Entera Bio Presents Dose Proportional Absorption and Correlation to BMD Clinical Response Data from its Phase 2 Study of EB613 in Post-Menopausal Osteoporosis Patients at the ASBMR 2022 Annual Meeting

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JERUSALEM, Sept. 12, 2022 (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 the details of "A Six-month Phase 2 Study of Oral PTH (EBP05) in Postmenopausal Women with Low Bone Mass – Dose Proportional Absorption and Effect on Lumbar Spine BMD (SUN-591)" poster presentation at the American Society for Bone and Mineral Research (ASBMR) Annual Meeting 2022, being held from September 9-12th in Austin, Texas. The full text of the abstract will be published to the ASBMR meeting website, and the e-poster will be viewable on Entera's website as of Sunday September 11 th as of 1pm CT.

The correlation results were derived from Entera's six-month phase 2 Study of lead clinical candidate, EB613 (EBP05), the first daily oral hPTH (1-34) teriparatide formulation in 161 post-menopausal women with low bone mass. The primary endpoint of change in P1NP at 3 months and secondary endpoints of change in lumbar spine (LS), total hip and femoral neck Bone Mineral Density (BMD) were met, as previously reported (ASBMR 2021 poster FRI-237 and oral presentation LB-1116). The current abstract and poster presentation reveals excellent correlations between the dose of the oral formulation of EB613 and teriparatide hPTH(1-34) plasma concentrations at the 15 min time point (R =0.996) and a linear dose response for the change in lumbar spine BMD after 6 months of treatment (R =0.998).

"These new analyses of blood hPTH concentration shortly after a dose of oral EB613 tablets confirm a strong, statistically significant correlation between mean blood level and the dose of EB613 taken. This finding is consistent with excellent correlation between change in lumbar spine BMD and dose of EB613 after 6 months of treatment," Said Dr. Arthur Santora, Chief Medical Officer at Entera.

"We are encouraged by this important correlation analysis from our positive phase 2 study of EB613. Recent debates at the ASBMR annual conference highlight the importance of potentially earlier intervention with osteoanabolic agents capable of repairing bone structure and increasing mass; versus initial treatment with anti-resorptive drugs that mostly stop bone loss. EB613 has unique potential in the osteoporosis treatment paradigm as the first convenient, daily tablets form of osteoanabolic treatment," said Miranda Toledano, Chief Executive Officer of Entera.

About EB613 (a.k.a. EBP05)

Parathyroid hormone (PTH) is an 84-amino acid hormone and the primary regulator of calcium and phosphate metabolism in bone and kidney. EB613 is an oral formulation of synthetic hPTH (1-34), (teriparatide), a peptide consisting of the first 34 amino acids of PTH which represent the functional region. Subcutaneous Forteo® (teriparatide injection) has been the leading anabolic treatment of osteoporosis since 2002. EB613 utilizes Entera's oral drug delivery platform which promotes enteric absorption and stabilizes teriparatide in the gastrointestinal tract. Entera's Oral PTH formulations have been administered collectively to a total of 225 subjects in two Phase 1 studies and 3 phase 2 studies (including 35 in 2 phase 2 hypoparathyroidism studies). The most recent study was a dose ranging Phase 2 study in postmenopausal women with low bone mass. This study met primary and key secondary endpoints and was presented in a late-breaker oral presentation at the ASBMR 2021 conference. For the primary efficacy endpoint: a statistically significant increase in P1NP (a bone formation marker) at 3 months was achieved. A significant dose response was observed for 0.5, 1.0, 1.5 and 2.5 mg oral PTH doses on P1NP, Osteocalcin and bone mineral density (BMD). Subjects receiving the 2.5 mg dose of EB613 showed significant increases in dose-related BMD at the lumbar spine, total hip, and femoral neck at 6 months. Subjects receiving the 2.5 mg dose of EB613 daily for 6 months had a significant placebo adjusted increase of 3.78% in lumbar spine BMD ($p<0.008$) which is similar to the 3.9% increase in lumbar spine BMD seen with Forteo® in clinical studies reported in the literature. Increases in total hip and femoral neck BMD were greater than those previously reported with Forteo®. EB613 exhibited an excellent safety profile, with no drug related serious adverse events. The most common adverse events included mild nausea, moderate back pain, moderate headache, and moderate upper abdominal pain.

About Entera Bio

Entera is a leader in the development of orally delivered macromolecules therapeutics including peptides and other therapeutic proteins, for use in areas with significant unmet medical need where adoption of injectable therapies is limited due to cost, convenience and compliance challenges for patients. The Company's proprietary, oral drug delivery technology is designed to address the technical challenges of poor absorption, high variability, and the inability to deliver large molecules to the targeted location in the body through the use of a synthetic absorption enhancer to facilitate the absorption of large molecules, and protease inhibitors to prevent enzymatic degradation and support delivery to targeted tissues. The Company's most advanced product candidates, EB613 for the treatment of osteoporosis and EB612 for the treatment of hypoparathyroidism are in clinical

development. The Company recently completed the phase 2 study for EB613 and has a Type C meeting scheduled with FDA with respect to its Phase 3 program in H2 2022. Entera also licenses its technology to biopharmaceutical companies for use with their proprietary compounds and, to date, has established a collaboration with Amgen Inc. 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 is contractually obligated to provide, such as those pursuant to Entera's agreement with Amgen; 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.

Contact: Entera Bio: Ms. Miranda Toledano Chief Executive Officer Entera Bio Email: miranda@enterabio.com Investor Relations: Christopher M. Calabrese Managing Director LifeSci Advisors 917-680-5608 ccalabrese@lifesciadvisors.com Kevin Gardner Managing Director LifeSci Advisors 617-283-2856 kgardner@lifesciadvisors.com