Entera Bio Reports Rapid Pharmacodynamic (PD) Response and Consistent Pharmacokinetic (PK) Data for its First-in-Class Oral PTH(1-34) Mini Tablets at the ASBMR 2023 Annual Meeting

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JERUSALEM, Oct. 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, presented 2 posters at the Annual Society of Bone and Mineral Research (ASBMR) 2023 Annual Meeting held on October 13-16, 2023 in Vancouver, BC, Canada. Both posters will be available on the Company's website, www.enterabio.com.

"Entera's ability to consistently deliver our oral PTH(1-34) peptide in a simple mini tablet format with reproduceable, dose dependent pharmacokinetics and rapid biological responses irrespective of gender, age, and health status is testament to the robustness of our oral peptide platform. This work also builds the foundation for our oral PTH(1-34) tablets to potentially treat diverse patient populations including younger men and women athletes at risk of stress fractures," said Miranda Toledano, Chief Executive Officer of Entera.

The lead drug candidate of Entera's EBP05 formulation, EB613 is currently being developed as the first once-daily oral anabolic therapy for the treatment of osteoporosis. In a 6-month, 161-patient, placebo-controlled Phase 2 study, EB613 produced rapid dose-proportional changes in biochemical markers and increased Bone Mineral Density (BMD) in postmenopausal women with low BMD osteoporosis.

Abstract Title: First Oral PTH(1-34) Tablet Treatment for Osteoporosis Demonstrates Rapid Pharmacodynamic Effect on Plasma Levels of Endogenous PTH(1-84)

A Phase 1 study comparing oral EB613, subcutaneous (SC) hPTH(1-34) 20 g (Forteo®) and a new generation of Entera's oral peptide delivery platform is ongoing. One of the first objectives of this study is to rapidly evaluate the pharmacodynamic (PD) effects of Entera's oral PTH(1-34) tablets. This analysis relates to Entera's lead formulation. Additional data on new formulations will be released later in 2023.

An increase in plasma ionized calcium should result in decreased secretion and plasma concentrations of endogenous PTH(1-84). Thus, a reduction in plasma PTH(1-84) should provide an early indication of the systemic exposure and pharmacologic activity of Entera's oral PTH(1-34) tablets. In the study, the mean percentage of endogenous plasma PTH (1-84) 120 minutes after dosing was 59.2%, 54.3%, and 52.3% for EB613 1.5 mg, 2.5 mg and Forteo®, respectively; and showed consistent effects across other early PD markers such as serum calcium, phosphorus, and 1,25-dihydroxyvitamin D.

"EB613 oral tablets (1.5 mg and 2.5 mg doses) rapidly decreased plasma concentrations of PTH(1-84) in all subjects, in a dose proportional manner. The results provide early proof of the systemic exposure and pharmacological activity to Entera's orally administered PTH(1-34) tablets. The ability to rapidly evaluate PD effects as early markers of therapeutic response is crucial to assessing a drug's activity in osteoporosis patients and potentially optimize their management. In contrast, response with conventional PD markers of bone metabolism may take several months. Thus, we plan to continue to measure PTH(1-84) responses in further clinical development of EB613," said Art Santora, MD, Entera's Chief Medical Officer.

Abstract Title: Pharmacokinetic (PK) Profile of EBP05/EB613 Oral Teriparatide Tablets in Women of Post Menopausal Age Versus Young Adult Men.

This retrospective analysis compares the pharmacokinetic profile of EBP05 in healthy young males versus female patients of menopausal age with hypoparathyroidism.

A single administration of the same dose, 2.25 mg oral PTH (1-34), in healthy young men (22 years, range 21-26) and women of postmenopausal age (62 years, range 49 -63) resulted in a median Cmax of 425 pg/ml vs 521 pg/ml, and a median AUC of 157 pg*hour/ml vs 158 pg*hour/ml respectively.

"The data showed a consistent PK profile following administration of oral EBP05 tablets in both young men and women of menopausal age. These similar profiles indicate that similar doses of our oral PTH tablets may be used across these different populations," said Gregory Burshtein PhD, Entera's Head of Research and Development.

About Entera Bio

Entera focuses on significant unmet medical needs where an oral form of a peptide treatment or protein replacement therapy holds the potential to transform the standard of care. The Company's oral PTH*(1-34) teriparatide mini tablets have been administered to a total of 240 subjects (153 patients) across Phase 1 and Phase 2 studies, with demonstrated bioavailability and clinical benefit across two distinct diseases. The Company's most advanced product candidate, EB613 (oral synthetic hPTH (1-34)), 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, with no prior fracture. 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 preparing to initiate a Phase 3 registrational study for EB613. EB612 is being developed as the first tablet peptide replacement therapy for the treatment of hypoparathyroidism. The Company is currently conducting a phase 1 PK study of novel PTH formulations using its proprietary, next generation oral delivery platform with data expected in the second half of 2023. Entera is also developing oral GLP-2 program as an injection-free alternative for patients suffering from short bowel syndrome and other severe intestinal and malabsorption metabolic conditions and oral Oxyntomodulin (GLP1/glucacon) for obesity in collaboration with OPKO Health. 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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