OPKO Health and Entera Bio Expand Partnership to Advance First-in-Class Oral Long Acting PTH Tablet for Patients with Hypoparathyroidism

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This is the third program that successfully combines Entera's oral peptide N-Tab ® platform with OPKO's advanced protein chemistry capabilities

The companies have accelerated this program and aim to file an investigational new drug (IND) application in late 2026

Injectable and oral oxyntomodulin (dual GLP-1/glucagon analog) for metabolic and fibrotic disorders advancing with initial Phase 1 data from injectable oxyntomodulin (OXM) expected in late 2026; oral OXM to enter clinic thereafter

Industry veteran Steve Rubin joins Entera's board

MIAMI and TEL AVIV, Feb. 04, 2026 (GLOBE NEWSWIRE) -- OPKO Health, Inc. (NASDAQ: OPK), through its wholly owned subsidiary, OPKO Biologics (OPKO), and Entera Bio Ltd. (NASDAQ: ENTX) (Entera or the Company), a leader in the development of oral peptide and protein replacement therapies, today announced the expansion of their 2025 Collaboration and License Agreement to advance the first oral long-acting PTH analog (LA-PTH) as a once-daily tablet for patients with hypoparathyroidism.

The additional program combines OPKO's proprietary long-acting PTH variants with Entera's proprietary N-Tab® technology. Following favorable pharmacodynamic and pharmacokinetic (PK/PD) data reported in December 2025, the companies have jointly decided to accelerate development and expect to file an IND application with the U.S. Food and Drug Administration (FDA) in late 2026.

Under the expanded collaboration agreement, OPKO and Entera will each hold a 50% pro-rata ownership interest in the LA-PTH hypoparathyroidism program and will each be responsible for 50% of the program's development costs. The companies maintain their previously announced 60%/40% (OPKO/Entera) ownership structure and cost-sharing arrangement for the oral OXM program for metabolic and fibrotic disorders.

Additionally, the companies announced that Steve Rubin, Executive Vice President of Administration and director at OPKO, has joined the board of directors of Entera as Gerry Ostrov steps down from the board. Mr. Rubin joins Entera with three decades of experience in corporate governance and strategic oversight of drug development across multiple public biotechnology companies.

"The partnership that our team has forged with OPKO since late 2023 has been very synergistic. Oral OXM and oral GLP-2 have both demonstrated robust PK profiles and bioavailability. Furthermore, preclinical data of oral LA-PTH suggests that this program holds the potential to transform the hypoparathyroidism landscape," said Miranda Toledano, Chief Executive Officer of Entera. "I would also like to take this opportunity to thank Gerry Ostrov for his contributions and service at Entera, and to extend a warm welcome to Steve Rubin to our board of directors."

Phillip Frost, M.D., Chairman and Chief Executive Officer of OPKO Health, remarked, "We are pleased to expand our successful collaboration with Entera to advance this promising long-acting PTH program for hypoparathyroidism. This program builds on OPKO's expertise in developing differentiated long-acting peptides and Entera's innovative oral peptide platform. Our goal is to provide patients with hypoparathyroidism a more convenient treatment option that eliminates the burden of daily injections while maintaining therapeutic efficacy."

Hypoparathyroidism is a heterogeneous, rare endocrine disorder that leads to abnormally low calcium and high phosphorus levels in the blood and requires chronic PTH replacement therapy. Today, the only approved PTH replacement treatment, YORVIPATH® developed by Ascendis Pharma, requires patients to administer daily injections, while investigational candidates may require weekly injections. Entera previously demonstrated proof-of-concept clinical data for its EB612 program using an unmodified oral PTH(1-34) analog in a 16-week Phase 2 study in patients with hypoparathyroidism (JBMR, 2021). The study showed significant reduction in calcium supplement use and maintenance of serum calcium levels above the lower limit for hypoparathyroidism (>7.5 mg/dL) throughout the study. However, the trial required a four-times-daily (QID) regimen with doses of up to 9mg daily. The current preclinical data with OPKO's long-acting PTH variant supports a single, once-daily tablet PTH replacement regimen at a significantly lower daily dose.

As part of OPKO's and Entera's collaboration, the companies are advancing into the clinic the first oral dual agonist GLP-1/glucagon peptide for patients with obesity, metabolic and fibrotic disorders. Since March 2025, the companies have completed in vivo PK/PD validation for both the subcutaneous injection and oral tablet formulations of oxyntomodulin. OPKO is planning to initiate a single ascending dose (SAD) and multiple ascending dose (MAD) Phase 1 clinical study with the subcutaneous injection formulation, with data expected by the end of 2026. The companies plan to file an IND for the oral OXM tablet formulation thereafter. Oxyntomodulin is a naturally occurring GLP-1/glucagon dual agonist peptide hormone found in the small intestine that acts to suppress appetite and induce weight loss, and has additional cardioprotective and anti-fibrotic properties. Currently, there are no approved dual GLP-1/glucagon agonists.

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 of 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). 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 metabolic syndromes; and first oral GLP-2 peptide 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, and Facebook.

About OPKO

OPKO 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 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.

Company Contact:

Entera Bio
Ms. Miranda Toledano
Chief Executive Officer
miranda@enterabio.com

OPKO Health
Alliance Advisors IR
Yvonne Briggs, 310-691-7100
ybriggs@allianceadvisors.com
or
Bruce Voss, 310-691-7100
bvoss@allianceadvisors.com