Entera Bio Reports Key Milestone Relating to Oral PTH (1-34) Peptide (EB613) Phase 3 Program: ASBMR-SABRE Has Submitted to FDA the Full Qualification Plan to Approve BMD as a Surrogate Endpoint for Osteoporosis

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JERUSALEM, Nov. 09, 2023 (GLOBE NEWSWIRE) -- Entera Bio Ltd. (NASDAQ: ENTX), ("Entera" or the "Company") a leader in the development of orally delivered peptides and therapeutic proteins, reports today that the American Society for Bone and Mineral Research (ASBMR) has announced that the SABRE (Strategy to Advance BMD as a Regulatory Endpoint) project team has submitted to the U.S. Food and Drug Administration (FDA) its full qualification plan to use the treatment-related change in bone mineral density (BMD) as a surrogate endpoint for fractures in future trials of new anti-osteoporosis drugs.

BMD is the first surrogate endpoint undergoing qualification by the FDA under the 21st Century Cures Act which was signed into law on December 13, 2016, to help accelerate medical product development and bring new innovations and advances to patients who need them faster and more efficiently.

"This submission is critical to the future of osteoporosis drug innovation which has been hampered by ethical and cost constraints associated with fracture outcome studies. We would like to sincerely acknowledge and thank the ASBMR-FNIH-SABRE team for its significant contributions and for furthering this key initiative with the FDA," said Miranda Toledano, Chief Executive Officer of Entera. "The last 15 months have been intense for Entera from a regulatory standpoint, and we believe EB613 stands as the first program to potentially avail itself of the ASBMR-SABRE BMD endpoint. We have powered our proposed phase 3 study using the published SABRE quantitative thresholds which statistically correlate to reductions in vertebral, non-vertebral and all site fracture risk. Much like biomarkers and validated surrogates that are routinely used across oncology, cardiovascular and metabolic disorders, we look forward to FDA's potential qualification of BMD for osteoporosis and to promptly advancing EB613 forward using this more ethical approach," said Ms. Toledano.

EB613 (oral PTH (1-34), teriparatide), is being developed as the first oral, osteoanabolic (bone building) once-daily tablet treatment for osteoporosis. In a phase 2, 6-month, 161-patient, placebo-controlled study EB613 produced rapid dose-proportional increases in biochemical markers of bone formation, reductions in markers of bone resorption, and increased lumbar spine, total hip, and femoral neck BMD in postmenopausal women with low mass or osteoporosis and no prior fracture. In October 2022, following a Type C meeting, Entera announced FDA's concurrence that a 2-year, placebo-controlled phase 3 (registrational) study with Total Hip BMD as primary endpoint could support an NDA for EB613.

About ASBMR-FNIH SABRE[i]

Initiated in 2013, the Foundation for the National Institutes of Health (FNIH) Biomarkers Consortium Bone Quality Project assembled data from more than 150,000 participants across more than 50 clinical trials of anti-osteoporosis drugs. The project team re-evaluated these existing data to understand which measurements could predict the ability of the treatment to reduce fractures. The study findings identified an increase in bone mineral density, as measured by a low-dose X-ray imaging technique, as a strong predictor of the extent to which treatments reduce fracture risk. A change in bone mineral density could therefore be used in future clinical trials to determine the effectiveness of osteoporosis drugs. Through a partnership with ASBMR, the FNIH extended and continues to support the original study, renamed SABRE, to seek FDA approval for the surrogate biomarker.

About the Cures Act

The 21st Century Cures Act (Cures Act), signed into law on December 13, 2016, is designed to help accelerate medical product development and bring new innovations and advances to patients who need them faster and more efficiently.

The law builds on FDA's ongoing work to incorporate the perspectives of patients into the development of drugs, biological products, and devices in FDA's decision-making process. Cures enhances our ability to modernize clinical trial designs, including the use of real-world evidence, and clinical outcome assessments, which will speed the development and review of novel medical products, including medical countermeasures.

It also provides new authority to help FDA improve our ability to recruit and retain scientific, technical, and professional experts and it establishes new expedited product development programs.

