Better Therapeutics Completes Exploratory Trial for Fatty Liver Disease and Announces Positive Topline Results

December 8, 2022

Study Conducted with Arizona Liver Health Met Primary Endpoint and Established Proof-of-Concept for Prescription Digital Therapy Platform to Improve Disease Biomarkers in NAFLD and NASH Patients

Company Intends to Apply for Breakthrough Device Designation with FDA

Company to Host Conference Call and Webcast Today at 8:30 a.m. ET

SAN FRANCISCO--(BUSINESS WIRE)--Dec. 8, 2022-- Better Therapeutics, Inc. (NASDAQ: BTTX), a prescription digital therapeutics (PDT) company developing cognitive behavioral therapy (CBT) to address the root causes of cardiometabolic diseases, today announced positive topline results of the first-ever study evaluating the feasibility of using a prescription digital therapeutic to reduce liver fat and improve liver disease biomarkers in Nonalcoholic Fatty Liver Disease (NAFLD) and Nonalcoholic Steatohepatitis (NASH).

The study included a cohort of 22 patients with NAFLD and NASH and used Magnetic Resonance Imaging - Proton Density Fat Fraction (MRI-PDFF) scans, a validated proxy for liver biopsies, to monitor changes in liver fat. Changes in a range of exploratory liver biomarkers were also assessed. Currently, there is no FDA approved treatment for these conditions, which affect approximately one in four Americans and cause approximately $100 billion in direct medical cost annually. And while some drug candidates are in various phases of research and development, they often present side effects that could limit their utility in patients, if approved.

“With approximately 90 million Americans affected by NAFLD, fatty liver disease is a public health crisis that has hit epidemic levels. Because there are currently no FDA approved therapies available to treat these patients, we need to evaluate every possible option to reduce the burden of this condition – and in this study we have found positive topline signals across multiple disease biomarkers for a potential new option in our fight against NAFLD and NASH,” said Mazen Noureddin, MD, Director of the Houston Liver Institute and who served as the Senior Scientific Advisor for the LivVita Study. “Since the cause and progression of these conditions are linked to behavioral factors like diet and activity level, the utilization of a prescription digital therapy that targets these behaviors is compelling and appears to have the potential to make a real difference in this costly disease.”

The LivVita Study met its primary endpoint, showing a statistically significant positive signal with an average relative reduction in MRI-PDFF of 16% (p=0.01) in the intent-to-treat population (N=19). Additional highlights include:

- A statistically significant mean reduction in Alanine transaminase (ALT) of -17 IU/L (p=0.002)
- A statistically significant mean change in FAST Score of 20% (p=0.01)
- No severe adverse events or device related adverse events
- High engagement and patient satisfaction with treatment, with Net Promoter Score of +75 and 94% of subjects still using the app after 90 days

“The results seen in the LivVita Study give us confidence that there is merit in further development of treatments for NASH and NAFLD that leverage digital therapies and CBT techniques,” said Naim Alkhouri, MD, Director of the Fatty Liver Program at Arizona Liver Health and Principal Investigator of the study. “We have long understood that making real changes to certain behaviors can result in slowed progression of this disease, but we have not had a reliable, scalable way to deliver the support people need to make them. If we can use smartphones as a delivery mechanism for meaningful therapy, it should certainly become a tool we lean on as we help patients live with these chronic conditions.”

The study relied on Better Therapeutics’ CBT platform, which has been developed with the intention of helping patients with cardiometabolic diseases – including NASH and NAFLD – access a tailored treatment that leverages CBT techniques to address underlying causes of these diseases and help them make sustainable behavioral changes. This platform has already shown progress elsewhere, leading to the submission of a de novo classification request for BT-001, Better Therapeutics’ prescription digital therapy for type 2 diabetes, currently under review by the FDA.

“In our initial work on BT-001, we have already seen indications that our novel form of CBT delivered through a prescription digital therapeutic may help with cardiometabolic conditions. The encouraging early results from our work with fatty liver disease continues to build that body of evidence,” said Mark Berman, MD, CMO of Better Therapeutics. “As we move towards 2023 and the anticipated launch of our first digital therapeutic, pending FDA authorization, we are more confident than ever in the promise of this approach to treating these conditions.”

Better Therapeutics intends to publish these data in a peer-reviewed journal, apply for breakthrough device designation with the FDA, and potentially seek a partner to accelerate development of a NAFLD/NASH specific PDT.

Conference Call and Webcast

Better Therapeutics will host a conference call and webcast today, December 8, 2022, at 8:30 a.m. ET / 5:30 a.m. PT to review the topline results from the LivVita Study. To access the conference call, please register at: https://register.vevent.com/register/BI2e2fa3ed900e4fa49b51635011507657. Upon registering, each participant will be provided with call details and access codes. All participants are encouraged to join 10 minutes prior to the start time. The live webcast may be accessed by visiting the event link at: https://edge.media-server.com/mmc/p/xpog3h3b. A replay of the webcast may be accessed from the Presentations & Events page in the Investors section of the Better Therapeutics corporate website at: investors.bettertx.com.

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 delivery of CBT and /or PDTs by Better Therapeutics to address the root causes of NAFLD, NASH, type 2 diabetes and other conditions, Better Therapeutics' plans regarding FDA submissions, expectations related to the potential benefits of BT-001 and CBT and their potential treatment applications and the limitations of other drug candidates to address the treatment of NAFLD and NASH, Better Therapeutics' plans regarding the research and advancement of its PDTs for NAFLD, NASH and additional treatments, plans and expectations regarding the commercialization of BT-001, if approved, expectations related to the interest of healthcare providers and payers in PDTs and legislative developments affecting PDTs and the outcome of such developments, 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, the risk that the results of previously conducted studies will not be 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 September 30, 2022 filed with the Securities and Exchange Commission (SEC) on November 14, 2022, and those that are included in any of Better Therapeutics' subsequent filings with the SEC.

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