



Entera Bio Announces Formation of Clinical and Scientific Advisory Board and Poster Presentation at ASBMR 2022 Annual Meeting

July 26, 2022 11:30 AM EDT

JERUSALEM, July 26, 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 formation of its Clinical and Scientific Advisory Board (CSAB), consisting of world class experts in bone diseases, endocrinology, and metabolic disorders. In addition, the Company announced today that it will be presenting new data from its 6-month Oral PTH (EB613) Phase 2 Study in postmenopausal women with low bone mass, or osteoporosis at the 2022 Annual Meeting of the American Society for Bone and Mineral Research (ASBMR), which will take place in Austin, Texas from September 9-12, 2022.

The inaugural members of Entera's CSAB include:

Professor John P. Bilezikian: Vice-Chair, Department of Medicine for International Research and Education; Chief, Emeritus, of the Division of Endocrinology; Director, Emeritus, of the Metabolic Bone Diseases Program at Columbia University Medical Center

Professor Maria Luisa Brandi: Professor of Endocrinology, FIRMO Foundation, Florence, Italy

Professor Bart Clarke: Professor of Medicine and Consultant, Division of Endocrinology, Diabetes, Metabolism, and Nutrition, Mayo Clinic

Professor Felicia Cosman: Professor of Medicine, Emerita, Columbia University College of Physicians and Surgeons, Division of Endocrinology; Co-Editor in Chief of the journal Osteoporosis International

Professor William Fraser: Professor of Medicine and Deputy Head of Norwich Medical School at the University of East Anglia and Consultant in Metabolic Medicine at the Norfolk and Norwich University Hospital, UK

Dr. Roger Garceau: Former Chief Medical Officer and EVP at NPS Pharmaceuticals and Shire plc (Natpara®); with previous senior management roles at Sanofi Aventis and Pharmacia

Professor Sophia Ish-Shalom: Vice President of the Israeli Foundation for Osteoporosis and Bone Diseases (IFOB), Endocrine Clinic Elisha Hospital; prior Head of Bone and Mineral Metabolism Unit, Rambam Health Care Campus, Haifa Israel

Professor Socrates Papapoulos: Emeritus Professor in Diseases of Bone & Mineral Metabolism, Advisor Center for Bone Quality, Leiden University Medical Center, The Netherlands

"We are honored to be working with this distinguished group of thought leaders and appreciate their support and guidance of our clinical development strategy," said Miranda Toledano, Entera's Chief Executive Officer. "Their extensive clinical and scientific experience in late-stage clinical trials have been invaluable to the advancement of our core osteoporosis and hypoparathyroidism programs." Arthur Santora, M.D., Ph.D., Chief Medical Officer of Entera said, "We have been working collaboratively to advance Entera's proprietary oral pipeline and the support of our CSAB provides phenomenal validation to our efforts. We look forward to benefitting from their collective expertise as we continue to move toward our mission of delivering oral therapeutic options to patients high unmet medical needs."

The title of the abstract accepted for presentation at the ASBMR 2022 National Meeting and current schedule for presentation follows:

Abstract Title: 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

Presentation Type: Poster Presentation

Session: Poster Session II & Poster Tours

Session Date/Time: Sunday, September 11, 2022 from 1:00 pm – 3:00 pm

Presentation Time: 1:00 pm – 3:00 pm

Location: ASBMR Discovery Hall

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 literature¹. 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.

¹ Leder BZ et.al. JCEM 2015

Contact: Entera Bio: Ms. Miranda Toledano Chief Executive Officer Entera Bio Email: miranda@enterabio.com Phone: +972-58-55-88-470 IR: Mr. Christopher M. Calabrese Managing Director LifeSci Advisors LLC Email: ccalabrese@lifesciadvisors.com Phone: (917) 680-5608