



Entera Announces Initiation of Phase 2 Dose Ranging Study for Oral PTH

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JERUSALEM, July 02, 2019 (GLOBE NEWSWIRE) -- Entera Bio Ltd. (Nasdaq: ENTX), announced today that it has initiated a Phase 2 study with its osteoporosis drug candidate EB613, an oral human PTH (1-34) tablet. This double blinded, placebo controlled, dose-ranging study will evaluate three different doses in postmenopausal women with low bone mass. The study will include up to 160 patients dosed once daily for a period of 6 months.

Human PTH (1-34) is a known anabolic treatment currently available as a daily subcutaneous injection, Forteo[®] (marketed by Eli Lilly[®]) with a known effect on bone formation biomarkers and bone mineral density (BMD). The primary endpoint of this study will be bone formation biomarkers at 3 months with an additional evaluation at 6 months, along with a BMD readout. The purpose of the study is to optimize the design of Entera's planned Phase 3 pivotal study, which Entera will explore performing with a larger pharmaceutical partner.

"We are very excited about this Phase 2 study for osteoporosis which, if successful, will further validate our platform oral drug delivery technology and significantly increase the value of our pipeline," stated Dr. Phillip Schwartz, CEO of Entera Bio. "Entera's oral PTH has been extensively tested and consistently shown to produce a systemic exposure profile similar to the exposure following a Forteo injection. Following the positive feedback from the FDA indicating that a fracture study would not be required and that the 505(b)2 pathway may be utilized to seek approval, this Phase 2 study has become more significant as the expected time to market for our oral PTH treatment for osteoporosis has decreased significantly."

The study was approved by the Israeli Ministry of Health and will be conducted at the osteoporosis clinics of 4 leading medical centers in Israel. These clinics have participated in a number of multinational osteoporosis trials for large pharmaceutical companies. All lab tests will be processed by an accredited central lab and BMD measurements will be monitored and analyzed in the US by a leading US CRO. The 3-month biomarker results are expected to provide preliminary insight into the efficacy of the oral PTH treatments and preliminary results may be obtained once the first half of the study population has been dosed for this period. A full study report will be generated upon completion of the 6-month biomarker and BMD analysis. It should be noted that preparations for the EB613 Phase 3 study are likely to commence after reviewing the 3-month biomarker data. The Company has already created a Phase 3 study outline and currently envisages a trial with a partner comparing EB613 to Forteo, enrolling 600 to 800 patients and with a primary endpoint based on non-inferiority in BMD outcome. Other details, including the EB613 dose and the length of the study, would be finalized based on the results obtained from the Phase 2 study.

"An oral anabolic agent would provide a significant practical advantage over the injectable options. Many elderly osteoporotic patients who would benefit from a bone anabolic treatment are often deterred by the injections required by the treatment options currently available," added Arthur Santora, MD, Chief Medical Officer of Entera Bio. "A new oral osteoporosis treatment may also allow for an individualized treatment regimen tailored to each patient's needs."

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. 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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