



## **Renexxion Ireland Ltd. and Dr. Falk Pharma GmbH Announce Initiation of Phase II Study of naronapride in patients with gastroparesis**

*Randomized, double-blind, placebo-controlled study to evaluate efficacy of novel pan-GI prokinetic in patients with gastroparesis*

ROSCREA, Ireland and FREIBURG, Germany, 15<sup>th</sup> February 2023/PR Newswire/ – Renexxion Ireland Limited, a private biopharmaceutical company committed to delivering innovative drugs to patients with high unmet need in gastrointestinal (“GI”) disorders, is pleased to announce that the first patient has been treated in Europe with naronapride, a potential best-in-class pan-GI prokinetic, in a Phase IIb trial for gastroparesis conducted by Dr. Falk Pharma GmbH (Dr. Falk Pharma).

The Phase IIb trial is a multi-center, randomized, double-blind, placebo-controlled study evaluating the efficacy, safety and tolerability of naronapride in patients with gastroparesis. Study investigators will enroll and randomize approximately 300 patients to receive either naronapride at 1 of 3 doses or placebo daily for 12 weeks. The primary endpoint of the trial is change from baseline in the signs and symptoms of either idiopathic or diabetic gastroparesis. Several additional secondary and exploratory endpoints will also be evaluated to further elucidate the efficacy and safety profile of naronapride, as compared to placebo.

Gastroparesis is a serious chronic disorder characterized by delayed gastric emptying leading to upper gastrointestinal symptoms such as nausea, vomiting or bloating. Gastroparesis is frequently associated with significant impairment of social and occupational functioning. Despite the high-unmet medical need, there is no approved drug in this indication available.

“At Renexxion Ireland, we are delighted to be working with Dr. Falk Pharma to bring naronapride to market in greater Europe. Naronapride accelerated gastric emptying in early clinical trials in the US and had a safety profile comparable with placebo in those studies. The results from this study will help further development of the drug for gastroparesis, a debilitating condition with a high unmet clinical need for which there are very few long term treatment options.”, said Peter Milner M.D., FACC, Chairman and CEO.

Roland Greinwald, PhD, Managing Director Medicine & Pharmaceuticals of Dr. Falk Pharma GmbH, adds, “The initiation of the Phase II study MOVE-IT marks an important milestone in our endeavor of developing an effective and safe drug for the treatment of gastroparesis. Together with Renexxion Ireland it is our goal to help patients suffering from this debilitating disorder which at this stage lacks satisfying treatment options.”

The Phase IIb, multi-center, pan-EU clinical trial is being undertaken as part of a licensing and collaboration agreement with Dr. Falk Pharma, to evaluate the efficacy, safety and tolerability of naronapride in a cohort of subjects with gastroparesis. The study will form part of the clinical development plan for use of naronapride in gastroparesis. Topline results for the Phase IIb trial are expected in H1, 2025.

### **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 5HT<sub>4</sub> receptor agonistic and dopamine D<sub>2</sub> receptor antagonistic properties, both clinically validated targets. Naronapride is designed to be minimally absorbable, is locally active in gut lumen, and in clinical studies its side-effect profile is indistinguishable from placebo. Four positive Phase II studies have been completed and naronapride is Phase III ready in chronic idiopathic constipation (CIC) and gastro-esophageal reflux disease (GERD).

Renexxion Ireland Limited  
A Limited Company registered in Dublin, Ireland

Company registration number: 667671

Registered address: Carlton House, 4<sup>th</sup> Floor, Henry Street, Limerick, V94 FD80, Ireland



Naronapride has been studied in 11 clinical studies and more than 1000 subjects to date. In these studies, naronapride has been well-tolerated with a safety profile that did not differ from the placebo-treated patients in clinical studies. Importantly, with naronapride no cardiovascular effects, including no effects on heart rate, blood pressure or ECG parameters, have been observed in clinical studies.

#### **About gastroparesis:**

Gastroparesis is a digestive disorder characterized by delayed gastric emptying of solid food in the absence of mechanical obstruction of the stomach, resulting in the cardinal symptoms of early satiety, postprandial fullness, nausea, vomiting, belching and bloating. It is now recognized as part of a broader spectrum of gastric neuromuscular dysfunction that includes impaired gastric accommodation. The total prevalent population of gastroparesis in the 7 major markets is expected to rise from 33,690,400 (2017) to 36,167,100 (2030) between 2017 and 2030. 44% of the 7 major market cases are in the European countries.

#### **About Renexxion Ireland:**

Renexxion Ireland Limited is a privately held, Irish biopharmaceutical company committed to delivering new drugs to patients with GI disorders. Renexxion Ireland is collaborating with Dr Falk Pharma to advance naronapride through the later stages of development and commercialization in Greater Europe and certain other Australasian countries. (For information: <https://www.prnewswire.com/news-releases/renexxion-ireland-ltd-announces-a-licensing-and-collaboration-agreement-with-dr-falk-pharma-gmbh-301392102.html>). Renexxion Ireland is currently advancing an additional research program in inflammatory bowel disease.

For more information: <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 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. Dr. Falk Pharma employs approximately 1000 individuals globally, thereof 216 in Freiburg.

For more information: <https://drfalkpharma.com>

#### **Contacts:**

**Renexxion Ireland:** Catherine Pearson, Chief Operating Officer: [Press@rnexltd.ie](mailto:Press@rnexltd.ie) / +353 61 539121.

**Dr. Falk Pharma:** Roland Greinwald, PhD, Managing Director Medicine & Pharmaceuticals: [zentrale@drfalkpharma.de](mailto:zentrale@drfalkpharma.de) / +49 761 1514-0.

Renexxion Ireland Limited  
A Limited Company registered in Dublin, Ireland

Company registration number: 667671

Registered address: Carlton House, 4<sup>th</sup> Floor, Henry Street, Limerick, V94 FD80, Ireland