Entera Bio Congratulates the FNIH-ASBMR-SABRE Team on FDA's Qualification of Total Hip BMD as Regulatory Endpoint: Huge Win for Osteoporosis Innovation

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FDA qualification of Total Hip BMD as a validated surrogate endpoint for novel osteoporosis drug development further bolsters Entera's July 2025 FDA alignment and regulatory strategy for EB613

Underscores Entera's mission to democratize anabolic treatment for osteoporosis patients and caregivers globally

JERUSALEM, Dec. 23, 2025 (GLOBE NEWSWIRE) -- Entera Bio Ltd. (NASDAQ: ENTX) ("Entera" or the "Company"), a leader in the development of oral peptide and protein replacement therapies, is thrilled to congratulate the FNIH-ASBMR-SABRE[1] team following the Food and Drug Administration (FDA) broad qualification of total hip bone mineral density (BMD) as a validated regulatory endpoint for novel drugs in development for post-menopausal women at risk for osteoporotic fracture.

"Since mid-2022, Entera has been steadfast in our public advocacy and support of the SABRE initiative and the FDA's plan to implement this significant regulatory reform," said Miranda Toledano, Chief Executive Officer of Entera. "Over 200 million women globally are estimated to have osteoporosis and remain vastly undertreated, yet no new drug for osteoporosis has been approved by FDA since 2019. Innovation has stalled largely due to the size, duration, cost and ethical constraints associated with fracture endpoint studies. In the last three years, we have been privileged to forge meaningful ties and build an ecosystem of patients, clinicians, and change agents committed to addressing this significantly underserved area," continued Toledano. "In July 2025, Entera was the first company to receive FDA alignment that a single Phase 3 study with total hip BMD as primary endpoint would support an NDA for EB613. The Agency's position paper and broad qualification may further simplify our path forward."

Key Takeaways from FDA's Review of Full Qualification Package:

- There is need for novel products with enhanced efficacy, tolerability, and ease of use
- Faster drug development is needed to help alleviate the costs, morbidity, and mortality associated with osteoporosis-related fractures, which are expected to increase substantially as the population ages
- Given the ethical considerations and recruitment challenges inherent in osteoporosis clinical trials, the development of a validated surrogate endpoint represents a highly valuable regulatory pathway
- BMD surrogate threshold effects (STEs) may serve as reference points for clinical trial planning rather than rigid pass/fail thresholds, providing sponsors flexibility in regulatory evaluation

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 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.

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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[1] The Foundation for the National Institutes of Health (FNIH); The American Society for Bone and Mineral Research (ASBMR); The Study to Advance BMD as a Regulatory Endpoint (SABRE)

Source: Entera Bio