Entera Bio Provides Guidance from FDA Type D Meeting Related to EB613 Pivotal Program

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JERUSALEM, April 03, 2023 (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 feedback from its Type D Meeting with the U.S. Food and Drug Administration (FDA) related to EB613's [daily oral hPTH(1-34), teriparatide, tablets] proposed registrational program for the treatment of postmenopausal women with osteoporosis. Entera submitted a draft phase 3 study protocol and requested the FDA's written responses to two questions.

On the first question, **"Based on the FDA's feedback provided in the Type C meeting written response August 19, 2022, and subsequent teleconference held on September 27, 2022, the Sponsor has updated the Phase 3 protocol design including the use of Total Hip Bone Mineral Density (BMD) as the primary endpoint. Does the FDA concur that the revised protocol meets its expectations?"** the FDA responded that it is not opposed to the use of BMD as a surrogate for fracture, including initiating a study under the proposed Foundation for the National Institutes of Health Bone Quality Project (FNIH BQP)[1] pathway, which is undergoing review. The FNIH-BQP approach to BMD as a surrogate endpoint for fracture was first discussed with Entera during its End of Phase 2 Meeting with the FDA (as announced in July 2022). In the Type D meeting responses, the FDA confirmed to Entera that a 24-month placebo-controlled phase 3 trial with the primary efficacy analysis at 24 months is acceptable and provided some guidance on the statistical evaluation of the study.

On the second question, **"Does FDA agree that the design of the population PK (pharmacokinetic) and exposure response evaluation incorporated in the draft Phase 3 study protocol meets FDA expectations?"** FDA responded that the Company's proposed PK sampling scheme in the phase 3 study seems reasonable.

"We thank the FDA for our Type D Meeting and their ongoing support for our EB613 program. We are very pleased that the agency has re-affirmed its acceptance of BMD as an endpoint and our placebo-controlled design. We will continue our dialogue with the FDA and we will be ready to initiate our study once the FDA provides us with final guidance on their review of the FNIH-BQP. The ethical concerns associated with placebo-controlled fracture endpoint studies in osteoporotic patients at high risk of fracture is a critical barrier to new drug development for this common disorder. Entera is proud to be part of this incredibly significant process with FDA, which is also sponsored by the ASBMR. Our conviction that EB613, as the first potential oral osteoanabolic treatment, may help millions of women globally is unwavering; and we look forward to initiating our pivotal Phase 3 study under this critical initiative. Meanwhile, we are preparing to start the PK study for our next generation platform, which may enable us to advance our EB612 program for the treatment of hypoparathyroidism into Phase 2 in 2024," stated Miranda Toledano, Chief Executive Officer of Entera.

About Entera Bio

Entera is a leader in the development of orally delivered macromolecules, including peptides and other therapeutic proteins. The Company focuses on significant unmet medical needs where a daily mini tablet form of a peptide treatment or replacement therapy holds the potential to transform the standard of care. The Company's most advanced product candidates, EB613 for the treatment of high risk, post-menopausal osteoporosis and EB612 for the treatment of hypoparathyroidism, are in clinical development. EB613 is the first oral, once daily mini tablet presentation of synthetic hPTH (1-34), (teriparatide), consisting of the exact same 34 amino acid sequence as daily subcutaneous teriparatide injection, Forteo®, which requires daily SC injections. A placebo controlled, dose ranging Phase 2 study of EB613 tablets (n= 161) met primary (PD/biomarker) and secondary endpoints (BMD) in a dose dependent manner and was presented at the ASBMR 2021 Annual Conference. A phase 1 PK study of novel PTH formulations is planned for H1 2023 to ascertain feasibility of a new hypo candidate (a prior formulation had positive Phase 2a data announced in 2015 and published in JBMR 2019) and for another potential indication. 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.
https://force-dsc.my.site.com/ddt/s/ddt-project?ddtprojectid=97

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[1] FNIH BQP is also knows as the ASBMR FNIH-SABRE, American Society for Bone and Mineral Research-Foundation for the National Institutes of Health (FNIH) Strategy to Advance BMD as a Regulatory Endpoint (SABRE); https://force-dsc.my.site.com/ddt/s/ddt-project?ddtprojectid=97

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