Better Therapeutics Receives FDA Breakthrough Device Designation for Digital Therapeutic Platform Targeting Advanced Liver Disease

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Signifies the FDA's recognition of the Company's novel Cognitive Behavioral Therapy as a potential treatment for metabolic dysfunction-associated steatohepatitis

Opens an accelerated path towards a potential second indication

SAN FRANCISCO--(BUSINESS WIRE)--Feb. 20, 2024-- Better Therapeutics, Inc. (NASDAQ: BTTX), a pioneer in developing prescription digital therapeutics (PDTs) for treating cardiometabolic diseases, today announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Device Designation for its novel Cognitive Behavioral Therapy (CBT) platform intended to treat adults with metabolic dysfunction-associated steatohepatitis (MASH), formerly known as NASH. Breakthrough status is reserved for technologies that demonstrate the potential to be more effective than current standard of care in patients with serious or life-threatening conditions.

Better Therapeutics earned breakthrough status based on the outcomes of its LivVita clinical study, which successfully met its primary endpoint by reducing liver fat within 90 days, while also achieving key secondary endpoints related to improved liver health without any device-related adverse events. Results of the study were published in *Gastro Hep Advances.*

"With breakthrough device designation in hand, we now have a pathway to accelerate the attainment of marketing authorization for a potential second indication and we are actively seeking strategic partnerships to expedite the development and commercialization of this therapy for the millions of patients with advanced liver disease," said Frank Karbe, President and Chief Executive Officer at Better Therapeutics. "This also reinforces the potential for our therapeutics platform to broadly address metabolic disorders."

Better Therapeutics' novel form of CBT works by targeting the lifestyle behaviors that are known to cause and/or contribute to the progression of metabolic diseases. The platform was developed to address the current gap in broadly accessible and standardized intensive behavioral therapies that effectively enable the implementation of existing treatment guidelines that call for behavior change as the foundation of treatment. The Company's CBT platform has already demonstrated clinically meaningful outcomes in type 2 diabetes (T2D), leading to the FDA authorization of AspyreRx ™ in 2023 as the first prescription digital therapy to deliver CBT as a treatment for T2D.

"Earning breakthrough status is a significant milestone and underscores the potential for digitally delivered CBT to offer a vital option for patients with MASH, where very few alternatives exist," said Naim Alkhouri, MD, Director of the Steatotic Liver Program at Arizona Liver Health and Principal Investigator of the LivVita Liver Study. "We are committed to advancing this innovative therapy and look forward to its potential to transform the lives of those affected by MASH."

About MASH

MASH represents an advanced stage of metabolic dysfunction-associated steatotic liver disease (MASLD), a condition tied to the escalating obesity and diabetes epidemics. One in four American adults is estimated to have MASLD[1], with up to 16.5 million adults diagnosed with severe liver complications, including MASH.

MASH is a leading cause of liver related mortality and an increasing burden on healthcare systems globally. Additionally, patients with MASH, especially those with more advanced metabolic risk factors (hypertension, concomitant type 2 diabetes), are at increased risk for adverse cardiovascular events and increased morbidity and mortality.

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' PDTs 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

About AspyreRx

AspyreRx (formerly BT-001) was granted marketing authorization by the FDA in July 2023 as the first prescription-only digital therapeutic to treat adults with type 2 diabetes (T2D). AspyreRx is backed by robust data demonstrating clinically meaningful and sustained reduction in A1c 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 from their smartphone. 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.

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, expectations regarding the amendment to the Hercules debt facility and the outcome and success of cost saving initiatives, including salary reductions, and operational plans and their impact on Better Therapeutics' financial position and cash runway, and expectations regarding the commercial traction of AspyreRx and partnering discussions, 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, Better Therapeutics' ability to continue as a going concern and continue its clinical development programs, and other risks and uncertainties included under the header "Risk Factors" in Better Therapeutics' quarterly report on Form-10-Q for the fiscal quarter ended September 30, 2023 filed with the Securities and Exchange Commission ("SEC") on November 09, 2023, and those that are included in any of the Company's subsequent filings with the SEC.

[1] https://www.niddk.nih.gov/health-information/liver-disease/nafld-nash/definition-facts

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