



Entera Presents Markedly Enhanced Anabolic Effects of EB613 (First-in-Class Oral PTH(1-34) Tablet) in Postmenopausal Women with Osteoporosis at High Risk of Fracture and Showcases Phase 3 Design at ASBMR 2026 Annual Meeting

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Post-hoc Phase 2 data show greater bone mineral density (BMD) gains and anabolic effect with EB613 in postmenopausal women with baseline T-scores of ≤ -2.5 (osteoporosis) versus T-scores of > -2.5 (osteopenia)

These findings support the potential benefit of EB613 in postmenopausal women with osteoporosis at high risk for fracture - consistent with the study population to be enrolled in Entera's Phase 3 study

TEL AVIV, Israel, Oct. 13, 2026 (GLOBE NEWSWIRE) -- Entera Bio Ltd. (NASDAQ: ENTX) ("Entera" or the "Company"), a leader in the development of oral peptides, today announced data from a Plenary Poster Presentation (abstract #7062) and a Late-breaking Poster Presentation (abstract #8726) at the American Society for Bone and Mineral Research (ASBMR) 2026 Annual Meeting which was held October 9-12, 2026, in Boston, Massachusetts.

"As we have learned about the importance of treatment sequence, our therapeutic strategies have evolved toward using anabolic therapy first to optimize osteoporosis patient management. Multiple studies illustrate the superiority of anabolic over anti-resorptive drugs at reducing fractures, building BMD, and restoring skeletal microarchitecture. Several major guidelines support this approach. Nonetheless, daily injections remain a barrier for both patients and prescribers. EB613 is uniquely positioned to be the first oral anabolic tablet for the treatment of osteoporosis. The oral tablet will allow us to overcome barriers to implementing the anabolic-first strategy. Our 6 month clinical data with EB613 show rapid stimulation of bone formation and robust early BMD accrual, especially in patients who start with lower BMD and who need the largest gains." said Felicia Cosman, M.D., Professor of Medicine at Columbia University.

"The evidence package to date has laid the foundation for our Phase 3 plans. The opportunity to evaluate the safety and efficacy of EB613 for product registration has generated excitement among clinical investigators and patients. As the first oral anabolic agent in late-stage clinical development, EB613 offers the potential to evolve the treatment paradigm to help address important needs of patients," said Rachel B Wagman, MD, Chief Clinical Advisor to Entera.

Abstract Title: EB613, Oral PTH(1-34) Tablet, Shows Markedly Enhanced Anabolic Effects in Postmenopausal Women with Osteoporosis at High Risk of Fracture: Insights from Phase 2 Trial

The Phase 2 study (Tripto-Shkolnik 2024) randomized 161 postmenopausal women with low bone mass or osteoporosis to placebo or four EB613 dose levels for 6 months. To explore the anabolic effect of EB613 2.5 mg daily, in women with osteoporosis (baseline T-score of ≤ -2.5), a post-hoc sensitivity analysis evaluated the relationship between baseline T-score and effects on BMD and bone turnover markers (BTMs) at 6 months.

Key findings included:

- **Greater BMD gains in women with baseline T-scores of ≤ -2.5 :** Mean placebo-adjusted BMD increases at 6 months were 4.23% (n=6) at the total hip and 4.22% (n=9) at the lumbar spine in women with baseline T-scores of ≤ -2.5 at each of those measured skeletal sites, compared with 1.02% (n=15) and 1.59% (n=12) in women with T-scores of > -2.5 . Across all 21 participants treated with EB613 2.5 mg, the pooled increases were 1.84% (TH) and 2.72% (LS).
- **Larger and more persistent bone turnover marker changes:** Similarly, changes in P1NP (bone formation) and CTX (bone resorption) were also somewhat larger and more persistent in women with a T-score of ≤ -2.5 at any measured skeletal site (n=15) than in women with

T-scores of >-2.5 at all sites (n=6).

This post-hoc, exploratory analysis produced hypothesis-generating findings that support the potential for EB613 treatment in postmenopausal women with osteoporosis at high risk for fracture.

"Although our Phase 2 data showed positive responses in postmenopausal women with low bone mass (osteopenia) as well as women with osteoporosis by T-score, this analysis further derisks our thesis for the population we intend to enroll in our Phase 3 study," said Miranda Toledano, Chief Executive Officer of Entera.

