



Renexxion Ireland Announces Issuance of a New US Patent covering Naronapride, a Clinical Stage Potential Best-in-Class Prokinetic Agent for Gastrointestinal disorders

ROSCREA, Ireland 23rd December, 2021 /PRNewswire/ – Renexxion Ireland Ltd., a private biopharmaceutical company committed to delivering innovative drugs to patients with high unmet need gastrointestinal (“GI”) disorders, announced today the issuance of a new US patent covering composition-of-matter of its lead drug candidate, naronapride, a unique late-stage GI prokinetic. The patent is also being prosecuted worldwide. Renexxion Ireland holds the worldwide rights to develop and commercialize naronapride.

- The new US composition-of-matter patent extends the loss of exclusivity for naronapride to 2038, excluding any patent-term adjustment.
- Naronapride is currently being developed for commercialization initially for high unmet medical need in gastroparesis in Greater Europe (including UK), Russia, Central Asian Republics and certain Australasian countries by its European licensing partner.
- Renexxion Ireland is considering potential development and commercialization partners in other areas worldwide, such as Greater China, Japan, and, possibly, North America.

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. Currently, the options to treat dysmotility disorders of the GI tract such as gastroparesis and other disorders such as IBS-c, GERD, and CIC, are limited.

“The new patent enables the company to develop and commercialize naronapride for multiple gastrointestinal disorders requiring a prokinetic over the next two decades in order to establish it as a potential best-in-class prokinetic.” said Peter Milner M.D., FACC, Chairman and CEO.

About unmet GI motility disorders

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such agents approved were cisapride (Propulsid®) and tegaserod (Zelnorm®), which each sold over \$1Bn annually and were withdrawn over 10 years ago due to cardiac safety concerns.

About Naronapride – Potential best-in-class blockbuster 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

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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>.

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