

# Better Therapeutics and Colorado Prevention Center Clinical Research Launch Real-World Evidence Study of Prescription Digital Therapeutic for Type 2 Diabetes

July 29, 2021

Open-label, randomized, controlled study will evaluate BT-001's cognitive behavioral therapy approach to change behaviors at the root cause of type 2 diabetes

Study to evaluate the durability of treatment effect and healthcare utilization changes associated with BT-001 in a diverse, real-world clinical setting

SAN FRANCISCO--(<u>BUSINESS WIRE</u>)--<u>Better Therapeutics</u>, <u>Inc.</u> ("Better Therapeutics"), a prescription digital therapeutics company delivering cognitive behavioral therapy to address the root causes of cardiometabolic diseases, in partnership with Colorado Prevention Center (CPC) Clinical Research, affiliated with the University of Colorado Anschutz Medical Campus, today announced the commencement of a real-world evidence study to evaluate the long-term effectiveness and healthcare utilization changes associated with the use of BT-001 for the treatment of type 2 diabetes. BT-001 is an investigational, prescription digital therapeutic that delivers a novel form of cognitive behavioral therapy to patients with uncontrolled type 2 diabetes.

The open-label, randomized, controlled study will evaluate approximately 500 patients with type 2 diabetes in the University of Colorado (UC) Health System using BT-001. Participants will include individuals with A1c levels between 7% and 11% across multiple insurance plans. The primary objective of the study is to evaluate effectiveness, durability of effect, changes in healthcare utilization and quality of life compared to the control group. Changes in blood pressure, blood lipids, weight, cardiometabolic medications, cardiometabolic medication costs and medical costs will also be evaluated. The study will be conducted for at least one year and may be extended.

"Despite the use of an increasing array of medications, the number of patients with uncontrolled type 2 diabetes continues to grow, leading to poorer outcomes and higher costs. At Better Therapeutics, we believe the system of care desperately needs therapeutics that address the root causes of disease," said Mark Berman, MD, Chief Medical Officer of Better Therapeutics. "We are excited to work with Marc Bonaca, MD, MPH, and his team at CPC to lead the study of BT-001 in a real-world setting. Dr. Bonaca, whom I had the good fortune to train with at the Brigham & Women's Hospital, is an internationally recognized cardiologist and has led multiple trials in cardiometabolic diseases. We look forward to the collaboration with his deeply experienced team that has executed over 150 clinical studies and published more than 1,000 peer-reviewed manuscripts."

"CPC is thrilled to collaborate with Better Therapeutics on this study of BT-001, and we have strong alignment with its vision to change the trajectory of type 2 diabetes in the United States by addressing behavioral root causes," said Dr. Bonaca, Executive Director of CPC Clinical Research and CPC Community Health. "We are encouraged with the past BT-001 data and are excited to bring this approach to our patients in a randomized, real-world study evaluating its potential to improve effectiveness, healthcare utilization and quality of life over a year or more."

The Better Therapeutics platform blends clinical, behavioral and psychological inputs into a series of therapy lessons and skill-building modules. These are designed to isolate and shift the underlying thoughts and beliefs which guide diet and lifestyle behaviors that cause a wide range of cardiometabolic diseases, including type 2 diabetes. BT-001 is concurrently being evaluated in a pivotal study as a prescribed treatment used under physician supervision for people with uncontrolled type 2 diabetes. If positive, the pivotal study will support a regulatory submission for marketing authorization from the U.S. Food & Drug Association (FDA).

BT-001 is Better Therapeutics' lead product candidate among their pipeline of FDA-regulated, prescription digital therapeutics designed to treat the underlying cause of a range of cardiometabolic conditions. It is anticipated that upon marketing authorization, primary care providers will prescribe and insurers will reimburse the company's therapeutics, much like they would a traditional medication.

Clinical data demonstrating the efficacy and safety of Better Therapeutics' developmental product candidates has been published in multiple peer-review journals, including <u>Journal of the Endocrine Society</u>, <u>JMIR Cardio</u>, <u>JMIR Diabetes</u> and more.

# About Colorado Prevention Center (CPC) Clinical Research

CPC Clinical Research, an academic research organization and an affiliate of the University of Colorado Anschutz Medical Campus, is a missiondriven non-profit organization that exists to improve health through innovative science and community engagement. For over 30 years, CPC has been a leader in research and implementation, experienced in clinical trial design, oversight, and management, including registration trials (Phase I-IV), real-world data, and pragmatic trials. Our proximity to and affiliation with the University of Colorado School of Medicine enables experienced faculty in a diverse group of specialties to spend time at the university and CPC. Our faculty members are on the cutting edge of scientific, clinical, and regulatory developments. Members of CPC's leadership team have chaired and/or served on FDA advisory committees, including the Cardiovascular and Renal, Endocrine and Metabolism, and Reproductive Health committees. Through our Community Health Programs, we develop innovative and evidence-based health promotion programs, interactive health technology, and community partnerships to help win the fight against cardiovascular disease in Colorado. As a result of these efforts, CPC Community Health has provided health education and/or coaching to over 82,000 individuals and made significant improvements in the lives of those at risk for cardiovascular disease.

Additional information can be found at our website: cpcclinicalresearch.org

# **About Better Therapeutics**

Better Therapeutics is a prescription digital therapeutics (PDT) company delivering a novel form of cognitive behavioral therapy 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 cognitive behavioral therapy delivered by Better Therapeutics' PDT enables 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 Mountain Crest Acquisition Corp. II

Mountain Crest Acquisition Corp. II is a blank check company formed for the purpose of effecting a merger, share exchange, asset acquisition, share purchase, reorganization or similar business combination with one or more businesses. Mountain Crest II 's efforts to identify a prospective target business will not be limited to a particular industry or geographic region, although the company intends to focus on operating businesses in North America.

