# First Patients Dosed in SPONTAN® Phase II Clinical Study

22 January 2026

## Highlights

- First patients dosed in SPONTAN® Phase II pharmacokinetic study
- Study on track with initial data expected Q2 CY2026
- Data is expected to support the FDA regulatory submission and represents a key value inflection milestone

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

First patient dosing marks the transition of the study from recruitment into active pharmacokinetic data generation, representing a significant execution milestone for the Company. The Phase II study is assessing 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 are aged 65 years or older. This data is expected to inform future prescribing information for older men, a population frequently managed with dose adjustments when using oral erectile dysfunction therapies. The resulting data is expected to play an important role in advancing SPONTAN's U.S. regulatory pathway and supporting the Company's broader commercial strategy.

Recruitment for the study commenced on 13 January 2026 (see ASX announcement dated 13 January 2026).

**LTR Pharma Executive Chairman, Lee Rodne, said:**

*"With first patients now dosed, our Phase II program is now actively generating data. This study will complete an important component of our FDA regulatory package, including pharmacokinetic insights for older patients that often require dose adjustments with oral ED 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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