Abstract Title: EB613 [Oral PTH(1-34)]: The First Oral Anabolic Tablet for the Treatment of Osteoporosis: Phase 3 Study Design

The registrational Phase 3 for EB613 is designed as a multinational, randomized, double-blind, placebo-controlled Phase 3 safety and efficacy study in postmenopausal women with osteoporosis. The study is designed to evaluate the effectiveness of EB613, based on change in Month 12 BMD at the total hip, compared with placebo. Secondary endpoints include lumbar spine and femoral neck BMD at Month 12, and total hip, lumbar spine and femoral neck BMD at Months 3 and 6.

Safety will be evaluated through assessment of adverse events, vital signs, physical examinations, and clinical laboratory tests. The PK of PTH(1-34) following oral administration of EB613 will be evaluated in a subset of study participants through a Population-PK (Pop-PK) sub-study and Full PK sub-study.

Approximately 900 participants will be randomized 2:1 to EB613 (N ~ 600) or placebo (N ~ 300) for a 12-month, double-blind, placebo-controlled study period. Eligible participants will be postmenopausal women 50-90 years of age and ≥5 years from the last menstrual period with osteoporosis diagnosed by DXA with BMD T-score ≤-2.50 at either lumbar spine, total hip, or femoral neck. Participants completing 12 months will be eligible to enroll in an extension study through Month 24. The objective of the extension study is to evaluate safety and durability of response of EB613 at 18 months and 24 months.

About Entera

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 a disruptive and proprietary technology platform (N-Tab®) and its pipeline of first-in-class oral peptide programs. 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 for osteoporosis. Entera is also developing the first oral acylated PTH(1-34) tablet as a replacement therapy for patients with hypoparathyroidism (EB612); the first oral oxyntomodulin, a dual targeted GLP1/glucagon peptide tablet for the treatment of obesity and metabolic syndromes; and the first oral GLP-2 tablet as an injection-free alternative for patients suffering from rare malabsorption conditions such as short bowel syndrome in collaboration with OPKO Health, Inc. For more information on Entera, visit www.enterabio.com or follow us on [LinkedIn](#), [Twitter](#), and [Facebook](#).

About EB613

Entera's EB613 program (oral PTH(1-34), teriparatide) is being developed as the first oral, once-daily anabolic tablet treatment for osteoporosis. Entera 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 increases in lumbar spine, total hip, and femoral neck BMD. The effects of EB613 on trabecular and cortical bone using 3D-DXA showed increases with EB613 compared to placebo on a variety of indices, including integral volumetric BMD and trabecular volumetric BMD, cortical thickness, and cortical surface BMD. Mechanistically, the findings suggest that bone strengthening and fracture resistance may occur rapidly with EB613. Furthermore, the data are consistent with that of published subcutaneous teriparatide at the 6-month time point.

About Osteoporosis

Osteoporosis is a chronic, progressive disorder in which bone resorption exceeds formation, resulting in decreased bone strength and increased susceptibility to fracture. Osteoporosis is a major and growing public health issue, responsible for over 2 million fractures annually in the US. After age 50, one in three women and one in five men will suffer an osteoporosis-related fracture in their remaining lifetime. Osteoporotic fractures lead to chronic pain, decreased quality of life, and increased disability, and contribute to premature death. Studies show that up to 20-24% of hip fracture patients die within one year of the fracture. The total medical cost of osteoporotic fractures is projected to increase from \$57 billion in 2018 to \$95 billion by 2040, largely related to the aging population. Postmenopausal women are at higher risk of developing osteoporosis-related fractures, particularly in the hip, spine, and wrist. The mechanism for low BMD in postmenopausal women is primarily estrogen deficiency, which leads to accelerated bone loss, especially in the first 5-10 years after menopause. Forteo® (Eli Lilly) was first approved by the FDA in 2002 for the treatment of postmenopausal women with osteoporosis and subsequently for treatment of men with primary or hypogonadal osteoporosis at high risk of fracture, and for osteoporosis associated with sustained systemic glucocorticoid therapy.

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, clinical development activities, collaboration arrangements and expected financial and operational results are 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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