Dr. Falk Pharma and Renexxion Reach Alignment with FDA and EMA on Phase 3 Program for Naronapride in Gastroparesis

Agencies aligned on trial design, endpoints and safety database; FDA agreed NDA-enabling studies can run in parallel with Phase 3

FREIBURG, Germany and ROSCREA, Ireland, October 21, 2026 (RENEXXION IRELAND) -- Dr. Falk Pharma GmbH ("Dr. Falk Pharma"), a research-based pharmaceutical company specializing in digestive and metabolic medicine, and Renexxion Ireland Limited ("Renexxion"), a clinical-stage biopharmaceutical company building leadership in GI motility disorders, today announced alignment with European and U.S. regulators on the Phase 3 program for naronapride in gastroparesis.

The alignment comes after successful completion of End of Phase 2 (EOP2) meetings with the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA), following the positive results from MOVE-IT (NCT05621811), a global Phase 2b, randomized, placebo-controlled trial of naronapride in adults with diabetic and idiopathic gastroparesis.

The FDA agreed that NDA (New Drug Application)-enabling studies, including in certain specific patient populations, can be conducted in parallel with the Phase 3 program, which the companies believe may streamline the overall development timeline.

Both agencies also aligned on the overall Phase 3 development strategy, including:

- Separate studies in diabetic and idiopathic gastroparesis
- Trial design and participant numbers
- Use of ANMS-GCSI-DD for primary and key secondary endpoints
- The planned safety database to support an NDA

This regulatory harmonization enables the companies to finalize Phase 3 plans which anticipate initiating the global program in the first half of 2027.

Dr. Kai Pinkernell, M.D., Managing Director Science & Innovation at Dr. Falk Pharma, commented: "We are very pleased with the outcome of our discussions with both the EMA

and FDA, and appreciate their collaborative approach as we advance the development of naronapride in gastroparesis. Patients living with this condition experience significant morbidity and increased healthcare utilization while long-term treatment options remain limited. We are committed to closing that gap in frontline GI care, with the aim of helping patients return to normal eating, daily functioning and better quality of life."

Peter Milner, M.D., FACC, Chairman and CEO of Renexxion, commented: "Naronapride was designed to act locally in the gut while limiting systemic exposure. With our Phase 3 plan defined, we can test again whether that design can help patients with gastroparesis and tackle an important unmet medical need. We look forward to advancing naronapride into late-stage development."

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About Naronapride

Naronapride is a potential best-in-class oral, locally acting pan-GI prokinetic designed to enhance coordinated motility across the digestive tract. Naronapride works through a differentiated dual mechanism of action- 5-HT4 receptor agonism and dopamine D2 receptor antagonism- modulating two validated targets on the luminal surface of the intestinal wall that regulate GI motility and nausea signaling. Naronapride's dual mechanism of action, minimal systemic bioavailability, and differentiated pharmaceutical and pharmacokinetic profile are designed to deliver targeted activity within the GI tract while limiting systemic exposure. To date, naronapride has demonstrated a favorable safety and tolerability profile across nine Phase 1 clinical trials and five Phase 2 clinical trials conducted in multiple indications including gastroesophageal reflux disease, erosive esophagitis and chronic idiopathic constipation.

About Gastroparesis

Gastroparesis is a chronic gastrointestinal disorder characterized by delayed gastric emptying and debilitating symptoms including nausea, vomiting, early satiety, upper abdominal pain and postprandial fullness. Approximately 22 per 100,000 individuals across US and Europe are formally diagnosed with gastroparesis. Despite the substantial disease burden, the availability of safe and effective long-term treatment options remains limited.

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 1,550 employees, with 450 of the employees based in Freiburg.

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

About Renexxion

Renexxion Ireland Limited is a late-stage clinical biopharmaceutical company building leadership in the treatment of gastrointestinal (GI) motility disorders. The Company's lead asset candidate, naronapride, is a safety-engineered prokinetic designed to restore gastrointestinal motility through dual validated mechanisms of action. Naronapride has demonstrated proof of concept in multiple indications, and has shown a favorable safety profile and no significant off-target safety concerns in studies. It is being developed for gastroparesis, PPI non-responsive GERD, and other motility-driven disorders. By addressing an underlying driver of disease rather than individual symptoms, Renexxion aims to improve outcomes for millions of patients living with chronic GI conditions while unlocking a significant multi-indication market opportunity.

Media/IR Inquiries:
ICR Healthcare
Sarah Elton-Farr, Ben Shannon, Jonathan Edwards
Tel: +44 20 3709 5700
Email: renexxion@icrhealthcare.com