking GLP-1s. A comprehensive management approach that combines effective pharmacotherapy along with effective digital therapeutics to support patients in making and sustaining behavioral change appears to be an optimal approach to achieving treatment goals,” said Marc Bonaca, MD, Executive Director of CPC Clinical Research, providing independent scientific analysis for the trial.

As previously reported, the BT-001 pivotal trial, the largest randomized controlled study ever conducted of a digital therapeutic to evaluate glycemic response in participants with T2D, met both its primary and secondary endpoints demonstrating statistically and clinically meaningful reductions in HbA1c over the control group receiving standard of care. The results achieved were sustainable and improved between day 90 and day 180 of the trial, demonstrating that AspyreRx has the potential to deliver meaningful, durable improvements in blood sugar control for a complex range of patients with T2D already on blood sugar lowering medications.

In addition, exploratory data revealed a host of cardiometabolic improvements alongside reduced medication and healthcare utilization in comparison to the control group, supporting the potential for AspyreRx to improve the overall health of patients with T2D and potentially reduce increasingly costly interventions associated with the progression of the disease. A cost effectiveness analysis, which was part of a broader Health Economics and Outcomes Research (HEOR) conducted by Better Therapeutics, indicates that the utilization of AspyreRx may not only be more effective than standard of care alone but may also be less costly for payers.

The new subgroup analysis data may be particularly relevant in the context of recent draft guidance from the FDA, titled 'Regulatory Considerations for Prescription Drug Use-Related Software,' released in September, which provides clarity about the agency’s views and intent to consider the combined effectiveness of pharmaceuticals and digital therapeutic solutions when making drug labeling decisions.

"The FDA's draft guidance opens up the possibility of expanding drug labeling to include the increased benefits patients may experience while also using PDTs. Strengthened drug labeling then has the potential to raise awareness about the concurrent benefits of drugs and PDTs, which enables providers to improve clinical outcomes. This differentiation may be particularly relevant within the highly competitive GLP-1 market. In this multi-billion-dollar category, PDTs like AspyreRx offer the chance to demonstrate added value by showing increased effectiveness of GLP-1 agents with a digital therapeutic," remarked Frank Karbe, CEO of Better Therapeutics.

RCT Trial Design

The BT-001 pivotal trial was an open-label, randomized, controlled trial designed to evaluate the efficacy and safety of a digitally delivered CBT approach among a diverse, nationally representative group of patients with difficult to treat T2D. 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 included using a “Standard of Care” comparison, as well as not constraining patients to a specific medication profile and not incentivizing patients to use the BT-001 therapy.

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.

About AspyreRx

AspyreRx (fka BT-001) was granted marketing authorization by the U.S. Food and Drug Administration (FDA) in July 2023 as the first prescription-only digital behavioral therapeutic device delivering a novel form of cognitive behavioral therapy (CBT) via smartphone to treat adults with type 2 diabetes (T2D). AspyreRx is backed by robust data demonstrating clinically meaningful and sustained reduction in HbA1c as well as improvements in other markers of cardiometabolic health when used up to 180 days. 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.

Indications for Use

AspyreRx 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. AspyreRx 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' expectations related to the efficacy and potential benefits of PDTs, including AspyreRx and CBT and their potential treatment applications and their ability to improve clinical outcomes, beliefs regarding the importance of behavior modification and comprehensive management approaches in diabetes treatment, statements related to recent draft guidance from the FDA and the potential of labeling to drive improved awareness of 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, 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 June 30, 2023 filed with the Securities and Exchange Commission (SEC) on August 9, 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 Enquiries:
Emma Williams
info@bettertx.com

Source: Better Therapeutics, Inc.