Entera Bio Reports Phase 1 Clinical Data of First-in-Class, Oral PTH(1-34) Peptide Candidate (EB612) for Patients with Hypoparathyroidism at ENDO 2024

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JERUSALEM, June 03, 2024 (GLOBE NEWSWIRE) -- Entera Bio Ltd. (NASDAQ: ENTX), ("Entera" or the "Company") a leader in the development of orally delivered peptides and small therapeutic proteins, today announced Phase 1 clinical data for its hypoparathyroidism focused investigational program, EB612, as presented on June 1st at the Endocrine Society ENDO 2024 Annual Meeting.

Entera's EB612 program aims to provide the first oral PTH daily tablet hormone replacement therapy for patients suffering from hypoparathyroidism. Late stage investigational PTH replacement treatments include TransCon PTH (palopegteriparatide) by Ascendis Pharma A/S and eneboparatide (AZP-3601) by Amolyt Pharma. Both these modalities require patients to administer injections every day. Entera previously published positive Phase 2a study results in hypoparathyroid patients with four times a day (QID) regimen (Ish-Shalom, JBMR 2021) of EB612.

The data reported from this Phase 1 clinical study include pharmacokinetic (PK), pharmacodynamic (PD) and safety results from the application of a new generation of Entera's N-Tab™ technology platform and EB612, the active peptide fragment 1-34 of the N-terminal region of human parathyroid hormone (teriparatide) dosed twice a day (BID).

Significant systemic exposure was reported following both administrations of EB612 tablets. Aside from positive PK measures, sustainable PD effects were reported, including serum levels of calcium (albumin corrected), phosphate, and $1,25(OH)_2$-Vitamin D (reaching +3.9%, -20.8%, and +73.2% change on average from baseline, respectively) and decreased endogenous serum PTH(1-84) (reaching -43.0% change on average from baseline). There were no treatment-emergent Adverse Events of hypercalcemia reported. There were no treatment-emergent Serious AEs. The only Study Drug-Related AE was mild headache, reported in two out of fifteen subjects. No significant findings were observed in blood and urine lab tests. All vital signs were within the normal range.

"The encouraging findings from this Phase 1 study reaffirm the ability of our N-Tab™ platform to develop simple oral tablet treatments of important peptide therapeutics. Here we suggest that a BID administration of our unmodified PTH(1-34) peptide may provide a viable alternative for patients with hypoparathyroidism who require a peptide replacement therapy for life and are intolerant, adverse or cannot access a daily injectable product," said Miranda Toledano, Chief Executive Officer at Entera.

The poster can be found on the Entera Bio website (Link to poster)

About Entera Bio

Entera is a clinical stage company focused on developing oral peptide or 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 includes five differentiated, first-in-class oral peptide programs, expected to enter the clinic (Phase 1 to Phase 3) by 2025. 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 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 pursuant to the FDA's qualification of a quantitative BMD endpoint which is expected to occur by January 2025. 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 first oral GLP-2 peptide tablet 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, Facebook, Instagram.

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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