Entera's Oral Delivery of GLP-2 Pre-Clinical Data to be Published in Peer Reviewed, International Journal of Peptide Research and Therapeutics

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JERUSALEM, May 03, 2023 (GLOBE NEWSWIRE) -- Entera Bio Ltd. (NASDAQ: ENTX) ("Entera" or the "Company") a leader in the development of orally delivered peptides and therapeutic proteins, today announced that its pre-clinical manuscript entitled "Oral Delivery Technology Enabling Gastro-Mucosal Absorption of Glucagon-Like-Peptide-2 Analog (GLP-2), Teduglutide - A Novel Approach for Injection-Free Treatment of Short Bowel Syndrome" has been accepted for publication by the International Journal of Peptide Research and Therapeutics.

Short bowel syndrome (SBS) 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). 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 cases of chronic intestinal failure in adults and 50% such events in children.[2] Teduglutide, a GLP-2 analog and mainstay treatment for SBS, is known to enhance intestinal absorption. Teduglutide treatment requires daily sub-cutaneous injections.

"There are several new generation GLP-2 analogs under development which may also require chronic injections. As part of our R&D initiatives, Entera is leveraging on its proprietary platform to enable a potential first-in-class oral GLP-2, daily tablet treatment for patients with short bowel syndrome (SBS) and other disorders requiring parenteral nutrition. We are looking forward to sharing our in vivo findings with the community in the coming weeks," said Miranda Toledano, Chief Executive Officer of Entera.

About Entera Bio

Entera is a leader in the development of orally delivered macromolecules, including peptides and other therapeutic proteins. The Company 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 most advanced product candidates, EB613 for the treatment of high risk, post-menopausal osteoporosis and EB612 for the treatment of hypoparathyroidism, are in clinical development. Both EB612 and EB613 are being developed to address undertreated diseases which disproportionately afflict women. EB613 is the first oral, once daily mini tablet presentation of synthetic hPTH (1-34), (teriparatide), consisting of the exact same 34 amino acid sequence as daily subcutaneous teriparatide injection, Forteo®, a mainstay anabolic treatment which requires daily SC injections. A placebo controlled, dose ranging Phase 2 study of EB613 tablets (n= 161) met primary (PD/biomarker) and secondary endpoints (BMD) in a dose dependent manner and was presented at the ASBMR 2021 Annual Conference. A phase 1 PK study of novel PTH formulations is planned for H1 2023 to ascertain feasibility of a new hypo candidate (a prior formulation had positive Phase 2a data announced in 2015 and published in JBMR 2019) and for another potential indication. For more information on Entera Bio, visit www.enterabio.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 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 is contractually obligated to provide, such as those pursuant to Entera's agreement with Amgen; 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.

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[1] https://rarediseases.org/rare-diseases/short-bowel-syndrome/

[2] 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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