Renexxion Ireland Ltd. and Dr. Falk Pharma GmbH Announce FDA Clearance of the Investigational New Drug Application for Naronapride to Treat Gastroparesis and Subsequent Expansion of the Ongoing Phase 2b MOVE-IT Study to the United States

ROSCREA, Ireland and Freiburg, Germany March 27th, 2024 – Renexxion Ireland Limited ("Renexxion"), a private biopharmaceutical company committed to delivering innovative drugs to patients with high unmet need in gastrointestinal ("GI") disorders, and European partner, Dr. Falk Pharma GmbH ("Dr. Falk Pharma"), announce U.S Food and Drug Administration (FDA) clearance of the Investigational New Drug (IND) application for naronapride to treat patients with gastroparesis. Naronapride is a potential best-in-class oral, locally acting pan-GI prokinetic, which 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. Renexxion and Dr. Falk Pharma will now expand patient enrollment for the ongoing global multi-center 320 patient placebo-controlled Phase 2b MOVE-IT study in gastroparesis to clinical sites in the United States (ClinicalTrials.gov ID: NCT05621811). Topline results for the Phase IIb trial are expected in mid-2025.

Gastroparesis is a serious chronic disorder characterized by delayed gastric emptying leading to upper gastrointestinal symptoms such as nausea, vomiting or bloating and is often caused by diabetes. It is an underdiagnosed condition with approximately 5.6 million people in the U.S. and 4.9 million people in the European Union, UK and Australia having symptoms consistent with gastroparesis. Current treatments for gastroparesis consist of prokinetic and anti-emetic medications which have limited efficacy and off-target side effects. Metoclopramide, a D_2 antagonist, is the only drug approved by the FDA for treatment in the U.S. and has a black-box warning. Naronapride is a potential solution for this large and underserved patient population due to its validated dual-action therapeutic mechanism and its favorable safety profile that has been demonstrated across four Phase 2 trials. Furthermore, naronapride has already demonstrated dose-dependent accelerated gastric emptying in a GI transit study of healthy human volunteers.

"Following the receipt of a May Proceed Letter and IND clearance from the FDA, we are pleased to be assisting our European partner, Dr. Falk Pharma, with conducting its multi-center Phase 2b MOVE-IT study in gastroparesis by expanding it to clinical sites in the U.S.," said Dr. Peter Milner M.D., FACC, Chairman and CEO of Renexxion. "Gastroparesis is becoming more prevalent globally, mainly as a consequence of rising cases of diabetes. Furthermore, the use of GLP-1 agonists in patients with obesity and obesity-related medical problems is surging and causing GI side effects consistent with symptomatic delayed gastric emptying, where prokinetics may be useful as an adjunct therapy. We are eager to accelerate the clinical development of naronapride to potentially satisfy the large unmet need for a safe and effective prokinetic, addressing the growing number of patients with delayed gastric emptying."

Dr. Kai Pinkernell, MD, Managing Director, Science & Innovation at Dr. Falk Pharma, added, "We are pleased to further advance our Phase 2b study in gastroparesis in close collaboration with our partner Renexxion, following this IND clearance from the FDA. We are

aligned in our belief in the transformative power of naronapride to revolutionize treatment for gastroparesis patients and its ability to reshape the gastroparesis treatment landscape."

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 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 H2 2024 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 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. In addition to developing its lead product candidate, naronapride, Renexxion Ireland is currently advancing an additional research program in inflammatory bowel disease ("IBD").

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 employs approximately 1250 individuals globally, thereof 294 in Freiburg.

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

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