#### **Additional Information**

On April 6, 2021, Better Therapeutics entered into a definitive merger agreement with Mountain Crest Acquisition Corp. II (Nasdaq: MCAD) ("Mountain Crest II"), a special purpose acquisition company for a proposed business combination.

In connection with the proposed business combination between Mountain Crest II and Better Therapeutics, Mountain Crest II has filed a registration statement on Form S-4 containing a proxy statement/prospectus (the "Form S-4") with the Securities and Exchange Commission (the "SEC"). The Form S-4 includes a proxy statement to be distributed to holders of Mountain Crest II's common stock in connection with Mountain Crest II's solicitation of proxies for the vote by Mountain Crest II's shareholders with respect to the proposed transaction and other matters as described in the Form S-4, as well as the prospectus relating to the offer of securities to be issued to Better Therapeutics' stockholders in connection with the proposed business combination. After the Form S-4 has been declared effective, Mountain Crest II will mail a definitive proxy statement, when available, to its stockholders. Investors and security holders and other interested parties are urged to read the Form S-4, any amendments thereto and any other documents filed with the SEC carefully and in their entirety when they become available because they will contain important information about Mountain Crest II, Better Therapeutics and the proposed business combination. Additionally, Mountain Crest II will file other relevant materials with the SEC in connection with the business combination. Copies of these documents may be obtained free of charge at the SEC's web site at www.sec.gov. Securityholders of Mountain Crest II are urged to read the Form S-4 and the other relevant materials when they become available before making any voting decision with respect to the proposed business combination because they will contain important information.

#### Participants in the Solicitation

Mountain Crest II and its directors and executive officers may be deemed participants in the solicitation of proxies with respect to the proposed business combination under the rules of the SEC. Securityholders may obtain more detailed information regarding the names, affiliations, and interests of certain of Mountain Crest II's executive officers and directors in the solicitation by reading Mountain Crest II's Form S-4 and other relevant materials filed with the SEC in connection with the proposed business combination. Information about Mountain Crest II's directors and executive officers and their ownership of Mountain Crest II common stock is set forth in Mountain Crest II's annual report on Form 10-K for the year ended December 31, 2020, dated March 30, 2021, as modified or supplemented by any Form 3 or Form 4 filed with the SEC since the date of that filing. Other information regarding the interests of Mountain Crest II's participants in the proposed business combination, which in some cases, may be different than those of their stockholders generally, are set forth in the Form S-4 relating to the proposed business combination. These documents can be obtained free of charge at the SEC's web site at <u>www.sec.gov</u>.

Better Therapeutics and its directors and executive officers may also be deemed to be participants in the solicitation of proxies from the stockholders of Mountain Crest II in connection with the proposed business combination. A list of the names of such directors and executive officers and information regarding their interests in the proposed business combination are included in the Form S-4 for the proposed business combination.

# Non-Solicitation

This press release shall not constitute a solicitation of a proxy, consent, or authorization with respect to any securities or in respect of the proposed business combination. This press release shall also not constitute an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any sale of securities in any states or jurisdictions in which such offer, solicitation, or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. No offering of securities shall be made except by means of a prospectus meeting the requirements of Section 10 of the Securities Act of 1933, as amended, or an exemption therefrom.

#### **Forward-Looking Statements**

This press release contains "forward-looking statements" within the meaning of the United States Private Securities Litigation Reform Act of 1995. These forward-looking statements include, but are not limited to, statements regarding the delivery of cognitive behavioral therapy by Better Therapeutics to address the root causes of type 2 diabetes and other cardiometabolic diseases; development of a proprietary platform and software-based solutions for treatment of type 2 diabetes, heart disease and other conditions; achievement of changes in neural pathways of the brain and lasting changes in behavior through cognitive behavioral therapy delivered by Better Therapeutics' PDT; the capability of Better Therapeutics to address the underlying causes of certain diseases and its related potential to improve patient health while lowering healthcare costs; the potential for Better Therapeutics' clinically validated mobile applications to be prescribed by physicians and reimbursed like traditional medicines; potential and significance of the results of the pivotal study of BT-001 or any clinical or other trial; the potential success of BT-001 as a prescribed treatment used under physician supervision for people with uncontrolled type 2 diabetes; the possibility for the results of the pivotal study to support a regulatory submission for marketing authorization from the FDA; the potential timing of, and Better Therapeutics' expected progress towards developing and approving FDA approval for its products, related research and validation studies. In addition, any statements that refer to projections (including EBITDA, adjusted EBITDA, EBITDA margin and revenue projections), forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. 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. Any forwardlooking statements in this press release are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to, the risk that the FDA may not be satisfied with the design of any of Better Therapeutics' studies and trials, and even satisfied, payers may not reimburse BT-001, if approved,, 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 the risk that the current COVID-19 pandemic will impact Better Therapeutics' platform validation, product testing, the timing of the Better Therapeutics' submission of the BT-001 for marketing approval from

the FDA and other operations. For a discussion of other risks and uncertainties, and other important factors, any of which could cause Better Therapeutic's actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" in Mountain Crest II's filings on file with the Securities and Exchange Commission, available at the Securities and Exchange Commission's website at <u>www.sec.gov</u>, and as well as discussions of potential risks, uncertainties and other important factors in Mountain Crest II and/or Better Therapeutics' subsequent/future filings, if any, with the Securities and Exchange Commission. All information in this press release is as of the date of the release, and the Company undertakes no duty to update this information unless required by law.

# Contacts

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