Entera Bio Receives Positive FDA Feedback on 12-Month Registrational Phase 3 Study for EB613 - the First Oral Anabolic Tablet in Development for Postmenopausal Women with Osteoporosis

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The planned Phase 3 trial in approximately 750 postmenopausal women with osteoporosis, with a primary endpoint of total hip bone mineral density (BMD) at Month 12, would support Entera's plan to submit a New Drug Application (NDA) for EB613

Entera expects to submit its NDA for EB613 based on 12-month data, with an open-label extension study to follow patients through 24 months to supplement EB613's safety, durability of effect and sequence data

Phase 3 initiation is planned for late 2026 with topline data anticipated in the second half of 2028

TEL AVIV, June 22, 2026 (GLOBE NEWSWIRE) -- Entera Bio Ltd. (NASDAQ: ENTX) ("Entera" or the "Company"), a leader in the development of oral peptides, today announced that it has received positive feedback from the U.S. Food and Drug Administration (FDA) on its Phase 3 registrational protocol for EB613 (oral PTH(1-34), teriparatide), the first oral anabolic (bone-building) tablet in development for the treatment of osteoporosis. The FDA feedback is in response to a Clinical Amendment submitted by Entera to its Investigational New Drug (IND) application, as announced in March 2026.

The FDA accepted Entera's plan to conduct a single, randomized, double-blind, placebo-controlled, Phase 3 trial in approximately 750 postmenopausal women with osteoporosis, with a primary endpoint of percent change from baseline in total hip BMD at Month 12 to support a potential New Drug Application (NDA) submission for EB613 for the treatment of women with post-menopausal osteoporosis. The proposed NDA package will also include Entera's scientific bridge analysis with Forteo® (teriparatide SC injection, Eli Lilly) under the 505(b)(2) pathway, and a transiliac crest bone biopsy sub-study in a subset of patients.

The FDA also agreed with Entera's proposal to continue following the randomized patients out to 24 months in an open-label extension study under a separate protocol. Entera will plan to submit data through up to 18 months as part of the 120-day safety update to its NDA. Additionally, Entera will submit the complete 2-year data upon completion of the open-label extension study to characterize further the durability of the treatment effect, safety, and sequence data for EB613 followed by a standard anti-resorptive therapy for 12 months.

The registrational study is powered to demonstrate EB613's clinical effectiveness with projected increases in total hip BMD that are comparable to reported outcomes for Forteo® at 12 months, changes associated with a 60% to 80% relative reduction in vertebral fracture risk.

Entera completed a placebo-controlled, 6-month, Phase 2 study of EB613 in 161 postmenopausal women. The study met its primary (PD/bone turnover biomarker) and secondary (BMD) endpoints, with statistically significant increases in BMD at the lumbar spine, total hip, and femoral neck (JBMR 2024). The increase in total hip BMD in this study was comparable to what has been reported for Forteo® at 6-months. Most recently, at ENDO 2026, comparative Phase 1 data presented as a Late-Breaking Oral Presentation demonstrated that the single tablet of EB613 achieved a pharmacokinetic and pharmacodynamic profile comparable to both the multi-tablet EB613 evaluated in the Phase 2 study and Forteo®.

The Company plans to initiate the registrational Phase 3 study in late 2026, with topline results anticipated in the second half of 2028.

"We are grateful to the FDA for their support of our program. Entera has a clear and optimized registrational path with the aim of getting EB613 to women with osteoporosis," said Miranda Toledano, Chief Executive Officer of Entera. "Our goal with EB613 is to democratize anabolic treatment and enable millions of women and men to protect their bones and potentially prevent the catastrophic consequences of fracture. In a silent and asymptomatic disease, access and ease of administration matter."

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. 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 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 of 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 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.

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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