



Interim Results from Ongoing Clinical Study Confirm EB613 Optimized Profile for Osteoporosis Treatment and Potential for Entera's Next Generation Oral Peptide Platform

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JERUSALEM, Nov. 29, 2023 (GLOBE NEWSWIRE) -- Entera Bio Ltd. (NASDAQ: ENTX), ("Entera" or the "Company") a leader in the development of orally delivered peptides and therapeutic proteins, reported today interim data from an ongoing Phase 1 study designed to assess and compare the pharmacokinetic (PK) and early pharmacodynamic (PD) profile of current and several next generation compositions of its oral peptide platform (NCT05965167).

EB613 Continues to Display an Optimal Profile as First-in-Class Oral PTH(1-34) Peptide for Osteoporosis

The Phase 1 study first compared the PK profile of Entera's Phase 3 candidate, oral once-daily PTH(1-34) mini-tablets (EB613, a.k.a. EBP05 formulation) with subcutaneous (SC) PTH(1-34) 20 g (Forteo®). Consistent with previously reported PK and bioavailability data, EBP05 induced a rapid and dose-proportional increase in plasma drug concentrations of PTH(1-34) at all doses tested. The target bioavailability of PTH (1-34) with EB613 at doses of 1.5 mg and 2.5 mg, covering the dose range planned for phase 3 was met. Additionally, EB613 exhibited consistent and statistically significant ($p < 0.05$) effects across all early PD markers such as plasma levels of endogenous PTH(1-84), serum calcium, phosphorus, and 1,25-dihydroxyvitamin D.

"EB613's reproducible PK profile across all our clinical studies, irrespective of age and gender, demonstrates the superiority of our platform to consistently deliver oral peptides in a small and convenient tablet form. Although the amino acid sequence in our oral PTH(1-34) is identical to commercially available injectable teriparatide, there is a clear difference in the exposure profile. EB613 appears to produce a shorter duration of osteoblast and osteoclast activation, which is essential for osteoporosis treatment. EB613 induces the "pulsatile" exposure required to simultaneously stimulate bone formation (anabolic) with a mild anti-resorptive property, as compared to Forteo®. This exciting mechanism is consistent with the primary endpoint, bone turnover data reported from our placebo-controlled Phase 2 study in post-menopausal women at high risk of osteoporosis and potentially, the reason we see more rapid BMD increases at 6 months of treatment with EB613, especially at the total hip and proximal femur sites," said Miranda Toledano, Chief Executive Officer of Entera.

Next Generation Platform Demonstrates Robust Bioavailability with Novel Oral Peptide Compositions

The Phase 1 PK study also assessed novel compositions comprising PTH(1-34) as a model peptide to test Entera's proprietary, next generation platform.

The new compositions show enhanced bioavailability (BA) versus our first-generation platform, as expected from pre-clinical data. All formulations demonstrated a consistent PK profile to EBP05 with rapid absorption and elimination; and induced fast PD responses increasing calcium, vitamin D levels along with reducing phosphate and endogenous PTH(1-84).

Entera expects to unveil additional data at an upcoming conference.

About Entera Bio

Entera focuses on significant unmet medical needs where an oral tablet 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 255 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 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, 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. Entera is also developing oral GLP-2 peptide as an injection-free alternative for patients suffering from short bowel syndrome and other severe intestinal and malabsorption metabolic conditions and oral Oxyntomodulin (GLP1/glucagon) peptide for obesity in collaboration with OPKO Health. For more information on Entera Bio, visit www.entera.bio

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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