Entera Bio to Present Phase 2 EB613 Oral PTH Osteoporosis Treatment 3-Month Findings at the American Society for Bone and Mineral Research Annual Meeting

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– The Study's Primary Endpoint was Met; P1NP, a Biochemical Marker of Bone Formation, was Significantly Increased at Month 3 in EB613 2.5 mg Treatment Group Versus Placebo –

– Full 3-Month Biochemical Markers of Bone Formation and Resorption to be Presented –

– Positioned to be the First Oral Bone-Building Agent for Osteoporosis –

BOSTON and JERUSALEM, Aug. 02, 2021 (GLOBE NEWSWIRE) -- Entera Bio Ltd. (NASDAQ: ENTX), a leader in the development of orally delivered large molecule therapeutics, today announced its poster presentation titled "A Six-month Phase 2 Study of Oral PTH in Postmenopausal Women with Low Bone Mass - An Interim Three-Month Analysis" has been selected by the Program Committee of the American Society for Bone and Mineral Research (ASBMR) for its Annual Meeting scheduled to take place on October 1-4, 2021 in San Diego, California. Dr. Arthur Santora, Entera's Chief Medical Officer, will present the poster at both the plenary session on October 1 and the general session on October 2, as well as a special session on the Biology of the Aging Skeleton Symposium on September 30.

The Phase 2 clinical trial of EB613, an oral formulation of human parathyroid hormone (PTH) (1-34), for the treatment of osteoporosis met its primary and key secondary endpoints, positioning it to be the first oral bone building (anabolic) product to treat osteoporosis patients. The full 3-month biomarker data will be presented at the ASBMR annual meeting. Three and 6 month results, previously reported by Entera in June 2021 can be found here.

Osteoporosis, characterized by low bone mass and deterioration of bone tissue, can lead to decreased bone strength and increased risk of fracture. An injectable form of PTH(1-34) currently on the market, Forteo® has been shown to reduce vertebral fractures by 65-80%. However, because injections deter many patients from receiving treatments, oral EB613 may address this unmet clinical need by reducing fractures at a similar rate.

"We look forward to presenting EB613's Phase 2 data to the leading physicians, researchers, and clinical investigators in the field of bone metabolism and health. The presentation, selected for multiple sessions, is recognition of the importance of our results and well-timed as we prepare for EB613's pivotal Phase 3 head-to-head study vs. Forteo which we expect to initiate in 2022," stated Entera CEO Spiros Jamas.

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 Phase 2 clinical development. 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" under the securities laws. 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 complete 3-month biomarker data from the ongoing Phase 2 clinical trial of EB613, the timing of data readouts from the ongoing Phase 2 clinical trial of EB613, the full results of the Phase 2 clinical trial of EB613, which is still ongoing 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; a possible suspension of the Phase 2 clinical trial of EB613 for clinical or data-related reasons; the impact of COVID-19 on Entera's business operations including the ability to collect the necessary data from the Phase 2 trial of EB613; 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 ability to find a dose that demonstrates the comparability of EB613 to FORTEO in the ongoing Phase 2 clinical trial of EB613; 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 annual and current filings which are on file 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 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 too heavily 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, and specifically declines any obligation, to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

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