Entera Bio Announces Successful EB613 End-of-Phase 2 Meeting with FDA: FDA Agrees to Phase 3 Twelve Month Study with Lumbar Spine BMD (bone mineral density) as the Primary Endpoint

January 4, 2022 1:30 PM EST

– Company plans to initiate multi-national Phase 3 Trial in 2022 –

BOSTON and JERUSALEM, Israel, Jan. 04, 2022 (GLOBE NEWSWIRE) -- Entera Bio Ltd. (NASDAQ: ENTX), today announced it has concluded its End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA) on EB613, its oral formulation of human parathyroid hormone (1-34), or PTH, for the treatment of osteoporosis and defined the path for Phase 3 development of EB613, confirming that a fracture study will not be necessary and that lumbar spine BMD at 12 months can be the primary endpoint. The meeting followed completion of its Phase 2 clinical trial, which met its endpoints, including increases in lumbar spine, femoral, neck and hip bone mineral density (BMD) versus placebo after six months of treatment, and demonstrated a safety profile consistent with subcutaneous PTH (1-34) (teriparatide injection) (Forteo®).

Based on FDA feedback at the meeting, Entera is currently proceeding with its plans for a Phase 3 registration study of EB613 this year. The FDA confirmed that a comparison of Entera's EB613 dosed at 2.5 mg versus subcutaneous PTH (1-34) with a lumbar spine BMD increase at 12 months as the primary endpoint for the trial would be acceptable. The company may rely on marketed drugs as part of a 505(b)(2) regulatory approval pathway. The FDA's 505(b)(2) new drug application (NDA) pathway helps avoid unnecessary duplication of studies already performed on previously approved drugs.

If approved, EB613 would be the first oral anabolic agent for the treatment of osteoporosis. Currently, more than 90% of osteoporosis patients are treated with oral agents. Osteoporosis is a silent disease, which causes little or no pain to the patient until an event occurs, and a bone is fractured. For this reason, many elderly patients are unwilling to take an injectable medication. If EB613 is approved, Entera believes that it could dramatically expand the number of patients who are treated with anabolic bone building therapies, as well as replacing the medication of some patients already on an injectable therapy. With more than 200 million osteoporosis patients worldwide, of which the vast majority are not treated, osteoporosis represents a market with incredible potential for growth.

"We are very pleased with the FDA's guidance on our development plan for EB613 as we focus on the work necessary to secure regulatory approval to deliver an oral PTH option for patients with osteoporosis. As an oral bone building drug, EB613 has the potential to dramatically expand the use of PTH to those patients who are reluctant to use injectables," stated Entera's CEO Spiros Jamas. "We look forward to commencing enrollment in the Phase 3 study in 2022."

About Entera Bio

Entera is a leader in the development of orally delivered large molecule therapeutics 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. 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.

Forward Looking Statements

Various statements in this 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 our interpretation of the 3-month biomarker data from the Phase 2 clinical trial of EB613, the timing of data readouts from the Phase 2 clinical trial of EB613, the full results of the Phase 2 clinical trial of EB613 and our analysis of those full results, the FDA's interpretation and review of our results from and analysis of our Phase 2 trial of EB613, 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, due to travel restrictions, lay-offs or forced closures or repurposing of hospital facilities; 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, if the FDA or other authorities are closed for prolonged periods, choose to allocate resources to review of COVID-19 related drugs or believe that the amount of Phase 2 clinical data collected are insufficient to initiate a Phase 3 trial, or a meaningful deterioration of the current political, legal and regulatory situation in Israel or the United States; the availability, quality and timing of the data from the Phase 2 clinical trial of EB613 in osteoporosis patients; the size and growth of the potential market for EB613 and Entera's other product candidates including any possible expansion of the market if an orally delivered option is available in addition to an injectable formulation; the scope, progress and costs of developing Entera's product candidates including EB612 and GLP-2; 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 expectations regarding its expenses, revenue, cash resources, liquidity and financial condition; Entera's ability to raise additional capital; Entera's interpretation of FDA feedback and guidance and how such guidance may impact its clinical development plans; 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 "Special Note Regarding Forward-Looking Statements," "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of Entera's filings with the SEC and available free of charge on the SEC's website at http://www.sec.gov. Additional factors may be set forth in those sections of Entera's Annual Report on Form 20-F for the year ended December 31, 2020, filed with the SEC in the first quarter of 2021. In addition to the risks described above and in Entera's annual report on Form 20-F and current reports on Form 6-K, Current Reports on Form 8-K and other filings with the SEC, other unknown or unpredictable factors also could affect Entera's results. 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 in such forward-looking statements and estimates will be achieved.

All written and verbal forward-looking statements attributable to Entera or any person acting on its behalf are expressly qualified in their entirety by the cautionary statements contained or referred to herein. Entera cautions investors not to rely on the forward-looking statements Entera makes or that are made on its behalf. The information in this release is provided only as of the date of this 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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