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## **Renexxion Ireland has Completed a Successful Pre-IND Consultation with the United States FDA for Development of Naronapride for Patients with PPI-non-responsive Symptomatic GERD**

ROSCREA, Ireland, Dec. 20, 2023 (GLOBE NEWSWIRE) -- Renexxion Ireland Limited (“Renexxion”), a private biopharmaceutical company committed to delivering innovative drugs to patients with high unmet need in gastrointestinal (“GI”) disorders, announced today that it has completed a successful pre-Investigational New Drug (pre-IND) consultation with the U.S. Food and Drug Administration (U.S. FDA) to discuss development of naronapride for patients with proton-pump inhibitor non-responsive symptomatic gastroesophageal reflux disease (PPI-nrsGERD). PPI-nrsGERD affects over 20 million patients in the U.S., and current treatments are focused solely on the mechanism of acid suppression without addressing gastrointestinal (GI) motility. Naronapride, Renexxion’s lead drug candidate, is a potential best-in-class oral, locally acting pan-GI prokinetic, which works by modulating two validated targets, 5-HT<sub>4</sub> receptor agonism and D<sub>2</sub> receptor antagonism, with a well-differentiated pharmaceutical, pharmacokinetics, safety, and efficacy profile from other 5-HT<sub>4</sub> agonists.

“As many patients with GERD do not adequately respond to PPI, the potential use of prokinetic therapy may represent a plausible pathophysiologic target for some patients, as when gastroparesis symptoms co-exist. However, commercially available prokinetics have not clearly demonstrated clinical benefit in the absence of gastroparesis. In this context, potential access to a safe and effective prokinetic could represent a welcome adjunctive therapeutic option for selected patients with GERD not adequately responding to PPI therapy,” said Dr. Amit Patel, MD, Gastroenterologist and Associate Professor of Medicine at Duke University.

The main purpose of the pre-IND consultation was to discuss key considerations related to indication, endpoints, clinical study design, development plan, and necessary data, to open an IND investigating naronapride in patients with PPI-nrsGERD. Renexxion is encouraged by the feedback from the Agency on submitted questions, as well as its acceptance of the potential for PPI-nrsGERD as a new indication for naronapride.

“Naronapride is a potential best-in-class pan-GI prokinetic which is currently in a multi-center Phase 2b study in patients with gastroparesis. It has completed four Phase 2 studies in related GI indications including as monotherapy in newly diagnosed GERD. With the recent feedback from the U.S. FDA our Company will pursue IND clearance to develop naronapride for an underserved new indication, PPI-nrsGERD,” said Peter Milner M.D., FACC, Chairman and CEO of Renexxion. “We look forward to collaborating with the Agency to demonstrate naronapride is both safe and effective for PPI-nrsGERD.”

### **About Naronapride:**

Renexxion Ireland’s lead program is naronapride, a late-stage potential best-in-class drug candidate for unmet GI indications in the upper and lower GI tract. In scientific studies naronapride has been demonstrated to possess a unique combination of both serotonin 5HT<sub>4</sub> receptor agonistic and dopamine D<sub>2</sub> receptor antagonistic properties, both clinically validated targets. Naronapride was designed to be minimally absorbable and locally active in the gut lumen to potentially enhance efficacy and safety. Four positive Phase 2 studies have been completed and naronapride is Phase 3 ready in chronic idiopathic constipation (“CIC”) and gastro-esophageal reflux disease (“GERD”).

**About Renexxion Ireland:**

Renexxion Ireland Limited, a wholly owned Irish subsidiary of California-based Renexxion, LLC, is a privately held biopharmaceutical company committed to delivering new drugs to patients with GI disorders. Renexxion Ireland is currently collaborating with a leading European GI Licensing partner to advance naronapride through the later stages of development and commercialization in Greater Europe and certain other Australasian countries. Renexxion Ireland is currently advancing an additional research program in inflammatory bowel disease (“IBD”).

For information: <http://www.rnexltd.ie>.

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