INNOVATION DRIVES EVERYTHING

Press release

Renexxion Ireland Ltd. & Dr. Falk Pharma GmbH announce a Licensing and Collaboration Agreement

Renexxion Ireland Ltd., a private biopharmaceutical company committed to delivering innovative drugs to patients with high unmet need gastrointestinal ("GI") disorders, announced today that it has entered into a Licensing and Collaboration Agreement with Dr. Falk Pharma GmbH to jointly develop and commercialize Naronapride, a unique late-stage GI prokinetic, initially for gastroparesis.

- Renexxion Ireland and Dr. Falk Pharma have entered an exclusive Licensing and Collaboration Agreement to advance Naronapride through the later stages of development in Greater Europe (including UK), Russia, Central Asian Republics, and certain Australasian countries.
- As part of the Licensing and Collaboration Agreement, Dr. Falk Pharma has made an up-front payment and has committed to significant development funding, clinical, regulatory and sales milestone payments plus double-digit tiered royalties in addition to clinical and operational support.
- Renexxion Ireland retains the remaining rights to Naronapride worldwide, including Greater China, the United States and Japan, and this collaboration with Dr. Falk Pharma will serve as an important catalyst to Renexxion advancing Naronapride to patients with GI motility disorders worldwide.
- Renexxion Ireland will manage its obligations under the Licensing and Collaboration Agreement including additional research from its base of operations in Roscrea, Ireland.

Naronapride is a late-phase clinical stage drug candidate which possesses a unique combination of both serotonin 5HT4 receptor agonistic and dopamine D2 receptor antagonistic properties, both of which are clinically validated targets and work in both the upper and lower GI tract.

"Dr. Falk Pharma is a leader in GI drug development and commercialization in Europe and has the knowledge, experience and deep clinical and commercial insights which will be a transformational collaboration for Renexxion Ireland, leading to key inflection points in the company's growth trajectory," said Peter Milner M.D., FACC, Chairman and CEO.

Roland Greinwald, PhD, Managing Director Medicine & Pharmaceutics of Dr. Falk Pharma GmbH], commented, "Naronapride, a GI prokinetic with a unique target profile, has the potential to be the first-in-class treatment for gastroparesis, a disorder which has no currently approved treatments."

According to Prof. Jan Tack as an expert for Gastrointestinal Disorders and Head of the Clinic, Department of Gastroenterology, University Hospitals Leuven, Belgium, "Naronapride is a perfect candidate with an expected best-in class potential, to fit for the treatment of gastroparesis due to its dual mode of action, i.e., pro-kinetic effect as a very potent 5-HT4 agonist and its anti-emetic properties as a dopamine D2 antagonist. At the same time, due to its rapid metabolism, Naronapride is expected to work essentially only topically and thus a very good safety profile is anticipated."

About unmet GI motility disorders and gastroparesis

No safe and effective GI motility agent is currently available to patients. The last such agents approved were cisapride (Propulsid®) and tegaserod (Zelnorm®), which each sold over $1Bn annually and were withdrawn over 10 years ago due to cardiac safety concerns.

Gastroparesis is a serious chronic disorder characterized by delayed gastric emptying leading to upper gastrointestinal symptoms such as nausea, vomiting or bloating. The estimated prevalence of gastroparesis has been reported to be 24.2 per 100,000 in U.S.; and appears to be more prevalent in women. Gastroparesis is frequently associated with significant impairment of social and occupational functioning. Despite the high-unmet medical need, there is currently no approved drug in this indication available.

About Naronapride – Potential best-in-class treatment for unmet GI indications

Naronapride is a late-phase clinical stage drug candidate which possesses a unique combination of both 5HT4 agonistic and D2 antagonistic properties and works in both upper and lower GI. It is locally active in gut lumen, designed to be minimally absorbable, side-effect profile indistinguishable from placebo. Four positive Phase 2 studies completed in upper and lower GI indications and is Phase 3 ready in CIC (chronic idiopathic constipation) and GERD (gastro-esophageal reflux). Naronapride was engineered to avoid any cardiac safety risk. Its oral formulation serves large unmet needs in CIC, IBS-c, PPI-resistant GERD and gastroparesis.

About Renexxion

Renexxion Ireland Ltd. is a privately held biopharmaceutical company committed to delivering new drugs to patients with GI motility disorders with its operations and drug development team based in Ireland. For more information, refer to 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 and Switzerland. Dr. Falk Pharma GmbH employs approximately 990 individuals globally, of those 214 in Freiburg.

Further information on Dr. Falk Pharma globally can be found online: https://drfalkpharma.com or by contacting Ms Babette Kopp, Corporate Communications, Dr Falk Pharma GmbH. Email babette.kopp@drfalkpharma.de or phone +49 761 1514-280.

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