TGA Provides Regulatory Clearance for SPONTAN® Phase II Clinical Study

10 December 2025

Highlights

- TGA provides regulatory clearance of CTN, completing all regulatory requirements for commencement of the SPONTAN® Phase II study in Australia
- Study includes 65+ cohort to generate prescribing data for older men, a key demographic often underserved by oral PDE5 therapies
- Patient recruitment expected to commence Q1 CY2026

LTR Pharma Limited (ASX:LTP) ("LTR Pharma" or "the Company") is pleased to announce that the Therapeutic Goods Administration (TGA) has confirmed and accepted the Company's Clinical Trial Notification (CTN) for the SPONTAN® Phase II clinical study, providing regulatory clearance for the commencement of clinical trial activities in Australia.

This regulatory clearance completes all requirements for study initiation following the recent Human Research Ethics Committee (HREC) approval granted by Bellberry.

The Phase II study will assess single- and multiple-dose pharmacokinetics in approximately 27 healthy male participants across three cohorts. In line with FDA guidance for geriatric-use assessments, approximately half of all participants will be aged 65 years or older. The study is expected to generate important prescribing insights for physicians treating older men, a population that is frequently prescribed lower doses of oral PDE5 inhibitors such as Viagra and Cialis.

With regulatory clearance now in place, site activation activities are underway, and patient recruitment is expected to commence in Q1 CY2026.

LTR Pharma Executive Chairman, Lee Rodne, said:

"The TGA's regulatory clearance of our CTN represents an important milestone that enables the formal commencement of our Phase II study. With both ethics and regulatory requirements now complete, we are firmly on track to begin recruitment early in 2026. Importantly, this study is designed to provide valuable clinical insights for physicians treating erectile dysfunction in men aged 65 and over, a population that often requires adjusted dosing when using traditional oral PDE5 therapies."

- ENDS –

This announcement has been approved by the Board of Directors.

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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