Entera Bio Presents Positive New Clinical Data from EB613 Phase 2 Trial Demonstrating Significant Bone Density Improvements in Early Postmenopausal Women

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Consistency of BMD gains presented at NAMS 2025 demonstrate EB613's efficacy in both young postmenopausal women and in women 10 years post-menopause

Data further support EB613 potential as a first-in-class oral anabolic treatment option that could dramatically expand patient access to bone-building therapy

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

JERUSALEM, Oct. 23, 2025 (GLOBE NEWSWIRE) -- Entera Bio Ltd. (Nasdaq: ENTX), a leader in the development of oral peptide and protein replacement therapies, today reported new clinical data from a post-hoc analysis of its Phase 2 trial of EB613, at the 2025 North American Menopause Society (NAMS) Annual Meeting in a poster presentation titled *"EB613 (Oral PTH[1-34] Tablets) Increases BMD Over 6 Months in Early Postmenopausal Women with Low Bone Mass or Osteoporosis: A Phase 2 Randomized Trial (P-66)."*

EB613, Entera's once-daily oral PTH(1-34) anabolic tablet, is being developed as the first oral bone-building therapy for postmenopausal women at high risk for fracture. Despite clear clinical guidelines recommending anabolic agents for their superior benefits, these therapies remain significantly underutilized due to injectable administration and high costs. In this new analysis of the Phase 2 trial, EB613 demonstrated its effect at the 2.5 mg dose (the regimen selected for the upcoming Phase 3 study) by producing significant and consistent gains in bone mineral density (BMD) at the spine, femoral neck and hip in women within 10 years of menopause, with improvements comparable to those observed in women more than 10 years post-menopause.

"These findings demonstrate that EB613 produces significant BMD improvements in early postmenopausal women, a critical population for fracture prevention," said Steven R. Goldstein, MD, Professor of Obstetrics and Gynecology at NYU School of Medicine and member of Entera's Clinical and Scientific Advisory Board, who presented the data at NAMS. "What's particularly significant is the consistency of response across different stages of menopause. The fact that we're seeing these results with an oral formulation addresses one of the most significant barriers in osteoporosis care, opening the door to introduce anabolic therapy earlier in the treatment journey, when injectable options are rarely used. This could be a game-changer for patient access and compliance."

Key Findings
In early postmenopausal women (≤10 years since last menstrual period), EB613 (n=8) versus placebo (n=19), statistically significant BMD increases were observed at six months:

- **Lumbar spine:** 3.1% increase vs placebo at six months (p=0.05), demonstrating significant bone density gains at a key fracture site.
- **Total hip:** 2.3% increase vs placebo (p=0.03), reflecting meaningful improvements in overall bone strength.
- **Femoral neck:** 2.0% increase, consistent with gains observed in later postmenopausal women.

These results were comparable to BMD improvements seen in women more than 10 years post-menopause, where EB613 increased femoral neck BMD by 3.2% (p=0.02) and lumbar spine BMD by 2.5% (p=0.08).

"EB613 has the potential to transform how osteoporosis is treated by bringing anabolic therapy into earlier stages of care, where it is rarely used today," said Miranda Toledano, Chief Executive Officer of Entera Bio. "By delivering bone-building therapy in a convenient oral tablet, we can broaden access for millions of postmenopausal women at risk of fracture and pioneer the first oral anabolic treatment option to address this critical unmet need.

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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