SPONTAN® Phase II Clinical Study Completes Recruitment

5 March 2026

Highlights

- Recruitment complete for the SPONTAN® Phase II pharmacokinetic clinical study, with all 27 participants enrolled across three cohorts
- Final cohort of eight participants now undergoing dosing at the clinical research facility
- Study includes a dedicated 65+ cohort, generating clinical data for a key demographic often underserved by oral ED therapies
- Study designed in accordance with FDA Pre-IND guidance; initial data expected Q2 CY2026

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

All 27 participants have been enrolled across three cohorts, with the final cohort of eight participants now residing at the clinical research facility for the 15-day dosing period. In line with FDA guidance for geriatric-use assessments, approximately half of all participants are aged 65 years or older. Dosing is underway, with participants undertaking a 15-day residential period receiving single and multiple doses of SPONTAN and a control vardenafil tablet.

As oral PDE5 inhibitors are commonly initiated at lower doses in men aged 65 years and older due to increased systemic exposure, this dedicated cohort will generate important pharmacokinetic data to inform dose optimisation and future U.S. labelling discussions.

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 Pharmacokinetic Study, which demonstrated 5x faster absorption versus oral tablets. Initial data is expected in Q2 CY2026.

LTR Pharma Executive Chairman, Lee Rodne, said:

"Completing recruitment on schedule demonstrates the continued disciplined execution of our clinical program. This study was identified as a key requirement during our FDA Pre-IND engagement, and with dosing now underway for our final cohort, we are systematically advancing through the steps needed for our 505(b)(2) submission. We are firmly on track to deliver initial data in the second quarter."

- 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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