Entera Bio's EB613 Demonstrates Early Impact on Both Trabecular and Cortical Bone Compartments with 6 Months of Treatment in Post-Menopausal Women with Osteoporosis - Highlighted as Oral Presentation at WCO-IOF ESCEO

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JERUSALEM, April 15, 2025 (GLOBE NEWSWIRE) -- Entera Bio Ltd. (NASDAQ: ENTX), a leader in the development of oral peptides and proteins replacement therapies, announced highlights from Dr. Rachel B Wagman's oral presentation at the 2025 World Congress on Osteoporosis, Osteoarthritis and Musculoskeletal Diseases (WCO-IOF-ESCEO) Congress in Rome entitled "EFFECTS OF EB613 TABLETS [ORAL PTH(1-34)] ON TRABECULAR AND CORTICAL BONE USING 3D-DXA: POST-HOC RESULTS FROM PHASE 2 STUDY."

EB613 is being developed as the first once-daily oral anabolic (bone forming) PTH(1-34) tablet treatment to support earlier osteoanabolic intervention for postmenopausal women with osteoporosis at high risk for fracture. The Phase 2 study randomized 161 postmenopausal women with low bone mass or osteoporosis to placebo or four EB613 doses levels for 6 months. Previously published changes in biochemical markers of bone turnover suggest a dual effect to stimulate formation and inhibit resorption. In addition, EB613 significantly increased BMD at each measured skeletal site as compared with baseline and placebo. To explore the dual actions of EB613 further, 3D-DXA analysis was performed using 3-D Shaper software to assess the effects on trabecular and cortical bone.

After 6 months of treatment, the findings showed increases with EB613 compared with placebo in a variety of indices, including integral volumetric BMD and trabecular volumetric BMD, cortical thickness, and cortical surface BMD. The evaluation, "Showed a fairly broad distribution of bone loss in the femur with placebo and a similarly broad distribution of bone gain in the femur with EB613," said Dr. Rachel B Wagman. "We look forward to further investigating the safety and efficacy of EB613 in the planned Phase 3 trial."

"Our results indicate that 6 months of daily EB613 compared with placebo shows evidence of an early effect on trabecular and cortical bone of the proximal femur. The findings potentially suggest that bone strengthening and fracture resistance may occur rapidly with this therapy. EB613 is under investigation as the first non-injectable anabolic for the large number of postmenopausal women with osteoporosis at high or very high risk of fracture who are currently not treated or not being treated with bone forming therapies," added Dr. Felicia Cosman.

"We are very pleased with these results. The 3D-Shaper analysis of our BMD findings from the Phase 2 study enabled us to further explore the mechanism the action of EB613. We know that areal BMD changes at 6 months showed substantial improvement at the total hip and femoral neck, largely related to cortical bone increments compared with baseline. This is another analysis that shows an early beneficial effect on cortical bone with EB613 and are completely consistent with those of subcutaneous teriparatide at the 6-month time point," said Miranda Toledano, Chief Executive Officer of Entera.

It is estimated that 50 percent of women and 20 percent of men over the age of 50 are at risk of a fragility fractures and approximately 1 in 5 adults will die within the year following a hip fracture. Postmenopausal osteoporosis afflicts more women than cancer and cardiovascular disease and is a serious health concern for an estimated 200 million women globally. "Available injectable anabolic treatments, while efficacious and recommended across medical guidelines, unfortunately do not provide a viable solution for most patients with high-risk osteoporosis requiring an anabolic intervention. Our EB613 program is being developed to address the treatment chasm in current osteoporosis care and hopefully present a treatment for the majority of patients to adequately manage their bone health with a simple once daily tablet treatment," said Toledano.

About Entera Bio

Entera is a clinical stage company focused on developing oral peptide and 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 (N-Tab™) and its pipeline includes five differentiated, first-in-class oral peptide programs targeting PTH(1-34), GLP-1 and GLP-2. The Company's most advanced product candidate, EB613 (oral PTH(1-34)), 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. 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. 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.

About 3D Shaper Medical
3D-Shaper Medical is a medical imaging software development company. Our mission is to provide the medical community with advanced imaging software solutions for musculoskeletal diseases. 3D-Shaper Medical is a spin-off company of Galgo Medical. For more information on 3D Shaper, visit https://www.3d-shaper.com/.

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Various statements in this presentation 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 presentation 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 ability to establish and maintain development and commercialization collaborations; Entera's operation as a development stage company with limited operating history; Entera's competitive position with respect to other products on the market or in development for the treatment of osteoporosis, hypoparathyroidism, short bowel syndrome, obesity, metabolic conditions and other disease categories it pursues; 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 Statement 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 Entera'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 presentation. The information in this presentation is provided only as of the date of this presentation, 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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