Entera Bio Announces Key Regulatory Milestone for Oral PTH(1-34) Peptide (EB613) Phase 3 Program: FDA Ruling on Qualifying BMD as a Surrogate Endpoint for Osteoporosis Drugs is Expected Within 10 Months

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JERUSALEM, March 26, 2024 (GLOBE NEWSWIRE) -- Entera Bio Ltd. (NASDAQ: ENTX) ("Entera" or the "Company"), a leader in the development of orally delivered peptides, announced today that The American Society for Bone and Mineral Research (ASBMR) announced on March 25 2024 that the U.S. Food and Drug Administration (FDA) has communicated to the SABRE (Study to Advance BMD as a Regulatory Endpoint) project team that a ruling to qualify the treatment-related change in bone mineral density (BMD) as a surrogate endpoint for fractures in future trials of new anti-osteoporosis drugs would be provided within 10 months.

The proposed registrational Phase 3 study for EB613, Entera's lead clinical candidate, which is a first-in-class PTH(1-34) daily tablet treatment for osteoporosis is designed to meet the quantitative BMD thresholds proposed by SABRE.

"Following our positive placebo-controlled Phase 2 study and multiple Type C and Type D meetings held with FDA from June 2022 through 2023, we designed our phase 3 study for EB613 to meet the SABRE quantitative target BMD thresholds which have been shown to correlate to reductions in vertebral, non-vertebral and all site fracture risk. We believe EB613 stands as the first program to potentially avail itself of the landmark SABRE initiative which is also the first biomarker to potentially be approved as part of the 2016 21st Century Cures Act. In November 2023 we issued a press release echoing ASBMR's announcement that SABRE had submitted its final qualification package to FDA for the replacement of fracture as a regulatory endpoint. Today we are thrilled to echo ASBMR's announcement that FDA has set a concrete timetable to issue its ruling. As the first potential oral tablet osteoanabolic treatment, EB613 holds the potential to address the treatment chasm in this severe, potentially lethal disease which remains significantly undertreated despite efficacious injectable treatments. Fracture rates continue to rise globally, and we have not seen any new drugs approved for osteoporosis since 2019, largely due to the ethical concerns, long duration and costs of fracture endpoint studies. Our discussions with key clinicians and patient advocacy groups and other key stakeholders in this ecosystem indicate that an oral anabolic treatment is warranted and a potential 'game changer' for the estimated 200 million women with osteoporosis globally," said Miranda Toledano, CEO of Entera.

The below is an excerpt from ABSMR March 25th press release[1]:

According to the Centers for Disease Control and Prevention, more than 53 million people in the United States alone have or are at a high-risk for osteoporosis, a bone disease that develops when bone mass decreases, leading to an increase in the risk of fractures. Fractures, particularly of the hip, are considered the most serious consequence of osteoporosis, which predominantly affects postmenopausal women and older men. Patients and their families collectively spend an estimated $52 billion annually in healthcare costs for osteoporosis-related bone breaks, an expense that is predicted to double in the next decades due to the increased aging of the US population.

"Preventing and treating osteoporosis-related fractures isn't just about strengthening bones; it's about enhancing quality of life and saving lives," added ASBMR President Laura Calvi, MD. "Embracing BMD as a surrogate endpoint in clinical trials will revolutionize the journey of novel therapeutic agents to the clinic, reducing both time and costs, and ultimately it will lead to improved treatment options for individuals with osteoporosis."

About ASBMR-FNIH SABRE

The American Society for Bone and Mineral Research (ASBMR) is the leading professional, scientific and medical society established to bring together clinical and experimental scientists involved in the study of bone, mineral and musculoskeletal research.

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. Analysis of these data by the project team indicated a strong association between the treatment-related increase in bone mineral density, as measured by dual-energy X-ray absorptiometry (DXA), and the observed reduction in fracture risk. These findings provide strong evidence that the change in bone mineral density could 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 Entera Bio

Entera is a clinical stage company focused on developing oral peptide or protein replacement therapies for significant unmet medical needs where an oral tablet form holds the potential to transform the standard of care. The Company leverages on a disruptive and proprietary technology platform and

its pipeline includes five differentiated, first-in-class oral peptide programs, expected to enter the into the clinic (Phase 1 to Phase 3) by 2025. 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 pursuant to the FDA's qualification of a quantitative BMD endpoint which is expected to occur by January 2025. The EB612 program is being developed as the first oral PTH(1-34) tablet peptide replacement therapy for hypoparathyroidism. Entera is also developing the first oral oxyntomodulin, a dual targeted GLP1/glucagon peptide, in tablet form for the treatment of obesity; and first oral GLP-2 peptide tablet as an injection-free alternative for patients suffering from rare malabsorption conditions such as short bowel syndrome in collaboration with OPKO Health. For more information on Entera Bio, visit www.enterabio.com or follow us on LinkedIn, Twitter, Facebook, Instagram.

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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[1] FDA Issues Timeline for Determination on FNIH-ASBMR-SABRE Application to Qualify BMD as a Surrogate Endpoint in Future Trials of Anti-Osteoporosis Drugs - American Society for Bone and Mineral Research

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