ENDO 2026 Oral Presentation Highlights Comparative Clinical Data for Entera's Breakthrough Single Tablet EB613 (First-in-Class Oral PTH(1-34) Anabolic for Osteoporosis)

June 15, 2026 12:45 PM EDT

The pharmacokinetic (PK) and pharmacodynamic (PD) profiles of single tablet EB613, multi-tablet EB613 and Forteo® reported for the first time as an oral presentation at ENDO 2026

Single tablet EB613 achieved a comparable PK/PD profile to Forteo® and multi-tablet EB613, which was evaluated in Entera's Phase 2 study in postmenopausal women with osteoporosis and low bone mass

This major scientific achievement supports advancing single tablet EB613 into Entera's planned Phase 3 study of EB613 in postmenopausal women with osteoporosis

TEL AVIV, June 15, 2026 (GLOBE NEWSWIRE) -- Entera Bio Ltd. (NASDAQ: ENTX) ("Entera" or the "Company"), a leader in the development of oral peptides, today reported comparative Phase 1 data evaluating single-tablet and multi-tablet oral EB613 with Forteo® (teriparatide SC injection, Eli Lilly).

The oral presentation "Transforming Anabolic Treatments for Osteoporosis: New Clinical Data Supports a Single EB613 Tablet [Oral PTH(1-34)] as the Final Candidate for a Phase 3 Study" was presented by Clinical Pharmacologist Helen S. Pentikis, PhD, as a Late-Breaking Oral Presentation at ENDO 2026, the annual meeting of the Endocrine Society, taking place in Chicago, Illinois.

Substantial evidence supports the use of anabolic (bone-building) therapies over anti-resorptive drugs for rapidly lowering fracture risk in osteoporosis patients at high risk of fractures. However, the three approved agents (Forteo®, Tymlos®, Evenity®) require daily or monthly injections and are used in only a minority of eligible patients. Entera is developing EB613 as the first oral, anabolic tablet treatment for patients with osteoporosis.

In the Phase 1 (NCT05965167) study, a cohort of 15 healthy participants each received single-tablet EB613, multi-tablet oral EB613, and subcutaneous Forteo® at doses ranging from 1 mg to 3 mg, to evaluate and compare the three treatments' pharmacokinetic (PK) and pharmacodynamic (PD) profiles. Key findings included:

- Single tablet EB613 showed a PK profile comparable to multi-tablet EB613, with similar Cmax, Tmax, and total systemic exposure (AUC).
- The AUC of single tablet and multi-tablet EB613 was comparable with Forteo®, exhibiting a slightly shorter duration of exposure, which is consistent with prior Phase 1 studies.
- Comparable calcemic effects (serum calcium) and consistent suppression of endogenous PTH(1-84) were shown for both oral EB613 treatments and Forteo®.
- The safety profile of EB613 was consistent with Forteo®, with no drug-related serious adverse events; all other adverse events were mild and resolved with no action taken.
- Based on an administration experience quality-of-life questionnaire, 14 of 15 participants preferred the single tablet to multi-tablet EB613, and all participants preferred a daily oral EB613 over the daily injection.

"Our ability to simplify the proposed dosing regimen for patients from the multi-tablet presentation of EB613, which was shown to be safe and effective in our Phase 2 osteoporosis study, to a single daily tablet is a significant scientific achievement. A single daily oral PTH tablet (EB613) could make anabolic treatment far more acceptable to many patients and health care providers and have a substantial impact toward reducing the treatment gap in

patients with osteoporosis," said Miranda Toledano, Chief Executive Officer of Entera.

About EB613
Substantial evidence supports the efficacy of anabolic therapies over bisphosphonates for lowering fracture risk in osteoporosis patients at high risk. However, all available anabolic therapies are administered by subcutaneous (SC) injection and used in a minority of eligible patients. Entera's EB613 program (oral PTH(1-34), teriparatide) 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 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 with placebo in 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 is 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, 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 due 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 primary estrogen deficiency, which leads to accelerated bone loss, especially in the first 5-10 years after menopause. Forteo® (Eli Lilly) was first approved by 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 for fracture, and for osteoporosis associated with sustained systemic glucocorticoid therapy.

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. 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 also developing the first oral Long Acting PTH(1-34) tablet as a replacement therapy for patients with hypoparathyroidism (EB612); the first oral oxyntomodulin, a dual-targeted GLP-1/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.

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.

Company Contact:
IR@enterabio.com


Entera