

Renexxion Ireland Ltd. Announces Issuance of Fifth New U.S. Patent Covering Novel Crystal Isoform of Naronapride

ROSCREA, Ireland, Nov. 26th, 2024 (GLOBE NEWSWIRE) - Renexxion Ireland Limited (“Renexxion”), a private biopharmaceutical company dedicated to delivering innovative treatments for patients with significant unmet needs in gastrointestinal (“GI”) disorders, is pleased to announce a major milestone in its intellectual property portfolio. The United States Patent and Trademark Office (“USPTO”) has granted the fifth patent (Patent No. 12,098,149) in a comprehensive series, securing broad protection for a novel crystal isoform of naronapride, Renexxion’s lead compound, and its use in the treatment of GI disorders.

“We are pleased to have secured this patent, which not only underscores the innovative nature of naronapride but also strengthens our ability to deliver transformative therapies to patients who urgently need new treatment options,” said Dr. Pascal Druzgala, PhD, Co-founder, Director and Chief Scientific Officer of Renexxion. “The patent is part of a comprehensive IP portfolio, solidifying our commitment to pioneering advancements in GI disorders as we continue to advance naronapride in mid-stage clinical trials.”

This new pharmaceutical composition patent marks the fifth in a series covering naronapride, with its novel crystal isoform; a potential best-in-class, orally administered pan-GI prokinetic agent. Naronapride functions by modulating two clinically-validated targets: 5-HT4 receptor agonism and D2 receptor antagonism. It has demonstrated a well-differentiated profile in terms of pharmaceutical properties, pharmacokinetics, safety, and efficacy compared to other 5-HT4 agonists in clinical studies. Naronapride is Renexxion’s lead drug candidate, currently in mid-stage clinical development for gastroparesis and proton-pump inhibitor non-responsive symptomatic gastroesophageal reflux disease (“PPI-nrsGERD”), both of which represent high unmet needs with limited or no existing treatments. The new patent is also being prosecuted worldwide, including in Europe, Japan, and Greater China.

“Securing this patent strengthens our intellectual property portfolio, continuing progress on naronapride’s global clinical development,” said Dr. Peter Milner, M.D., FACC, Chairman and CEO of Renexxion. “We are dedicated to sustaining this momentum and eagerly anticipate further achievements.”

About Naronapride:

Naronapride is Renexxion Ireland’s flagship program, addressing critical unmet needs in both upper and lower GI tract disorders. It uniquely combines serotonin 5-HT4 receptor agonistic and dopamine D2 receptor antagonistic properties, targeting clinically-

validated receptors. Designed for minimal absorption and local activity in the gut lumen, naronapride aims to optimize both efficacy and safety. Following the completion of four successful Phase 2 studies, a global Phase 2b study in gastroparesis is currently underway (ClinicalTrials.gov ID: NCT05621811). An additional Phase 2b study targeting PPI-nrsGERD is anticipated to launch within the next year, following the FDA's May Proceed Letter and IND clearance. Furthermore, Renexxion is preparing naronapride for Phase 3 trials in chronic idiopathic constipation ("CIC").

About Renexxion Ireland:

Renexxion Ireland Limited, a wholly-owned subsidiary of California-based Renexxion, Inc., is a privately held biopharmaceutical company committed to pioneering innovative treatments for GI disorders. In addition to developing its lead product candidate, naronapride, Renexxion Ireland is advancing a research program targeting inflammatory bowel disease ("IBD") through novel protein-drug conjugates.

For further information on Renexxion Ireland, please visit: <http://www.rnexltd.ie>.

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