Better Therapeutics Announces Publication of LivVita Liver Disease Study Results in Gastro Hep Advances

October 5, 2023

Authors conclude the totality of positive efficacy, safety and usability data indicates the potential of Better Therapeutics' digitally delivered Cognitive Behavioral Therapy to help address the significant unmet clinical needs observed in MASLD and MASH

Company expects to submit request to the FDA for Breakthrough Device Designation in Q4 2023

SAN FRANCISCO--(BUSINESS WIRE)--Oct. 5, 2023-- Better Therapeutics, Inc. (NASDAQ: BTTX), a pioneer in developing prescription digital therapeutics (PDTs) to treat cardiometabolic diseases, today announced the pre-print publication of the LivVita study's results in Gastro Hep Advances, a peer reviewed journal produced by the American Gastroenterological Association (AGA). The study 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. The company anticipates submitting a request to the FDA for Breakthrough Device Designation by the end of 2023.

The study's authors conclude that the positive efficacy, safety, and usability data underscore the potential of Better Therapeutics' digitally delivered novel form of Cognitive Behavioral Therapy (CBT) to address the significant unmet clinical needs associated with metabolic dysfunction-associated steatotic liver disease (MASLD) and metabolic dysfunction-associated steatohepatitis (MASH), formerly known as NAFLD and NASH.

Growing rates of MASLD and MASH, linked to the increasing prevalence of obesity and diabetes, pose pressing public health concerns. Despite their impact and prevalence, there are currently no FDA approved treatments. Standard of care guidelines emphasize the importance of lifestyle changes in the management of these conditions, yet implementing behavior change counseling in clinical practice remains challenging due to provider constraints and patient difficulties in translating recommendations into sustainable new behaviors without adequate support.

The LivVita study evaluated Better Therapeutics' novel CBT platform that targets individuals' thoughts and beliefs related to improving healthy behaviors, such as diet and physical activity. Over the course of 90 days, the investigational treatment was delivered to participants without requiring additional intervention from healthcare providers.

"Behavior change has long been recognized as a means to slow or halt disease progression, but delivering scalable patient support has remained a challenge," said Naim Alkhouri, MD, Director of the Fatty Liver Program at Arizona Liver Health and Principal Investigator of the study. "The reduction in liver fat and enzymes observed with this digital therapy within a short time frame is promising and, if authorized, has the potential to revolutionize the treatment of MASLD and MASH by providing a practical tool we can prescribe to help patients living with these chronic conditions."

This first-of-kind study demonstrated improvements in multiple markers, including MRI-PDFF, FibroScan CAP score, weight, Fast^{TM} score, and ALT, suggesting therapeutic potential in a larger patient population. Additionally, there were no device-related adverse events, even in patients with a large number of comorbidities and background pharmacotherapy use.

Mazen Noureddin, a scientific advisor to the study, noted, "The positive signals in this pilot study across multiple disease biomarkers established a proof-of-concept for this prescription digital therapy platform to potentially offer a new option for the treatment of MASLD and MASH and could help to address the significant unmet clinical and public health needs by providing scalable, accessible, and effective behavioral therapy.

Better Therapeutics' novel CBT platform has already demonstrated clinically meaningful outcomes in type 2 diabetes (T2D), hypertension, and hyperlipidemia. A randomized controlled pivotal trial demonstrated clinically meaningful and sustained reduction in HbA1c as well as improvements in other markers of cardiometabolic health when used up to 180 days, leading to FDA authorization of AspyreRx as the first prescription-only digital behavioral therapeutic delivering a novel form of CBT via smartphone to treat adults with T2D. AspyreRx is expected to launch commercially in Q4 2023.

Mark Berman, MD, Chief Medical Officer at Better Therapeutics, concluded, "As we witness the transformative impact of digital therapeutics on conditions like type 2 diabetes, MASLD and MASH, we envision a future where PDTs not only serve as first-line treatments, but also complement pharmacotherapy, empowering patients to achieve treatment goals and enhance their quality of life."

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 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 PDTs and CBT and their potential treatment applications, including in MASLD and MASH, Better Therapeutics' plans regarding its request to the FDA for Breakthrough Device Designation and Better Therapeutics' expectations regarding the data from the LivVita Study, 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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