Patient Recruitment Commences for SPONTAN® Phase II Clinical Study

13 January 2026

Highlights

- Patient recruitment commenced for SPONTAN® Phase II pharmacokinetic study in Australia
- Study includes a dedicated 65+ cohort to generate prescribing data for older men, a key demographic often underserved by oral PDE5 inhibitor therapies
- Initial data expected Q2 CY2026

LTR Pharma Limited (ASX:LTP) ("LTR Pharma" or "the Company") is pleased to announce the commencement of patient recruitment for its Phase II pharmacokinetic clinical study of SPONTAN®, its rapid-acting intranasal spray for the treatment of erectile dysfunction.

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 designed 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.

Recruitment follows completion of all regulatory requirements, including Human Research Ethics Committee (HREC) approval granted by Bellberry and TGA acceptance of the Company's Clinical Trial Notification (CTN), announced 10 December 2025.

LTR Pharma Executive Chairman, Lee Rodne, said:

"Commencing recruitment for our Phase II study is an important milestone that reflects the disciplined execution of our clinical development program. By including a dedicated cohort of men aged 65 and over, we are building clinical evidence for a population often underserved by oral ED therapies – and where SPONTAN's rapid, predictable intranasal delivery provides a meaningful advantage."

- 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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