Entera Bio Presents Positive Effects of EB613 on Both Trabecular and Cortical Bone in Postmenopausal Women with Osteoporosis at ASBMR 2025

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EB613 Demonstrates Significant Effects on Both Trabecular and Cortical Bone Compartments After Just 6 Months of Treatment in Phase 2 Study; Cortical Improvements Comparable to Injectable Teriparatide and Abaloparatide

Company Plans to Initiate Global Registrational Phase 3 Study Following July 2025 FDA Concurrence

Entera also Presented Promising Pharmacokinetic Data for Next-Gen EB613 Single Tablet Candidate as Potential Future Franchise Extension

JERUSALEM, Sept. 08, 2025 (GLOBE NEWSWIRE) -- Entera Bio Ltd. (NASDAQ: ENTX), a leader in the development of oral peptides and proteins replacement therapies, today announced data selected for presentation at the American Society for Bone and Mineral Research (“ASBMR”) 2025 Annual Meeting in Seattle, Washington, for its lead program EB613 which is in late stage clinical development for post-menopausal women with osteoporosis. 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 less than 30% of patients are adequately treated with available medications.

"The data presented at ASBMR this year marks important progress for our EB613 program," said Miranda Toledano, Chief Executive Officer of Entera. "Available injectable anabolic treatments, while efficacious and recommended across medical guidelines, are only accessible to a minority of patients globally. Our EB613 program is being developed to address the treatment chasm in osteoporosis care with a viable anabolic treatment in tablet format for patients to adequately protect their bones.”

In the oral presentation titled **"Effects of EB613 Tablets [Oral PTH(1-34)] on Trabecular and Cortical Bone Using 3D-DXA: Results from Phase 2 Study,"** Rachel B. Wagman, MD presented data using 3D-DXA modelling in a post-hoc analysis of EB613 Phase 2 results to look at the treatment’s impact on trabecular and cortical bone. After 6 months of treatment, EB613 2.5 mg demonstrated significant increases in both trabecular and cortical bone parameters as compared with placebo. Mechanistically, the findings suggest that bone strengthening, and fracture resistance may occur rapidly with EB613.

"The improvements across multiple parameters, including integral volumetric BMD, cortical thickness, and cortical surface BMD, suggest that there is an early strengthening effect with EB613 and a deterioration with placebo,” said Dr. Wagman. “We look forward to studying the safety and efficacy of EB613 in Phase 3.”

- Increases in integral volumetric BMD of the TH and FN by 1.7% ($p<0.08$) and 2.6% ($p<0.03$), respectively
- Increases in FN trabecular volumetric BMD by 4.4% vs. placebo ($p<0.03$) and increases in TH trabecular volumetric BMD by 2.8% ($p=0.05$ vs. baseline, NS compared with placebo)
- Increases in cortical thickness at the TH and FN by 1.3% ($p=0.04$) and 1.7% ($p=0.056$), respectively Improvements in cortical surface BMD at the TH and FN by 1.5% and 2.1%, respectively (both $p<0.05$)

In a poster presentation titled **"Advancing Oral Anabolic Treatments for Osteoporosis: Pre-Clinical Data for Next-Gen EB613 Tablet Utilizing N-Tab™ Proprietary Technology'** Entera presented preclinical data for its Next-Gen EB613 candidate. In a cross-over pharmacokinetic study in minipigs, a single 1.5 mg Next-Gen EB613 tablet demonstrated comparable PK to the current formulation of EB613, with identical AUClast and Tmax values (1.2 min*ng/ml and 20 min, respectively), and comparable Cmax. A Phase 1 clinical trial of Next-Gen EB613 is planned to begin in late 2025.

About EB613

Substantial evidence supports the efficacy of anabolic treatments over anti-resorptive drugs for lowering fracture risk in osteoporosis patients. However, all available anabolic therapies are administered by subcutaneous (SC) injection and used in a minority of eligible patients. EB613 (oral PTH

(1-34)), is being developed as the first oral, once-daily anabolic tablet treatment for osteoporosis. EB613 completed a phase 2, 6-month, 161-patient, placebo-controlled study that met all biomarker and BMD endpoints without significant safety concerns in women with postmenopausal osteoporosis or low BMD (JBMR 2024). 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.

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 of 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), 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. A placebo-controlled, dose-ranging Phase 2 study of EB613 tablets (n= 161) met primary (PD/bone turnover biomarker) and secondary endpoints (BMD). 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 metabolic syndromes; and first oral GLP-2 peptide 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, and Facebook.

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 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 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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