OROFLOW® Clinical Study Receives Ethics Approval, Expanding LTR Pharma's Intranasal Platform into Gastrointestinal Disease

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Highlights

- OROFLOW® becomes the first gastrointestinal application of LTR Pharma's proprietary intranasal platform to enter formal clinical evaluation.
- Human Research Ethics Committee (HREC) approval received for investigator-initiated clinical study following encouraging early clinical observations.
- Study builds on preliminary clinical experience suggesting potential improvements in swallowing function and eating-related chest pain in patients with Oesophageal Motility Disorders (OMD), a global market projected to reach approximately US$8.1 billion by 2034[1].
- Study to be independently led by Dr Peter Wu, Director of St George Motility Services.
- OROFLOW® is designed as a non-invasive alternative to current invasive OMD procedures, including surgery, pneumatic dilation and botulinum toxin injection.

LTR Pharma Limited (ASX:LTP) ("LTR Pharma" or "the **Company**") is pleased to announce that the South Eastern Sydney Local Health District Human Research Ethics Committee (HREC) has approved an investigator-initiated clinical study evaluating OROFLOW® in patients with Oesophageal Motility Disorders (OMD). The study will be independently led by Dr Peter Wu, Director of St George Motility Services at St George Hospital. The study follows preliminary clinical observations by Dr Wu suggesting that intranasal PDE5 inhibitor therapy may improve swallowing function and reduce eating-related chest pain in patients with oesophageal motility disorders.

PDE5 inhibitors have been investigated in oesophageal motility disorders for their ability to relax smooth muscle and reduce lower oesophageal sphincter pressure. This may render the oesophagus more distensible, allowing swallowed food to pass and empty more effectively. The anticipated clinical benefit is improved oesophageal emptying and a reduction in dysphagia (difficulty swallowing) and chest pain during eating, potentially helping patients return to more normal eating patterns and daily activities.

As a non-invasive intranasal spray, OROFLOW may be particularly suited to patients with swallowing difficulties, removing the need to take an oral tablet while offering a rapid route of administration.

Study Design

The PILOT study will be conducted in two stages. It will first assess the time course of OROFLOW's effect in healthy volunteers before progressing to patients with OMD. Investigators will evaluate effects on oesophageal contractility, bolus flow timing and bolus distension pressure.

The study population includes individuals diagnosed with achalasia, oesophageal outflow obstruction, diffuse oesophageal spasm and oesophageal hypercontractility who are scheduled to undergo Peroral Endoscopic Myotomy (POEM).

The Company expects study initiation in the coming quarter and will provide updates on recruiting progress and data availability as milestones are achieved.

Dr Peter Wu said:

"Patients with achalasia and related motility disorders often face a difficult choice between living with debilitating symptoms and undergoing invasive procedures such as surgery or repeated dilation. In my practice, I have treated several achalasia patients with this intranasal approach and observed meaningful improvements in their ability to swallow, along with a reduction in chest pain during eating. These early observations are encouraging, but they need to be tested rigorously, which is the purpose of the PILOT study. If we can confirm a measurable effect on oesophageal function, a fast-acting and non-invasive treatment could change how these patients are managed, potentially reducing or delaying the need for surgery."

Strategic Significance

The study represents the first formal clinical evaluation of LTR Pharma's proprietary intranasal platform outside erectile dysfunction and is expected to provide important proof-of-concept data regarding the broad applicability of the platform. Success could support the development of additional intranasal therapies beyond erectile dysfunction and further expand the commercial potential of the platform. OMD remains an area of significant unmet need, with many patients ultimately requiring invasive interventions including surgery, pneumatic dilation or botulinum toxin injection. The global OMD treatment market was estimated at approximately US$4.5 billion in 2024 and is projected to reach US$8.1 billion by 2034.[1] Further updates, including study timelines, will be provided as the program progresses.

The study is funded by a research grant from LTR Pharma, administered through the South Eastern Sydney Local Health District. As an investigator-initiated study, it is designed, led and conducted independently by Dr Wu and his team, with no payments made to the investigators beyond their usual salaries.

LTR Pharma Executive Chairman, Lee Rodne, said:

"OROFLOW represents an exciting opportunity to apply the same rapid-acting intranasal delivery technology underpinning SPONTAN and ROXUS to a completely new therapeutic area. The decision by a leading motility specialist to independently evaluate this approach reflects growing clinical interest in the broader potential of our

platform. We are pleased to support research that could ultimately provide patients with a fast-acting, non-invasive alternative to existing treatment approaches."

About Oesophageal Motility Disorders

Oesophageal motility disorders are conditions characterised by abnormal movement and coordination of the oesophagus, leading to impaired swallowing and painful oesophageal contractions. Subtypes include achalasia, oesophageal outflow obstruction, diffuse oesophageal spasm and hypercontractile oesophagus.

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This announcement has been approved by the Board of Directors.

[1] Fact.MR. "Ineffective Oesophageal Motility Treatment Market Analysis | 2034." Fact.MR, 2024.

About LTR Pharma

LTR Pharma is a commercial-stage pharmaceutical company delivering innovative therapies to address significant unmet medical needs through its proprietary intranasal drug-delivery platform. The Company has successfully commercialised its rapid-acting treatment technology in Australia and is expanding access whilst advancing regulatory pathways in the US and other key markets.

LTR's lead products, **SPONTAN®** and **ROXUS®**, are fast-acting intranasal sprays for the treatment of erectile dysfunction, enabling onset of action in 10 minutes or less. Building on this proven technology, the Company is now advancing **OROFLOW®**, a novel intranasal spray under development for the treatment of Oesophageal Motility Disorders (OMD) – a debilitating group of conditions affecting swallowing function.

Through strategic partnerships, LTR Pharma is expanding its pipeline and global footprint to deliver differentiated, patient-centric treatments that enhance quality of life.

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