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OPKO Health and Entera Bio Enter into Collaboration Agreement to Advance Oral GLP-1/Glucagon Tablet Candidate into the Clinic to Treat Obesity and Metabolic Disorders

MIAMI and JERUSALEM, March 17, 2025 (GLOBE NEWSWIRE) -- OPKO Health, Inc. (NASDAQ: OPK) and Entera Bio Ltd. (NASDAQ: ENTX), a leader in the development of oral peptides and proteins replacement therapies, entered into a collaboration and license agreement to advance into the clinic the first oral dual agonist GLP-1/glucagon peptide as a once-daily tablet treatment for patients with obesity, metabolic and fibrotic disorders. The program combines OPKO's proprietary long-acting oxyntomodulin analog (OPK-88006) and Entera's proprietary N-Tab™ technology. Favorable pharmacodynamic, pharmacokinetic and bioavailability data in vivo were reported in September 2024. The companies expect to file an Investigational New Drug application with the U.S. Food and Drug Administration (FDA) later this year.

Under the terms of the agreement, OPKO and Entera will hold 60% and 40% pro-rata ownership interests, respectively, in the program and be responsible for 60% and 40% of the program's development costs, respectively. In connection with the execution of the agreement, OPKO purchased 3,685,226 ordinary shares of Entera for a purchase price equal to $2.17 per share. Entera has agreed to utilize the proceeds from the sale of the shares to fund its 40% share of costs through Phase 1 of the development program. Following the completion of the Phase 1 stage, Entera has the option to continue to fund its 40% share to maintain its pro-rata ownership interest of the program. Should Entera opt-out, Entera will retain a 15% ownership interest in the Oral OXM program, while OPKO will retain 85% and be responsible for ongoing development activities and funding of the program.

"We are pleased to continue working with Entera on this promising program to develop the first oral GLP-1/glucagon dual agonist in addition to our subcutaneous injectable dual agonist GLP-1/glucagon program. Our goal with this franchise is to provide additional options for patients with obesity, metabolic and fibrotic diseases," said Phillip Frost, M.D., Chairman and Chief Executive Officer of OPKO.

"We have enjoyed our synergistic partnership with OPKO. This expanded collaboration on the GLP-1/glucagon program reinforces our shared vision to develop first in class differentiated oral peptide treatments for patients to better manage their health," said Miranda Toledano, Entera Chief Executive Officer.

Oxyntomodulin is a naturally occurring GLP-1/glucagon dual agonist peptide hormone found in the small intestine that acts to suppress appetite, induce weight loss and has additional

cardioprotective and anti-fibrotic attributes. OPK-88006 is a GLP-1/glucagon dual agonist peptide that has been modified to maintain its long-acting profile while increasing its potential potency. Currently, there are no approved dual GLP-1/glucagon agonists available.

About Entera Bio

Entera is a clinical stage company focused on developing oral peptide and protein replacement therapies for significant unmet medical needs where an oral tablet form holds the potential to transform the standard of care. The Company leverages on a disruptive and proprietary technology platform (N-Tab™) and its pipeline includes five differentiated, first-in-class oral peptide programs targeting PTH(1-34), GLP-1 and GLP-2. The Company's most advanced product candidate, EB613 (oral PTH(1-34)), is being developed as the first oral, osteoanabolic (bone building) once-daily tablet treatment for post-menopausal women with low BMD and high-risk osteoporosis. 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 pursuant to the FDA's qualification of a quantitative BMD endpoint. The EB612 program is being developed as the first oral PTH(1-34) tablet peptide replacement therapy for hypoparathyroidism. Entera is also developing the first oral oxyntomodulin, a dual targeted GLP-1/glucagon peptide, in tablet form for the treatment of obesity; and first oral GLP-2 peptide tablet as an injection-free alternative for patients suffering from rare malabsorption conditions such as short bowel syndrome in collaboration with OPKO Health. For more information on Entera Bio, visit www.enterabio.com or follow us on LinkedIn, Twitter, Facebook, Instagram.

About OPKO Health

OPKO Health is a multinational biopharmaceutical and diagnostics company that seeks to establish industry-leading positions in large, rapidly growing markets by leveraging its discovery, development and commercialization expertise, and its novel and proprietary technologies. For more information, visit www.opko.com.

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, including those 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 and OPKO'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, whether by Entera, OPKO or their respective collaboration and laboratory partners; impacts to research and development or clinical activities that Entera or OPKO 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 our product candidates; the parties' reliance on third parties to conduct clinical trials; Entera's and OPKO's expectations regarding licensing, business transactions, including OPKO's development efforts should Entera opt-out, 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 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 and OPKO's intellectual property positions and their ability to protect their respective 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 each of Entera's and OPKO's most recent Annual Reports on Form 10-K filed with the SEC, as well as the companies' respective 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 and OPKO will be realized or, even if substantially realized, that they will have the expected consequences to, or effects on, Entera or OPKO, as applicable. Therefore, no assurance can be given that the outcomes stated or implied in such forward-looking statements and estimates will be achieved. Entera and OPKO caution investors not to rely on the forward-looking statements made in this press release. The information in this press release is provided only as of the date of this press release, and neither Entera nor OPKO undertakes any 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.

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