Renexxion Ireland's European Partner, Dr. Falk Pharma GmbH, has Elected PPI-non-responsive Symptomatic GERD as the Second Naronapride Indication to Develop and Commercialize in their Licensed Territories

ROSCREA, Ireland, and FREIBURG, Germany (GLOBE NEWSWIRE) [February, 7, 2024]– Renexxion Ireland Limited ("Renexxion"), a private biopharmaceutical company committed to delivering innovative drugs to patients with high unmet need in gastrointestinal ("GI") disorders, announced today that its European Partner, Dr. Falk Pharma GmbH ("Dr. Falk Pharma"), has elected to advance the development of naronapride for patients with proton-pump inhibitor non-responsive symptomatic gastroesophageal reflux disease (PPI-nrsGERD) as the second indication in their licensed territories. This marks an expansion of a pre-existing partnership that also encompasses the evaluation of naronapride for gastroparesis, which is currently undergoing a Phase 2b trial in Europe.

In October 2021, Renexxion and Dr. Falk Pharma announced an exclusive Licensing and Collaboration Agreement to advance naronapride initially for gastroparesis in Greater Europe (including UK), Russia, Central Asian Republics, and certain Australasian countries. Today, Renexxion is pleased to confirm that Dr. Falk Pharma will also advance naronapride for PPI-non-responsive symptomatic GERD in these regions. Renexxion will receive undisclosed development and commercial milestones related to this expanded collaboration.

GERD is a prevalent disease affecting between 10-20% of Europeans. Up to 30-40% of patients do not achieve adequate control with PPIs and there is a high unmet need for an adjunctive therapy to achieve greater symptom control.

Naronapride is a late-stage potential best-in-class oral, locally acting pan-GI, dual-action 5-HT_4 agonist/D_2 antagonist prokinetic that is in development as an adjunctive therapy for GERD patients who fail to respond adequately to acid-suppression treatments. Renexxion recently received IND clearance from the U.S. Food and Drug Administration (FDA) for the development of naronapride for patients with PPI-non-responsive symptomatic GERD and plans to begin a U.S. Phase 2b trial in this condition later in 2024.

"Approximately one-third of GERD patients continue to suffer from heartburn and regurgitation despite using PPIs. It's becoming increasingly clear that GI dysmotility may be a significant contributor to the persistence of these symptoms. Combining PPIs with 5-HT_4 prokinetics has shown greater effectiveness than PPIs alone. However, many marketed prokinetics are not safe to use long-term and do not provide significant benefit. Access to a safe and effective prokinetic could be a valuable adjunctive therapeutic option for PPI-nrsGERD patients." said Professor Ahmed Madisch M.D., Center of Gastroenterology Bethany, Agaplesion Hospital Bethany, Frankfurt, Germany.

Kai Pinkernell, Ph.D., Managing Director, Science & Innovation at Dr. Falk Pharma added "We believe naronapride has great potential to benefit patients with a wide variety of medical conditions arising from impaired GI motility. As the partner in Europe and Australasia, we are excited to be joining Renexxion in developing naronapride for PPI-non-responsive symptomatic GERD, as we see the positive impact naronapride can bring to this large

population of patients. This is a welcomed addition to our pipeline which includes naronapride for gastroparesis."

"We are very pleased that our European partner, Dr. Falk Pharma, chose PPI-nrsGERD as its next indication for development for naronapride in their territories. This partnership is pivotal to our mission, as it aims to expand access for the substantial segment of GI patients who are currently underserved by existing treatment options," said Peter Milner M.D., FACC, Chairman and CEO of Renexxion.

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 $5HT_4$ 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 have been completed and naronapride is Phase 3 ready in chronic idiopathic constipation ("CIC") and gastro-esophageal reflux disease ("GERD").

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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