Renexxion Ireland Ltd. and Dr. Falk Pharma GmbH Announce Expansion of the Phase 2b MOVE-IT Study of Naronapride in Gastroparesis and Dosing of the First United States Patient

ROSCREA, Ireland, and FREIBURG, Germany (GLOBE NEWSWIRE) [Aug 13, 2024] – Renexxion Ireland Limited ("Renexxion"), a private biopharmaceutical company committed to delivering innovative drugs to patients with high unmet need in gastrointestinal ("GI") disorders, in collaboration with its partner Dr. Falk Pharma GmbH ("Dr. Falk Pharma"), announce dosing of the first patient in the United States (U.S.) in the ongoing global Phase 2b MOVE-IT study (ClinicalTrials.gov ID: NCT05621811) evaluating the safety and efficacy of naronapride for the treatment of gastroparesis. The MOVE-IT study started dosing patients in Europe in February 2023 and has now expanded to include U.S. patients after recent IND clearance from the FDA for investigating naronapride in gastroparesis patients.

"As a part of our goal to harmonize clinical development and regulatory pathways in the U.S. and EU, we are delighted to announce the dosing of the first U.S. patient in our collaborative Phase 2b study with Dr. Falk Pharma, marking a key milestone in the development of naronapride for gastroparesis. This latest achievement is a testament to the strength of our joint-clinical development team, and our unwavering commitment to provide a safe and effective treatment for gastroparesis." said Dr. Peter Milner M.D., FACC, Chairman, and CEO of Renexxion. "The rapid integration of multiple research sites across the U.S. signifies the widespread recognition of the potential benefits that naronapride may offer to patients with gastroparesis."

Dr. Kai Pinkernell, M.D., Managing Director, Science & Innovation at Dr. Falk Pharma, added, "As the partner in Europe and Australasia, we are pleased to announce that Renexxion has facilitated the expansion of our ongoing Phase 2b MOVE-IT study to clinical sites in the U.S. The extension of this study is a testament to our strong partnership and will expedite the clinical development of naronapride for gastroparesis in our respective territories, as well as for other indications related to impaired GI motility."

Naronapride is a potential best-in-class oral, locally acting pan-GI prokinetic that works by modulating two validated targets on the luminal surface of the intestinal wall, 5-HT_4 receptor agonism and D_2 receptor antagonism, with a well-differentiated pharmaceutical, pharmacokinetics, safety, and efficacy profile from other 5-HT_4 agonists.

Gastroparesis is characterized by delayed gastric emptying in the absence of mechanical obstruction and is caused primarily by diabetic and idiopathic etiologies, with some recent increases in iatrogenic disease potentially associated with widespread use of anti-obesity medications such as glucagon-like peptide-1 (GLP-1) agonists. Gastroparesis is a prevalent condition globally, with approximately 1.7% of the population in the U.S. and 1% in Europe having gastroparesis-like symptoms. Gastroparesis affects 9.3% of patients with diabetes, while 15-30% of patients taking GLP-1 agonists experience nausea and 5-10% experience vomiting, both of which are common symptoms of gastroparesis.

There is a large, unaddressed demand for a safe and efficacious long-term therapy for gastroparesis. GI prokinetics play a crucial role in managing this condition. However, the

most prescribed options have limited efficacy and cause off-target side effects, including permanent damage to the central nervous system and life-threatening cardiac arrhythmias. Naronapride is a potential best-in-class solution for this large and underserved patient population due to its clinically validated dual-action therapeutic approach and its favorable safety profile to date, which has been demonstrated across four Phase 2 trials and eight Phase 1 trials. Moreover, naronapride has already shown dose-dependent acceleration of gastric emptying in a GI transit study involving healthy human volunteers.

"The rising prevalence of gastroparesis means increasingly more patients are experiencing symptoms of abdominal discomfort, nausea and vomiting, without having access to a safe and efficacious long-term treatment," said Jan Tack, MD, PhD, Professor and Head of Clinic in the Department of Gastroenterology at University Hospitals Leuven, Leuven, Belgium, and Principal Investigator for the MOVE-IT study. "A recently published meta-analysis demonstrated that pure 5-HT_4 agonists are associated with significant improvement in gastroparesis cardinal symptom index (GCSI) scores and faster gastric emptying time. This evidence supports the development of a novel 5-HT_4 receptor agonist with the added synergistic benefit of D_2 receptor antagonism, as a viable treatment for gastroparesis", he added.

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 5-HT_4 receptor agonistic and dopamine D_2 receptor antagonistic properties, both clinically validated targets. Naronapride was designed to be minimally absorbable and locally active in the gut lumen following oral administration to potentially enhance efficacy and safety. Four positive Phase 2 studies of naronapride have been completed. A Phase 2b study of naronapride in PPI-non-responsive symptomatic GERD is expected to commence in the next 12 months following the recent receipt of a May Proceed Letter and IND clearance from the FDA. Naronapride is also Phase 3 ready in chronic idiopathic constipation ("CIC").

About MOVE-IT

MOVE-IT is a Phase 2b, double-blind, randomized, multicenter, placebo-controlled study designed to evaluate the efficacy, safety, and tolerability of naronapride in treating patients with idiopathic or diabetic gastroparesis. This trial compares the effects of three daily doses of naronapride (10 mg, 20 mg, and 40 mg TID) versus placebo over 12 weeks in approximately 320 patients, aiming to alleviate gastroparesis symptoms and improve quality of life.

About Renexxion Ireland

Renexxion Ireland Limited, a wholly owned Irish subsidiary of California-based Renexxion, Inc, is a privately held biopharmaceutical company committed to developing new drugs for patients with GI disorders. In addition to developing its lead product candidate, naronapride, Renexxion Ireland is currently advancing an additional research program focused on developing innovative drug candidates for inflammatory bowel disease ("IBD") through the utilization of novel protein-drug conjugates.

Further information on Renexxion Ireland can be found online: http://www.rnexltd.ie.

About Dr. Falk Pharma GmbH

Dr. Falk Pharma GmbH has been developing and marketing innovative medicines to treat a wide range of gastrointestinal disorders like inflammatory bowel disease or eosinophilic esophagitis as well as hepato-biliary disorders such as primary biliary cholangitis for over 60 years. As the international experts in digestive and metabolic medicine, the company brings together physicians, scientists, and patients to devise new and powerful approaches to patient care. Dr. Falk Pharma engages in pre-clinical and clinical stage research that aims to meaningfully improve therapeutic practice as well as patient health and well-being. A family-owned business with a global presence, Dr. Falk Pharma has ten affiliates in Europe and Australia and is continuously growing. The company has its headquarters and R&D facilities in Freiburg, Germany, its pharmaceutical products are manufactured in Europe, mainly at sites in Germany, France, Italy, and Switzerland. The Falk Group has a global workforce of around 1,250 employees, with 294 of the employees based in Freiburg.

Further information on Dr. Falk Pharma can be found online: https://drfalkpharma.com.

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