Entera Bio Reports Positive PK Data for First-in-Class Oral GLP-2 Tablet Treatment for Patients with Short Bowel Syndrome at the 2025 ESPEN Congress

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Preclinical Data for OPK-8801003 Demonstrate Substantially Longer Biological Half-Life with Peak Plasma Levels Comparable to Gattex®, the Only Approved GLP-2 Therapy

Oral GLP-2 Tablet Could Transform Treatment Paradigm for 30,000 Short Bowel Syndrome (SBS) Patients Currently Dependent on Daily Injections of the Peptide

JERUSALEM, Sept. 15, 2025 (GLOBE NEWSWIRE) -- Entera Bio Ltd. (NASDAQ: ENTX), a leader in the development of oral peptides and protein replacement therapies, today announced the presentation of a poster titled "**A First-in-Class Oral GLP-2 Analog for Treatment of Short Bowel Syndrome**" at the 47 th European Society for Clinical Nutrition & Metabolism (ESPEN) Congress in Prague, Czech Republic, highlighting pharmacokinetic (PK) data relating to its oral GLP-2 analog program.

Entera and OPKO Health, Inc. entered into a research collaboration in 2023 to develop oral peptide candidates for intestinal malabsorption syndromes, combining OPKO's proprietary long-acting GLP-2 analog (OPK-8801003) with Entera's N-Tab™ oral peptide platform. Currently, the only approved GLP-2 therapy is Gattex® (teduglutide), which generates approximately $800 million in annual sales despite requiring daily subcutaneous injections with challenging compliance rates and limited patient access.

"The pharmacokinetic data presented at ESPEN represent a significant milestone in our journey to develop the first oral GLP-2 therapy and an incremental milestone in validating our N-Tab™ oral peptide platform," saidMiranda Toledano, Chief Executive Officer of Entera. "Given the robust oral bioavailability demonstrated in our preclinical studies, we believe this daily GLP-2 tablet candidate could fundamentally change how SBS patients are treated, offering a less-invasive administration that can be titrated to enable personalized dosing in this rare and heterogeneous condition."

Key Data Presented at ESPEN

- **Extended Half-Life:** OPK-8801003 GLP-2 tablet demonstrated a plasma half-life of approximately 15 hours in minipigs, representing an approximate 18-fold improvement over teduglutide, which has a half-life of only 0.85 hours in the same species.
- **Robust Oral Bioavailability:** Following oral administration of OPK-8801003 tablets in minipigs, peak plasma concentrations reached ~200 ng/ml (Cmax), substantially exceeding the reported Cmax of 36.8 ng/ml for daily 0.05 mg/kg teduglutide subcutaneous injection in humans.
- **Sustained Exposure:** Systemic exposure (AUC ~2 h*µg/ml) was maintained for more than 24 hours with relatively low variability, supporting once-daily oral dosing.
- **Favorable Safety Profile:** No signs of toxicity were observed in the preclinical studies.

About Short Bowel Syndrome

Short bowel syndrome is a rare and potentially life-threatening malabsorptive condition caused by a significant loss of functional bowel mass (secondary to congenital defects or disease-associated loss of absorption) or physical bowel mass (secondary to extensive intestinal resection). Approximately 30,000 patients across the U.S. and EU are living with SBS, and current annual sales of GATTEX® (teduglutide), the only approved therapy for SBS, total roughly $800 million. SBS patients have a reduced ability to absorb nutrients and fluids and are at risk of malnutrition, unintended weight loss and additional symptoms due to the loss of essential vitamins and minerals.[1] SBS is the most common cause of chronic intestinal failure, accounting for approximately 75% of chronic intestinal failure cases in adults and 50% of such events in children.[1]

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), teriparatide), 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 GLP1/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,

Cautionary Statement Regarding Forward Looking Statements

Various statements in this presentation 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 presentation regarding our prospects, plans, financial position, business strategy and expected financial and operational results, including statements about the anticipated prospects for our oral GLP-2 tablet and its preclinical 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: whether the data presented support further development as a differentiated treatment for SBS; whether the preclinical data are indicative of future clinical results; 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, 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 Entera’s most recent Annual Report on Form 10-K filed with the SEC, as well as its 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 made 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.

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[1] Zhu C, Li Y. An updated overview of glucagon-like peptide-2 analog trophic therapy for short bowel syndrome in adults. J Int Med Res. 2022 Mar;50(3):3000605221086145. doi: 10.1177/03000605221086145. PMID: 35343263; PMCID: PMC8966062.

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