Entera Bio Hosting Key Opinion Leader Webinar on the Treatment Landscape for Osteoporosis and EB613's Potential Impact on Wednesday, September 28th @ 10am ET

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JERUSALEM, Sept. 21, 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 that it will host a key opinion leader (KOL) webinar on the company's lead asset EB613, and its potential impact on the osteoporosis market on Wednesday, September 28, 2022 at 10:00am ET.

The webinar will feature presentations from KOLs John P. Bilezikian, MD, PhD, from Columbia University, Felicia Cosman, MD, also from Columbia University, and Bart L. Clarke, MD, from Mayo Clinic. The event will provide insight into the current treatment landscape and unmet medical need for post-menopausal women with osteoporosis. The discussion will focus on Entera Bio's development of EB613, a proprietary formulation of PTH (1-34, teriparatide) as the first potential orally administered osteoanabolic treatment. Entera leadership will review their Phase 2 EB613 data, which will be followed by an overview of the Company's proposed registrational Phase 3 plan submitted to FDA.

A live Q&A session will follow the presentations. To register for the event, please click here.

Dr. John Bilezikian, the Dorothy L. and Daniel H. Silberberg Professor of Medicine at the Vagelos College of Physicians & Surgeons, Columbia University, is Vice Chair of the Department of Medicine for International Education and Research and Chief, Emeritus, of the Division of Endocrinology. He is Director, Emeritus, of the Metabolic Bone Diseases Program at Columbia University Medical Center.

Dr. Bilezikian received his undergraduate training at Harvard College, his medical training at the College of Physicians & Surgeons, and his residency training at Columbia Presbyterian Medical Center, and his training in Metabolic Bone Diseases and in Endocrinology at the NIH under the tutelage of Dr. Gerald Aurbach. He belongs to the American Society of Bone and Mineral Research (ASBMR) and the International Society of Clinical Densitometry (ISCD), both of which he served as President.

Dr. Bilezikian's major research interests are related to the clinical investigation of metabolic bone diseases, particularly primary hyperparathyroidism, hypoparathyroidism and osteoporosis, His studies of parathyroid hormone in these disorders regarding etiology, clinical manifestations, pathophysiology, mechanisms of skeletal involvement, and therapy are known throughout the world as landmark contributions to our knowledge of these disorders. Over 900 publications and numerous awards speak to these active original investigative initiatives as well as his authorship of many reference sources of endocrinology and metabolic bone diseases.

Dr. Felicia Cosman is a clinical scientist, osteoporosis specialist, Professor of Medicine, Emerita, at Columbia University and North American Co-Editor in Chief of the journal Osteoporosis International since 2016. She received a BA from Cornell, MD from Stony Brook, and completed internship, residency and endocrinology fellowship at Columbia University College of Physicians and Surgeons. She received the ACE Distinction in Endocrinology Award in 2019 and the ASBMR Bartter Award for clinical research in September 2020.

Dr. Cosman has had many grants from NIH, DOD, foundations and industry, and has published over 190 peer-reviewed papers and over 50 book chapters. The main focus of her research has been in the use of anabolic medications and treatment sequencing. Dr. Cosman has investigated the effect of teriparatide on biochemical and bone densitometry outcomes, bone strength by finite element analysis, and cellular action using iliac crest bone biopsy. She also studied the effect of teriparatide on bone formation in the human femoral neck in patients undergoing hip arthroplasty and performed a series of studies investigating cyclic, combination and sequential regimens of teriparatide and antiresorptive agents. Dr. Cosman has been a primary investigator on multiple studies evaluating the efficacy of abaloparatide and romosozumab treatment for osteoporosis. She is also well known for her work evaluating the importance of treatment sequence to optimize the effect of anabolic and antiresorptive medications, longterm treatment strategies, and implementing therapeutic goals for osteoporosis management.

Dr. Bart L. Clarke is Consultant and a member of the Metabolic Bone Disease Core Group in the Division of Endocrinology, Diabetes, Metabolism, and Nutrition at the Mayo Clinic, and Professor of Medicine in the Mayo Clinic College of Medicine. His current clinical research interests include postmenopausal osteoporosis, glucocorticoid- and transplantation-induced osteoporosis, parathyroid disorders, rare bone diseases, new anabolic therapies for osteoporosis, and tumor-induced osteomalacia. He is Past-President and a former Council member of the American Society for Bone and Mineral Research, and a member of the Endocrine Society, American Association of Clinical Endocrinologists, and the American College of Physicians. He is on the editorial board for the Journal of Bone and Mineral Research, Bone, and Osteoporosis International, served on the FDA Reproductive Health Drug Advisory Board, and is a current Chair of the Mayo Clinic Institutional Review Board.

About EB613
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.

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