Entera Bio Ltd Provides Update on Phase 2 Clinical Trial of EB613 in Postmenopausal Women With Osteoporosis

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– Institutional Review Boards (IRBs) Approve Amended Phase 2 Protocol with Newly Enrolled Patients Receiving a 2.5 mg Dose, 1.5 mg Dose, or Placebo –

– Company Continues to Expect Completion of Enrollment in Q3:20 and Intends to Follow All Patients for Bone Mineral Density and Biomarker (BMD) Data After Six Months of Treatment –

– Biomarker Data from the Higher Dose Groups Expected in Early Q1:21 with Full Six-month BMD Data Expected in Early Q2:21 –

BOSTON and JERUSALEM, July 07, 2020 (GLOBE NEWSWIRE) -- Entera Bio Ltd. (NASDAQ: ENTX), a leader in the development of orally delivered large molecule therapeutics, announced receipt of approval from the IRBs at the clinical sites for the amendment to its Phase 2 protocol to include the testing of higher doses of EB613.

The amendment was submitted after the analysis of the interim Phase 2 biomarker and safety data supported the evaluation of a higher dose of EB613 in the trial. The interim readout demonstrated statistically significant effects on the P1NP biomarker after one month of treatment ($p<0.001$) compared to the placebo, and meaningful increases at months two and three compared to the placebo with the highest EB613 dose (1.5 mg). There was also a dose response at one month, with those trends continuing at two months. The two lower doses (0.5 mg and 1.0 mg) demonstrated suboptimal increases and therefore, have been discontinued in the amended protocol. Sites have restarted new patient enrollment to include the 2.5mg dose, 1.5mg dose and placebo. There are currently 106 patients enrolled out of the targeted 160 patients in the trial, including the new high-dose group. The Company expects to complete enrollment for the trial in Q3:20.

“Based on our analysis of the interim three-month biomarker data from the lowest doses in the first 50% of the patients enrolled in the trial, we believe the observed early positive trends and favorable safety profile of EB613 warranted the continued testing of the 1.5 mg dose and the addition of a 2.5 mg dose,” stated Adam Gridley, CEO of Entera. “We expect to report incremental biomarker and six-month BMD data from the first 50 percent of patients at the lower doses in Q3:20. Given the small sample size of this limited interim BMD data readout, we may see some interesting trends but believe the more relevant data will come from the final analysis of all the patients, including those at the higher doses. After the limited interim analysis of bio markers indicated that our oral PTH had some effect on bone remodeling, we look forward to seeing the full data set, including BMD data, as BMD is the ultimate measure of efficacy for an osteoporosis drug.”

EB613 Phase 2 Clinical Trial

The Phase 2 clinical trial of EB613, the Company’s orally delivered PTH 1-34, is a dose-ranging, placebo-controlled, 160-patient clinical trial in postmenopausal female patients with osteoporosis, or low BMD, being conducted at four leading medical centers in Israel. Patients who were previously randomized received one of three doses of EB613, 1.5 mg, 1.0 mg, or 0.5 mg, or a placebo. Under the new amendment, patients are randomized to receive either a 2.5 mg dose or 1.5 mg dose of EB613, or a placebo. The primary endpoint of the study is the change in P1NP from baseline during treatment with oral PTH doses at three months compared to the change from baseline with placebo. Secondary endpoints include change in BMD, change in P1NP, serum CTX (a marker of bone resorption), and a variety of other measures at three and six months. Upon completion of the study, if successful, the Company intends to meet with the United States Food and Drug Administration, or FDA, to discuss the results and the design of a potential single Phase 3 clinical trial to support the regulatory approval of EB613.

About Entera Bio Ltd.

Entera is a leader in the development of orally delivered macromolecule 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: 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 enrollment in the Phase 2 clinical trial for EB613 in patients with osteoporosis and 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 so far 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; 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; 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. 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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