

## **Dr. Falk Pharma and Renexxion Proceed to Late-Stage Development of Naronapride, Moving Towards Approval in the US and Europe, Following Positive Global Phase 2b Results in Gastroparesis**

- Renexxion plans to file new drug application (NDA) with the Food and Drug Administration (FDA) using future Phase 3 results

ROSCREA, Ireland and FREIBURG, Germany, June 01, 2026, Renexxion Ireland Limited (“Renexxion”), a private biopharmaceutical company committed to delivering innovative drugs to patients with high unmet need in gastrointestinal (“GI”) disorders, today announced that its partner Dr. Falk Pharma GmbH (“Dr. Falk Pharma”), a research-based pharmaceutical company specializing in digestive and metabolic medicine, is advancing the development of naronapride beyond Phase 2b into pivotal studies on the treatment of gastroparesis. This marks the next stage in the partnership’s regulatory-harmonized global development program, with Renexxion planning to use the Phase 3 results to file a new drug application for approval in the US.

This step follows positive results achieved in the 328-patient global Phase 2b MOVE-IT study (ClinicalTrials.gov ID: NCT05621811) evaluating naronapride in gastroparesis.

“We are highly encouraged by the positive Phase 2b results for naronapride, which underscore its potential to address the significant unmet need in gastroparesis,” said Dr. Kai Pinkernell, M.D., Managing Director, Science & Innovation at Dr. Falk Pharma. “These data reinforce our commitment to the program, and we look forward to advancing naronapride through late-stage development, working with Renexxion’s team and bringing this important therapy to patients in need.”

“We are proud of Dr. Falk Pharma’s continued commitment to advancing naronapride for gastroparesis,” said Dr. Peter Milner, M.D., FACC, Chairman and CEO of Renexxion. “Moving into pivotal studies is a significant milestone for naronapride and for the gastroenterology community. We look forward to continued collaboration towards approval.”

Today's announcement represents a significant step towards providing access to naronapride for patients in need worldwide.

### **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-HT<sub>4</sub> receptor agonism and dopamine D<sub>2</sub> 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, while up to 12-times more experience symptoms consistent with the disease. 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. Falk employs approximately 1,550 individuals globally and 450 in Freiburg.

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

### **About Renexxion**

Renexxion Ireland Limited is a wholly owned Irish subsidiary of California-based Renexxion, Inc. Renexxion is a privately held biopharmaceutical company committed to developing new therapies for patients with gastrointestinal disorders. Renexxion's lead program is naronapride, a late-stage drug candidate being developed for multiple unmet indications in the upper and lower GI tract.

Further information on Renexxion can be found online: <https://www.rnexltd.ie>

### **Media Inquiries:**

Press@rnexltd.ie

+353 61 539121