Entera's EB613, the First Once Daily PTH(1-34) Tablet Treatment Dedicated to Post-Menopausal Women with High Risk Osteoporosis Abstract Selected for Presentation at the ASBMR 2024 Annual Meeting - Key SABRE Update Also Expected

August 1, 2024 12:30 PM EDT

JERUSALEM, Aug. 01, 2024 (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 new comparative pharmacological data for its investigational agent EB613 vs. Forteo® was selected for presentation at the American Society for Bone and Mineral Research (ASBMR) 2024 Annual Meeting which will be held on September 27-30, 2024 in Toronto, ON, Canada.

EB613 is being developed as the first once-daily oral anabolic (bone forming) PTH(1-34) mini tablet therapy for post-menopausal women with high risk osteoporosis. It is estimated that 50 percent of women and 20 percent of men over the age of 50 are at risk of a fragility fractures and approximately 1 in 5 adults will die within the year following a hip fracture. Post menopausal osteoporosis afflicts more women than cancer and cardiovascular disease and is a serious health concern for an estimated 200 million women globally.

"Available injectable anabolic treatments, while efficacious and recommended across medical guidelines, unfortunately do not provide a viable solution for most women with high-risk osteoporosis requiring an anabolic intervention. Our EB613 program is dedicated to address the treatment chasm in current osteoporosis care and hopefully present a treatment for the majority of women to adequately manage their post-menopause bone health with a simple once daily tablet treatment. Importantly, we look forward to the SABRE (Study to Advance BMD as a Regulatory Endpoint) UPDATE at the ASBMR 2024 meeting. On March 26th 2024, Entera echoed the ASBMR announcement that the U.S. Food and Drug Administration (FDA) had communicated to SABRE that a ruling to qualify bone mineral density (BMD) as a surrogate endpoint for fractures in future trials of new anti-osteoporosis drugs would be provided within 10 months. The proposed registrational Phase 3 study for EB613, is designed to meet the quantitative BMD thresholds proposed by SABRE," said Miranda Toledano, Chief Executive Officer at Entera.

Abstract Title: 3079 - EB613 (Oral PTH(1-34) Tablets) Shows Differentiated Pharmacokinetic Profile From Forteo – New Results from Phase 1b Open-Label Study
Presentation Number: Sat-LB 589
Session Date/Time: Saturday, September 28, 2024, 2:15 – 3:45 PM

SABRE Project Update

Speakers: Dennis M. Black , PhD, University of California, United States; Theresa E. Kehoe , MD, CDER/FDA, United States

Session Date / Time: Sunday September 29, 2024 9:45 – 10:45 AM

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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