Ethics Approval Received for SPONTAN® Phase II Clinical Study

3 December 2025

Highlights

- Ethics approval received for SPONTAN® Phase II pharmacokinetic and multiple-dose clinical study
- Study designed in accordance with FDA Pre-IND guidance to characterise single and multiple-dose pharmacokinetics
- Approximately 50% of participants aged 65+, addressing FDA geriatric use requirements
- Study expected to generate prescribing information for doctors treating men aged 65+, who are often prescribed lower doses of oral PDE5 tablets (Viagra, etc.)
- Recruitment to commence Q1 CY 2026
- Initial data expected Q2 CY 2026; full results mid-2026

LTR Pharma Limited (ASX:LTP) ("LTR Pharma" or "the Company") is pleased to announce that Human Research Ethics Committee (HREC) approval has been received from Bellberry, a leading independent ethics committee certified by the National Health and Medical Research Council (NHMRC), for the SPONTAN® Phase II clinical study, enabling the Company to progress toward patient recruitment in early 2026.

Study Design

The randomised cross-over study will be conducted at Scientia Clinical Research in Sydney and will recruit approximately 27 healthy male participants across three cohorts. In line with FDA guidelines for geriatric use, approximately half of all participants will be aged 65 years or older. This geriatric cohort is expected to provide important clinical data to guide prescribers on dosing considerations for older men, a group that is frequently prescribed lower doses of oral PDE5 inhibitors (such as Viagra) due to pharmacokinetic or tolerability factors.

Each participant will complete a 15-day residential period, receiving both single and multiple doses of SPONTAN, along with a control vardenafil tablet. Southern Star Research has been appointed as the Clinical Research Organisation (CRO), with Resolian Bioanalytics conducting pharmacokinetic blood sample analysis. Initial data is expected in Q2 CY 2026, with full study results mid-2026.

Regulatory Pathway

A Clinical Trial Notification will now be submitted to the Therapeutic Goods Administration (TGA) in Australia. The Phase II study represents a key requirement in LTR Pharma's FDA 505(b)(2) development pathway, building on the Company's completed Phase I study, which demonstrated 470% faster absorption versus oral tablets.

The inclusion of a robust 65+ cohort is expected to support future FDA and TGA guidance regarding prescribing recommendations in older men.

LTR Pharma Executive Chairman, Lee Rodne, said:

"Securing ethics approval allows us to commence a targeted Phase II study expressly designed to meet FDA expectations for multiple-dose pharmacokinetics and geriatric representation. Importantly, this study will generate valuable data to help physicians make informed prescribing decisions for men aged 65 and older, who often receive reduced-dose oral PDE5 therapies. With ROXUS on track for US market entry in the first half of 2026 and SPONTAN progressing through clinical development, we continue to execute our multi-market commercial strategy."

- 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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