Entera Bio Ltd Announces Completion of Enrollment In Phase 2 Clinical Trial of Eb613 In Osteoporosis

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– Company Expects to Report Interim 3 Month Biomarker Data for All Enrolled Patients in Q1:21 with Final Bone Mineral Density, or BMD, Data Expected in Q2:21 –

– Results Expected Are Expected to Inform the Design of Potential Global Phase 3 Clinical Trial –

BOSTON and JERUSALEM, Israel, Nov. 09, 2020 (GLOBE NEWSWIRE) -- Entera Bio Ltd. (NASDAQ: ENTX), a leader in the development of orally delivered large molecule therapeutics, announced the completion of enrollment in the ongoing Phase 2 clinical trial of EB613. EB613 is an orally delivered human parathyroid hormone (1-34), or PTH, positioned as the first potential oral bone building product to treat osteoporosis patients.

The Phase 2 clinical trial of EB613 is a dose-ranging, placebo-controlled study in postmenopausal female subjects with osteoporosis, or low bone mineral density (BMD), and is being conducted at four leading medical centers in Israel. The trial was initially designed with three treatment groups including doses of 0.5mg, 1.0mg and 1.5mg. In July 2020, the Company amended the Phase 2 protocol based on a review of the 3-month interim biochemical marker and safety data from the first 80 subjects randomized. The two lower doses (0.5 mg and 1.0 mg) of EB613 were discontinued and a 2.5 mg dose of EB613 was added. The initial target enrollment was 160 subjects, with final enrollment of 161 subjects.

In August 2020, the Company announced 6-month interim biomarker and BMD data from the first 50%, or 80 patients, enrolled in this trial. The data indicated EB613 has a meaningful and positive impact on lumbar spine BMD in a dose dependent manner. EB613 generated a mean placebo adjusted increase in lumbar spine BMD of 2.15% ($p = 0.08$) for the 14 patients in the 1.5 mg treatment arm, as compared to the 16 patients in the placebo arm. The placebo-adjusted increase was comprised of a mean BMD increase of 1.44% in the 1.5 mg treatment arm compared to a mean decrease of 0.71% in the placebo arm. An additional analysis of BMD changes in all EB613 treatment groups showed a significant dose-dependent trend in the percentage change in lumbar spine BMD.

“There is a clear and compelling need for an oral PTH treatment that builds bone in patients with osteoporosis and we look forward to reporting the full topline results from this trial in the second quarter of 2021,” stated Roger Garceau, MD, Director and Interim CEO of Entera. “We are excited that we were able to complete enrollment given the extraordinary challenges related to the COVID-19 pandemic. I would like to thank the patients for their participation and the sites and investigators for their efforts to both enroll and follow-up with the patients in the trial.”

Entera expects to report efficacy results for the EB613 Phase 2 clinical trial including the full 3-month biomarker data in the first quarter of 2021, and the efficacy and safety results for the full trial in the second quarter of 2021. As of September 30, 2020, the Company had cash and cash equivalents of $7.1 million and believes its current cash position will be sufficient to fund its operations into the second quarter of 2021.

About EB613

EB613 is an orally delivered human parathyroid hormone (1-34), or PTH, program positioned as the first potential oral bone building product to treat osteoporosis patients. Teriparatide for injection (marketed under the brand name Forteo®) was approved by the U.S. in 2002 for the treatment of osteoporosis in men and postmenopausal women who are at high risk for having a fracture and is taken daily via a subcutaneous injection. Entera Bio completed enrollment of a 6-month phase 2 study in postmenopausal women evaluating the effects of a range of oral EB613 doses (and placebo) on bone mineral density, or BMD, of the spine and proximal femur (hip), and anticipates reporting top-line BMD efficacy and safety results for the trial in the second quarter of 2021.

About Osteoporosis

Osteoporosis is a disease characterized by low bone mass and structural deterioration of bone tissue, which leads to greater fragility and an increase in fracture risk. Osteoporosis is also a silent disease, often displaying no signs or symptoms until a fracture occurs, leaving the majority of patients undiagnosed and untreated, representing a high unmet medical need. The debilitating effects of osteoporosis have substantial costs and osteoporotic fractures create a significant healthcare burden. An estimated two million osteoporotic fractures occur annually in the United States, and this number is projected to grow to three million by 2025. The National Osteoporosis Foundation (NOF) has estimated that eight million women already have osteoporosis, and another approximately 44 million may have low bone mass placing them at increased risk for osteoporosis. In US women 55 years of age and older, the hospitalization burden of osteoporotic fractures and population facility-related hospital cost is greater than that of myocardial infarction, stroke, or breast cancer.

About Entera Bio Ltd.

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 interim data from the ongoing Phase 2 clinical trial of EB613, the timing of data readouts from the ongoing Phase 2 clinical 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 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 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; 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, including the amount of cash and cash equivalents as of September 30, 2020 referenced above, which has not been audited or reviewed by Entera's independent registered public accounting firm and should be viewed in the context of all other available information regarding Entera's results of operations, 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 Quarterly Report on Form 6-K for the quarter ended September 30, 2020, to be filed with the SEC in the fourth quarter of 2020. 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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