Renexxion Ireland Ltd. and Dr. Falk Pharma GmbH Announce Completion of Enrollment of the Global Phase 2b Study Evaluating Naronapride in Gastroparesis (MOVE-IT)

ROSCREA, Ireland and FREIBURG, Germany, May. 27, 2025

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"), today announced the successful completion of patient enrollment for the 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 achieved its target enrolment of 320 patients, with topline results expected in the second half of 2025.

"We are delighted to have collaborated with our European partner, Dr. Falk Pharma, on this critical Phase 2b study, successfully completing patient enrollment." said Dr. Peter Milner M.D., FACC, Chairman and CEO of Renexxion. "This achievement underscores our shared commitment to harmonizing U.S. and EU clinical development and regulatory pathways, as we work to deliver a much-needed therapeutic option for patients suffering with gastroparesis."

Dr. Kai Pinkernell, M.D., Managing Director, Science & Innovation at Dr. Falk Pharma, added, "The completion of enrollment is a significant milestone in our partnership, reflecting the strength of collaboration between the clinical development, regulatory, and CMC teams at both companies, as well as the pressing need to address this life-altering condition. We eagerly anticipate the data readout in the second half of 2025 and are actively planning global Phase 3 studies to bring this promising therapy closer to patients in need."

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-HT4 receptor agonism and D2 receptor antagonism, with a well-differentiated pharmaceutical, pharmacokinetics, safety, and efficacy profile from other 5-HT4 agonists.

Gastroparesis is characterized by delayed gastric emptying in the absence of mechanical obstruction and is caused primarily by diabetic and idiopathic etiologies. 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 approximately 9.3% of patients with diabetes.

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 demonstrated limited efficacy and can 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 significantly underserved patient population due to its clinically validated dual-action therapeutic approach, minimal systemic bioavailability, and a favorable safety profile to date; 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.

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-HT4 receptor agonistic and dopamine D2 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 twelve months following 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 global 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 320 patients. The primary endpoint is the change from baseline in the average weekly total symptom score, as measured by the American Neurogastroenterology and Motility Society (ANMS) Gastroparesis Cardinal Symptom Index (GCSI) Daily Diary, a content-validated tool for assessing gastroparesis symptoms. Secondary endpoints will include additional efficacy measures, safety assessments, and patient-reported outcomes.

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 1,400 employees, with 340 of the employees based in Freiburg.

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

Media Inquiries:
Press@rnexltd.ie
+353 61 539121