Entera Bio to Present Two Abstracts on its First-in-Class, Once Daily Oral hPTH(1-34) Peptide Tablets (EB613) for the Treatment of Post-Menopausal Women at High Risk of Fracture at the American Society for Bone and Mineral Research (ASBMR) Annual Meeting

August 16, 2023 12:30 PM EDT

JERUSALEM, Aug. 16, 2023 (GLOBE NEWSWIRE) -- Entera Bio Ltd. (NASDAQ: ENTX), ("Entera" or the "Company") a leader in the development of orally delivered peptides and therapeutic proteins, today announced that it has been selected to present data for its investigational agent EB613 at the ASBMR 2023 Annual Meeting on October 13-16, 2023 in Vancouver, BC, Canada.

EB613 [hPTH(1-34) tablets] is being developed as the first once-daily oral anabolic (bone forming) mini tablet therapy for post-menopausal women with high risk osteoporosis. It is estimated that 54 million adults, representing 50 percent of the U.S. adult population over age 50, are at risk of a fragility fracture and approximately 1 in 5 older adults will die within the year following a hip fracture. Due to a lower peak bone density as compared to men and decreases in estradiol after menopause, women are affected in greater numbers. Post menopausal osteoporosis afflicts more women globally than cancer and cardiovascular disease and is a serious health concern. "Available treatments, while efficacious, fail to provide a viable solution for patients that no longer respond to antiresorptive medications and are unwilling to take an injectable anabolic drug or cumbersome device. As potentially, the first once daily hPTH(1-34) peptide tablet therapy, our EB613 program is dedicated to address the vast treatment gap in current osteoporosis care," said Miranda Toledano, Chief Executive Officer at Entera.

Abstract Title: Pharmacokinetic (PK) Profile of EBP05/EB613 Oral Teriparatide Tablets in Women of Post Menopausal Age Versus Young Adult Men
Presentation Number: SAT-456
Presentation Type: Poster Presentation
Session: Poster Session I
Session Date/Time: Saturday, October 14, 2023, 1:30 pm – 3:00 pm

Abstract Title: First Oral hPTH(1-34) Tablet Treatment for Osteoporosis Demonstrates Rapid Pharmacodynamic Effect on Plasma Levels of Endogenous PTH(1-84)
Presentation Number: LB SUN-646
Presentation Type: Late Breaking Poster Presentation
Session: Late-Breaking Poster Session I
Session Date/Time: Sunday, October 15, 2023, 1:30 pm – 3:00 pm
Presentation Time: 1:30 pm – 3:00 pm

About Entera Bio

Entera is a leader in the development of orally delivered macromolecules, including peptides and other therapeutic proteins. The Company focuses on significant unmet medical needs where a daily mini tablet form of a peptide treatment or replacement therapy holds the potential to transform the standard of care. The Company's most advanced product candidates, EB613 for the treatment of high risk, post-menopausal osteoporosis and EB612 for the treatment of hypoparathyroidism, are in clinical development. EB613 is the first oral, once daily mini tablet presentation of synthetic hPTH (1-34), consisting of the same 34 amino acid sequence as daily subcutaneous teriparatide injection, Forteo®. A placebo controlled, dose ranging Phase 2 study of EB613 tablets (n= 161) met primary (PD/biomarker) and secondary endpoints (BMD) in a dose dependent manner and was presented at the ASBMR 2021 Annual Conference. Entera is currently preparing to initiate a Phase 3 registrational study for EB613. A phase 1 PK study of novel PTH formulations was initiated in H1 2023 to ascertain feasibility of a new hypo candidate (a prior formulation had positive Phase 2a data announced in 2015 and published in the JBMR in 2019) and for another potential indication. For more information on Entera Bio, visit www.enterabio.com

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 expectations regarding licensing, business transactions and strategic collaborations; Entera's operation as a development stage company with limited operating history; 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 Statements 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 the company'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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