Entera Bio Announces Positive Feedback and Guidance from the US FDA Regarding its Development Plans for Oral PTH in Osteoporosis

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JERUSALEM, Jan. 31, 2019 (GLOBE NEWSWIRE) -- Entera Bio Ltd. (Nasdaq: ENTX), announced today the positive outcome of a pre-IND meeting held with the US Food and Drug Administration (FDA) to discuss the Company's development plan for Oral PTH for the treatment of osteoporosis. The feedback and guidance were summarized in the formal meeting minutes that Entera subsequently received from the FDA. In addition to discussing various aspects of the nonclinical and clinical development plan, the meeting focused on the 505 b(2) regulatory pathway and the use of bone mineral density (BMD) rather than fracture incidence as the primary endpoint to support a New Drug Application (NDA). Based on the FDA's response, Entera believes that the Phase 3 study may use BMD as the primary efficacy endpoint and that a fracture endpoint study will not be required.

"We were very pleased with the positive pre-IND meeting with the FDA in late 2018 and greatly appreciate the detailed guidance in FDA's official minutes of the meeting," stated Dr. Arthur Santora, Chief Medical Officer of Entera Bio. "As we anticipated, the FDA expressed its willingness to accept Entera's plan to bridge nonclinical and clinical study data for our oral PTH (1-34) to data from prior studies of the commercially available PTH (1-34) injection (Forteo®). The FDA provided us with an overall direction for the nonclinical and clinical and regulatory path forward; successful bridging between the effects of oral PTH and subcutaneous PTH would allow Entera to conduct a Phase 3 study with a bone mineral density efficacy endpoint rather than fracture endpoint study. While a BMD endpoint study comparing Oral PTH and subcutaneous PTH is still a large study, it would be substantially less costly and several years shorter than a fracture endpoint trial."

Entera Bio's Oral PTH (1-34) has been shown to produce a blood level profile similar to Forteo ® (teriparatide), which was approved by the FDA in 2002 for the treatment of osteoporosis in men and postmenopausal women who are at high risk for fractures. "Forteo ® is currently one of two injectable treatments for osteoporosis which are classified by the FDA as "bone building" (anabolic). The potential osteoporosis drug market is estimated at almost $20 billion worldwide. If a "blockbuster" drug with comparable efficacy to injectable Forteo ® were available as a once-daily pill, we believe that it would potentially win market share and significantly expand the market for anabolic agents to osteoporotic patients at high risk of fracture who are reluctant to use an injectable medication," stated Dr. Phillip Schwartz, CEO of Entera Bio.

Developers of osteoporosis drugs that contain new chemical entities are required to conduct extensive clinical studies that employ an endpoint which measures the reduction in fractures. These trials often require thousands of patients over a multi-year period, and typically cost hundreds of millions of dollars. Once fracture risk reduction has been demonstrated, the FDA and other regulatory agencies have allowed new formulations or treatment regimens of the same active ingredient to be approved using BMD as the primary efficacy endpoint. "The similarity of Oral PTH (1-34) to the commercially available Forteo®, and use of the BMD endpoint, are expected to significantly reduce the time and cost of bringing Entera's oral PTH to market. Based on Entera's successful trials with its oral PTH (1-34) and the favorable safety profile observed in healthy volunteers and patients with hypoparathyroidism, we are very confident that the safety and efficacy of Oral PTH (EB-613) will be similar to that of subcutaneous PTH for the treatment of osteoporosis," continued Dr. Schwartz.

Post FDA feedback, the Company is proceeding with the development of EB-613 for osteoporosis. The next step in this clinical development program will be to conduct a dose-ranging study in approximately 140 osteoporosis patients, in order to study both safety and the optimal dose to advance into a Phase 3 pivotal study. This dose-ranging study will commence in the first half of this year and will include bone marker, bone mineral density and safety endpoints. The Company will be conducting several nonclinical safety assessment studies in parallel. Assuming a favorable outcome of these studies, the Company is planning a single Phase 3, multicenter study comparing Oral PTH with Forteo® over a 12-month treatment period, to begin in 2020. Although still at the early stages of planning, such a study would likely be conducted in the U.S. and Europe, and potentially enroll between 600 and 800 patients in total, depending on statistical powering assumptions.

About Entera Bio Ltd.
Entera Bio is a clinical-stage biopharmaceutical company focused on the development and commercialization of orally delivered large molecule therapeutics for use in orphan indications and other areas with significant unmet medical needs. The Company is initially applying its technology to develop an oral formulation of a human parathyroid hormone analog, Oral PTH (1-34), for treatment of hypoparathyroidism and osteoporosis.

Entera has developed a proprietary platform technology that enables oral delivery of biologicals and large molecule drugs, which are typically delivered via injections and or other non-oral pathways. However, oral drug delivery is the easiest method for self-administering medications, offers patients greater dosing flexibility, and has the highest patient acceptance and compliance rates as compared to all other routes of drug administration. The Company employs this technology for its own pipeline products and may enter into licensing agreements with biopharma companies for application of the technology to their proprietary compounds, such as the Amgen strategic research collaboration.

Forward Looking Statements
This press release contains "forward-looking statements." Words such as "may," "should," "could," "would," "predicts," "potential," "continue," "expects," "anticipates," "future," "intends," "plans," "believes," "estimates," and similar expressions, as well as statements in future tense, often signify forward-looking statements. 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. Forward-looking statements are based on information that the Company has when those statements are made or management's good faith belief as of that time with respect to future events, and are subject to risks and uncertainties that could cause actual performance or results to differ materially from those expressed in or suggested by the forward-looking statements. Investors are cautioned that no assurances can be given that the clinical development plan referenced herein will be found by FDA to be sufficient for an NDA filing for Oral PTH or, even if the NDA is accepted for filing, that the NDA will be ultimately be approved by FDA. For a discussion of these and other risks that could cause such differences and that may affect the realization of forward-looking statements, please refer to the "Special Note Regarding Forward-Looking Statements" and "Risk Factors" in the Company's Registration Statement on Form F-1 and other filings with the Securities and Exchange Commission (SEC). Investors and security holders are urged to read these documents free of charge on the SEC's web site at http://www.sec.gov. The Company assumes no obligation to publicly update or revise its forward-looking statements as a result of new information, future events or otherwise.

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