Entera Bio Announces Collaboration with OPKO Biologics to Develop Oral Peptide Tablet Formulations for Obesity and Intestinal Malabsorption Syndromes

JERUSALEM– September 12th, 2023 (GLOBE NEWSWIRE) -- Entera Bio Ltd. (NASDAQ: ENTX, "Entera") and OPKO Biologics, Inc. , a subsidiary of OPKO Health, Inc. (NASDAQ: OPK, "OPKO") have entered into a Research Collaboration Agreement. Under the terms of the Agreement, OPKO will supply its proprietary long-acting GLP-2 peptide and certain Oxyntomodulin (OXM) analogs for the development of oral tablet formulations using Entera's proprietary oral delivery technology.

It is challenging to administer peptides orally due to their rapid degradation in the gastrointestinal tract and negligible permeability. Treatment with Glucagon-Like Peptide-2 (GLP-2) analogs has been shown to improve the absorption of nutrients in patients with short bowel syndrome (SBS) and reduce parenteral support requirements. Teduglutide, the only approved GLP-2 analog, requires daily subcutaneous injections. In SBS patients, oral drug delivery is particularly challenging because the site of absorption, the intestine, is short and less functional. Entera recently published pre-clinical data demonstrating that its oral peptide delivery platform enables gastric absorption of teduglutide, as a convenient potential tablet alternative to daily injections.

Oxyntomodulin is a naturally occurring peptide hormone found in the colon, with glucagon-like-peptide 1 (GLP-1) and glucagon dual agonist activity which suppresses appetite and induces weight loss. OPKO has developed several proprietary, modified OXM analogs as potential candidates for treating obesity, including an injectable pegylated peptide which demonstrated significant reductions in weight loss and decreased plasma triglyceride levels in a 420 patient phase 2B study.

Under the terms of the agreement, Entera and OPKO will each be responsible for specific phases of development of the two oral peptides to the point of demonstrated in vivo feasibility. Further details of the agreement were not made public.

"This collaboration with OPKO is important for Entera as it enables us to expand our oral delivery technology across additional high value peptides," said Miranda Toledano, Chief Executive Officer of Entera. "OPKO is a leader in the development and commercialization of highly differentiated, long-acting peptides. Most important, we share a common vision to create first in class peptide treatments to help patients better manage serious, undertreated chronic diseases in a more comfortable way."

"This collaboration fits with OPKO's strategy to expand our pipeline to develop orally administered tablet presentations of long-acting peptides. Working with Entera and its unique oral delivery platform compliments our previous experience in the development of NGENLA, our once weekly human growth hormone product, in collaboration with Pfizer and serves to enhance the diversity and strength of our development portfolio. We look forward to working with Entera," said Phillip Frost, Chairman and Chief Executive Officer of OPKO Health.

About Entera Bio

Entera focuses on significant unmet medical needs where a daily mini tablet form of a peptide treatment or replacement therapy holds the potential to transform the standard of care. The Company's oral hPTH*(1-34) teriparatide mini tablets have been administered to a total of 240 subjects (153 patients) across Phase 1 and Phase 2 studies, with demonstrated bioavailability and clinical benefit across two distinct diseases. The Company's most advanced product candidate, EB613 (oral synthetic hPTH (1-34)), is being developed as the first oral, osteoanabolic (bone building) once a day tablet treatment for post-menopausal women with low BMD and high-risk osteoporosis, with no prior fracture. A placebo controlled, dose ranging Phase 2 study of EB613 tablets (n= 161) met primary (PD/bone turnover biomarker) and secondary endpoints (BMD). Entera is preparing to initiate a Phase 3 registrational study for EB613. EB612 is being developed as the first tablet peptide replacement therapy for the treatment of hypoparathyroidism. The Company expects to report results from a phase 1B PK study of novel PTH formulations using its proprietary, next generation oral delivery platform in the second half of 2023. In May 2023, Entera announced pre-clinical results from its oral GLP-2 program which is being developed as an injection-free alternative for patients suffering from short bowel syndrome and other severe intestinal and malabsorption metabolic conditions. For more information on Entera Bio, visit www.enterabio.com

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Cautionary Statement Regarding Forward Looking Statements

Various statements in this press release are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. All statements (other than statements of historical facts) in this press release regarding our prospects, plans, financial position, business strategy and expected financial and operational results may constitute forward-looking statements. 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 the interpretation of clinical data; results of our clinical trials; the FDA's interpretation and review of our results from and analysis of our clinical trials; 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; the potential disruption and delay of manufacturing supply chains; loss of available workforce resources, either by Entera or its collaboration and laboratory partners; impacts to research and development or clinical activities that Entera may be contractually obligated to provide; overall regulatory timelines; the size and growth of the potential markets for our product candidates; 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 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 "Cautionary Statements Regarding Forward-Looking Statements," "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of Entera's most recent Annual Report on Form 10-K filed with the SEC, as well as the company's subsequently filed Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. 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 or implied in such forward-looking statements and estimates will be achieved. Entera cautions investors not to rely on the forward-looking statements Entera makes in this press release. The information in this press release is provided only as of the date of this press release, and Entera undertakes no obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise, except to the extent required by law.