About Entera Bio

Entera focuses on significant unmet medical needs where an oral tablet form of a peptide treatment or protein replacement therapy holds the potential to transform the standard of care. The Company's oral PTH (1-34) teriparatide mini tablets have been administered to a total of 240 subjects (153 patients) across Phase 1 and Phase 2 studies, with demonstrated bioavailability and clinical benefit across two distinct diseases. The Company's most advanced product candidate, EB613 (oral PTH (1-34), teriparatide), is being developed as the first oral, osteoanabolic (bone building) once-daily tablet treatment for post-menopausal women with low BMD and high-risk osteoporosis, with no prior fracture. A placebo controlled, dose ranging Phase 2 study of EB613 tablets (n= 161) met primary (PD/bone turnover biomarker) and secondary endpoints (BMD). Entera is preparing to initiate a Phase 3 registrational study for EB613. EB612 is being developed as the first tablet peptide replacement therapy for the treatment of hypoparathyroidism. The Company is currently conducting a phase 1 PK study of novel PTH formulations using its proprietary, next generation oral delivery platform with data expected in the second half of 2023. Entera is also developing oral GLP-2 peptide as an injection-free alternative for patients suffering from short bowel syndrome and other severe intestinal and malabsorption metabolic conditions and oral Oxyntomodulin (GLP1/glucagon) peptide for obesity in collaboration with OPKO Health. For more information on Entera Bio, visit www.enterabio.com

Cautionary Statement Regarding Forward Looking Statements

Various statements in this press release are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. All statements (other than statements of historical facts) in this press release regarding our prospects, plans, financial position, business strategy and expected financial and operational results may constitute forward-looking statements. Words such as, but not limited to, "anticipate," "believe," "can," "could," "expect," "estimate," "design," "goal," "intend," "may," "might," "objective," "plan," "predict," "project," "target," "likely," "should," "will," and

"would," or the negative of these terms and similar expressions or words, identify forward-looking statements. Forward-looking statements are based upon current expectations that involve risks, changes in circumstances, assumptions and uncertainties. Forward-looking statements should not be read as a guarantee of future performance or results and may not be accurate indications of when such performance or results will be achieved.

Important factors that could cause actual results to differ materially from those reflected in Entera's forward-looking statements include, among others: changes in the interpretation of clinical data; results of our clinical trials; the FDA's interpretation and review of our results from and analysis of our clinical trials; unexpected changes in our ongoing and planned preclinical development and clinical trials, the timing of and our ability to make regulatory filings and obtain and maintain regulatory approvals for our product candidates; the potential disruption and delay of manufacturing supply chains; loss of available workforce resources, either by Entera or its collaboration and laboratory partners; impacts to research and development or clinical activities that Entera may be contractually obligated to provide; overall regulatory timelines; the size and growth of the potential markets for our product candidates; the scope, progress and costs of developing Entera's product candidates; Entera's reliance on third parties to conduct its clinical trials; Entera's expectations regarding licensing, business transactions and strategic collaborations; Entera's operation as a development stage company with limited operating history; Entera's ability to continue as a going concern absent access to sources of liquidity; Entera's ability to obtain and maintain regulatory approval for any of its product candidates; Entera's ability to comply with Nasdaq's minimum listing standards and other matters related to compliance with the requirements of being a public company in the United States; Entera's intellectual property position and its ability to protect its intellectual property; and other factors that are described in the "Cautionary Statements Regarding Forward-Looking Statements," "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of Entera's most recent Annual Report on Form 10-K filed with the SEC, as well as the company's subsequently filed Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. There can be no assurance that the actual results or developments anticipated by Entera will be realized or, even if substantially realized, that they will have the expected consequences to, or effects on, Entera. Therefore, no assurance can be given that the outcomes stated or implied in such forward-looking statements and estimates will be achieved. Entera cautions investors not to rely on the forward-looking statements Entera makes in this press release. The information in this press release is provided only as of the date of this press release, and Entera undertakes no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise, except to the extent required by law.

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[i] https://www.asbmr.org/about/news-release-detail/asbmr-sabre-team-submits-full-qualification-plan-t

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