

Dr. Falk Pharma and Renexxion announce positive results on naronapride in gastroparesis from the global phase 2b MOVE-IT trial

- MOVE-IT met the primary endpoint with statistically significant improvement in gastroparesis symptoms in 20 mg and 40 mg TID doses vs placebo
- Improvements observed across key symptoms, including nausea, early satiety, post-prandial fullness and upper abdominal pain
- Favorable safety and tolerability profiles
- Late-breaking oral presentation delivered at Digestive Disease Week (DDW) 2026 in Chicago, IL

FREIBURG, Germany and ROSCREA, Ireland – May 4, 2026 – 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, today announced positive results from MOVE-IT (NCT05621811), a global Phase 2b, randomized placebo-controlled trial evaluating the efficacy, safety, and tolerability of naronapride in adults with gastroparesis.

The double-blind, multicenter, 12-week study enrolled 328 adults with moderate-to-severe idiopathic or diabetic gastroparesis symptoms and objective evidence of delayed gastric emptying. Eligible patients received either 10 mg, 20 mg, 40 mg naronapride, or placebo, administered orally three times a day (TID) for 12 weeks.

MOVE-IT met the primary endpoint, demonstrating statistically significant improvement versus placebo in the American Neurogastroenterology and Motility Society Gastroparesis Cardinal Symptom Index Daily Diary (ANMS GCSI-DD) Core Symptom Score in the 20 mg TID ($p=0.0046$) and 40 mg TID ($p=0.0156$) groups. The ANMS GCSI-DD is a content-validated, patient-reported outcome instrument that assesses the five cardinal gastroparesis symptoms: nausea, vomiting, early satiety, postprandial fullness and upper abdominal pain.

Table 1. Primary endpoint – Change from baseline to Week 12 in the average weekly ANMS GCSI-DD Core Symptom Score

		Naropride 10 mg TID	Naropride 20 mg TID	Naropride 40 mg TID	Placebo TID
Total Population		N=83	N=80	N=80	N=85
Baseline (BSL)	Mean (SD)	2.450 (0.388)	2.429 (0.341)	2.462 (0.450)	2.402 (0.396)
Week 12	Mean (SD)	1.155 (0.797)	0.883 (0.759)	0.907 (0.780)	1.280 (0.911)
Change to Week 12	LS Mean (SE)	-1.244 (0.100)	-1.512 (0.102)	-1.452 (0.100)	-1.106 (0.095)
	+/- 95% CI	[-1.440, -1.048]	[-1.712, -1.311]	[-1.649, -1.256]	[-1.293, -0.920]
Difference to Placebo	LS Mean (SE)	-0.138 (0.136)	-0.405 (0.137)	-0.346 (0.136)	
Dunnett-Hsu Adjusted	97.5%-CI p-value†	[-∞, 0.183] 0.3112	[-∞, -0.081] 0.0046	[-∞, -0.024] 0.0156	

CI = Confidence interval; LS Means = Least square means; N = Number of participants in analysis population; SD = Standard deviation; SE = Standard error. † One-sided

Naropride also demonstrated statistically significant improvements versus placebo from baseline to Week 12 across key secondary and exploratory endpoints in the total population:

- **ANMS GCSI-DD Composite Score (core score excluding vomiting):** Statistically significant improvements observed in 20 mg ($p=0.0024$) and 40 mg ($p=0.0117$) TID dose groups versus placebo.
- **Responder Analyses:** Approximately 15-20% more participants achieved clinically meaningful improvement (defined as >1.0 decrease in ANMS GCSI-DD Composite Score) with naropride 20 mg or 40 mg TID vs. placebo, with no added benefit of 40 mg over 20 mg.
- **Patient-Reported Quality of Life (QoL):** Global improvements reflecting meaningful benefit beyond core symptom reduction and supporting consistency of treatment effect across validated symptom assessment instruments.
- **Improvement in gastric emptying breath test (GEBT):** All active doses achieved greater gastric emptying versus placebo. Maximum improvement with 20 mg (mean -21.95 minutes) and 40 mg (mean -14.92 minutes) versus placebo (mean -10.96 minutes).

Consistent with previous studies, the safety and tolerability profiles were favorable, with no new safety signals identified versus placebo, including cardiac, neuropsychiatric, or prolactin-related signals. To date, naropride has been studied in over 1200 subjects, with a safety profile reflecting its minimal systemic absorption.

Dr. Kai Pinkernell, M.D., Managing Director Science & Innovation at Dr. Falk Pharma, commented: “We are excited about the outcomes showing a significant and clinically meaningful impact on gastroparesis symptoms, all combined with a favorable safety profile. This is an important step towards providing physicians and patients with a treatment option where few effective choices exist. We look forward to sharing these results with the scientific community, engaging with regulatory authorities, and moving decisively toward registration studies later this year and eventual commercialization.”

Dr. Peter Milner, M.D., FACC, Chairman and CEO of Renexxion, commented: “These Phase 2b results represent a significant milestone for the naronapride program, demonstrating statistically significant improvement in gastroparesis symptoms with a favorable safety and tolerability profile. We believe naronapride’s locally acting, dual mechanism pharmacology and safety-by-design profile position it as a potential best-in-class therapy for gastroparesis, a disease with significant unmet medical need and limited, safe, effective long-term treatment options. Together with our partner Dr. Falk Pharma, we are now focused on advancing naronapride into late-stage development with the goal of bringing an important new treatment option to physicians and patients.”

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 pharmacology, 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 hepatobiliary 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, a wholly-owned Irish subsidiary of California-based Renexxion, Inc., 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>

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