Renexxion Announces Opening of Investigational New Drug (IND) Application for Naronapride for the Treatment of Gastrointestinal Dysmotility in Cystic Fibrosis Patients

ROSCREA, Ireland, 10th January, 2023 /PRNewswire/ – Renexxion Ireland Limited (Renexxion), a private biopharmaceutical company committed to delivering innovative drugs to patients with high unmet need in gastrointestinal ("GI") disorders, is pleased to announce opening of the Investigational New Drug (IND) application with the U.S Food and Drug Administration (FDA) for naronapride for the treatment of GI motility disorders in patients with cystic fibrosis (CF), a first step towards conducting clinical trials of this drug candidate in CF patients. Naronapride, post approval, could be a potential best-in-class pan-GI prokinetic for the treatment of GI Dysmotility in CF.

GI dysmotility in CF has a complex neuroendocrine pathophysiology causing significant morbidity and it is listed as a top research priority by patients. GI dysmotility affects more than half of the patients with CF and is characterized by gastroparesis, abdominal pain, and severe refractory constipation. Although there have been advances in the treatment of CF, there is still an unmet need for the treatment of GI symptoms. Naronapride is a novel small molecule, pan-GI prokinetic with positive results from Phase II clinical trials in upper and lower GI indications and has demonstrated a comparable safety profile to placebo, making naronapride a potentially safe and effective treatment for GI dysmotility in CF.

"We are very excited about the potential of naronapride to improve the quality of lives of individuals with CF. Following discussions with the CF Foundation, CF Key Opinion Leaders and our European partner; we have identified a high unmet need for the treatment of GI dysmotility in CF. We have received constructive input from the FDA on both our clinical development plan and Phase II clinical trial design. Receiving IND clearance represents a major milestone in moving forward with our clinical development plan in parallel with our partner in EU in gastroparesis", said Peter Milner M.D., FACC, Chairman and CEO.

"The global cystic fibrosis patient community remains in need of effective treatments for gastrointestinal motility complications like constipation and gastroparesis. Despite advances in treatments for the pulmonary complications of cystic fibrosis, no pro-motility drugs have replaced cisapride since its withdrawal from the market," said Zachary Sellers, MD, PhD, Assistant Professor of Pediatrics-Gastroenterology at Stanford University School of Medicine.

Confirming the unmet need for a GI promotility agent in patients with CF, Dhiren Patel, M.D., Associate Professor of Pediatrics at the St. Louis University School of Medicine said, "We welcome clinical trials of naronapride in cystic fibrosis patients with gastrointestinal motility disorders. If naronapride is proven to be effective in treating these patients, it would significantly improve their quality of life."

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 5HT4 receptor agonistic and dopamine D2 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).

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. Importantly, with naronapride no cardiovascular effects, including no effects on heart rate, blood pressure or ECG parameters, have been observed in clinical studies.

About Renexxion:

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

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