

Final Phase II report confirms SPONTAN® six-fold faster absorption and completes FDA pharmacokinetic dataset

1 October 2026

Highlights

- **Final report completes the FDA pharmacokinetic dataset** for LTR Pharma's planned 505(b)(2) submission and U.S. licensing discussions, confirming the interim results with full statistical analysis.
- **Final dataset supports progression to submission-enabling activities in 2H CY2026**, with the pivotal Phase III study targeted to commence in 1H CY2027.
- **SPONTAN® achieves six-fold faster absorption than oral vardenafil tablets** (median 10 minutes for SPONTAN 5 mg versus 60 minutes for the 20 mg oral tablet), a statistically significant difference ($p < 0.0001$).
- **Predictable, approximately dose-proportional exposure across the SPONTAN doses studied**, with substantially lower metabolite exposure than the oral tablet.
- **No drug accumulation over five days of once-daily dosing and comparable pharmacokinetics in men aged 65 and over**, both key FDA requirements.
- **Favourable safety profile**: no serious adverse events, no Grade 3 or higher events and no discontinuations across all doses.

LTR Pharma Limited (ASX:LTP) ("LTR Pharma" or "the Company") confirms that the final Clinical Study Report for the SPONTAN® Phase II pharmacokinetic study (the Study) supports the [interim results announced on 1 May 2026](#) with full statistical analysis and completes the pharmacokinetic dataset agreed with the FDA for the planned U.S. 505(b)(2) submission. The report was prepared by independent clinical research organisation Southern Star Research.

SPONTAN reached peak blood concentration (T_{max}) in a median of 10 minutes (5 mg dose) and 11 minutes (2.5 mg dose), versus 60 minutes for the 20 mg oral vardenafil tablet. The difference between SPONTAN 5 mg and the oral tablet was statistically significant ($p < 0.0001$).

Exposure tracked dose closely. The fourfold lower dose of SPONTAN 5 mg produced approximately fourfold lower total exposure (AUC) than the 20 mg tablet, while doubling the SPONTAN dose from 2.5 mg to 5 mg approximately doubled exposure. Dose-normalised AUC point estimates were broadly comparable across treatments. Half-life was generally consistent across both routes, confirming that the principal difference between SPONTAN and the tablet was in the absorption phase rather than elimination. Exposure to the major metabolite (M1), by both C_{max} and AUC, was substantially lower for SPONTAN than for the oral tablet, an expected result as intranasal delivery avoids first-pass metabolism.

Five days of once-daily dosing showed no drug accumulation, and no clear pharmacokinetic differences were observed between men aged 65 and over, who made up 14 of the 27 participants, and younger adults. Both findings



address requirements agreed with the FDA at the Pre-IND meeting. Oral PDE5 inhibitors often require dose adjustment in older men.

SPONTAN was well tolerated. The safety analysis did not identify any new or unexpected treatment-emergent adverse events. Treatment-related events were predominantly mild and self-resolving, with no serious adverse events, Grade 3 or higher events, treatment discontinuations or study withdrawals. The most frequently reported treatment-related events included nasal congestion and headache, consistent with the known pharmacology of vardenafil and the intranasal route of administration.

LTR Pharma Chief Medical Officer, Professor Geoffrey Strange, said:

"The final report confirms the interim analysis and is consistent with the rapid absorption we demonstrated in our Phase I study. A median time to peak concentration of 10 minutes at a quarter of the oral dose, with no accumulation on repeat dosing and comparable pharmacokinetics in men aged 65 and over, gives us a complete, well-characterised pharmacokinetic picture. These results strongly support SPONTAN's positioning as a rapid-onset, on-demand therapy."

Comparative Pharmacokinetic Results

Parameter	SPONTAN® 5 mg	SPONTAN® 2.5 mg	Vardenafil 20 mg oral tablet
Tmax, median (range)	10 minutes (10–15)	11 minutes (5–60)	60 minutes (30–186)
Cmax (mean ± SD, ng/mL)	8.9 ± 6.8	5.8 ± 4.9	19.8 ± 8.8
Half-life (t½, mean)	4.4 hours	3.8 hours	4.4 hours
Dose-normalised AUC0-inf (ng·h/mL/mg)	3.6	4.8	3.2
Accumulation ratio (5 days once-daily dosing)	1.0 ± 0.9	n.a.	n.a.
Serious adverse events / Grade 3+ TEAEs / discontinuations	0	0	0

Final Clinical Study Report results (SDS089 (SPONTAN)-PK-02; n=27, including 14 participants aged ≥65 years). Tmax is presented as median (range). Cmax and accumulation ratio are presented as mean ± SD. The Tmax difference between SPONTAN 5 mg and oral vardenafil 20 mg was statistically significant (p<0.0001). Lower absolute exposure reflects lower administered doses. n.a. = not applicable.

Study Outline

The Study involved 27 healthy adult males, including 14 aged 65 and over, in a randomised, open-label, three-way crossover design agreed with the FDA under Pre-IND guidance. Part 1 compared single doses of SPONTAN (2.5 mg and 5 mg) with the 20 mg oral tablet; Part 2 evaluated SPONTAN 5 mg once daily for five days. All participants completed the Study, which was conducted at Scientia Clinical Research in Sydney, with Southern Star Research as the CRO and Resolian Bioanalytics providing bioanalysis. Refer to the Company's [ASX announcement dated 1 May 2026](#) for a full Study overview.

Regulatory Pathway and Next Steps

The final report completes the pharmacokinetic dataset supporting evaluation of SPONTAN by potential U.S. licensing and commercial partners and further engagement with the FDA:

- **A differentiated product profile.** Oral PDE5 inhibitors take 30 minutes to over two hours to reach peak concentration, and reported dropout rates exceed 50%, with lack of spontaneity a consistently cited reason.¹ SPONTAN's 10-minute Tmax positions it to address a key driver of patient attrition.
- **Built to FDA specification.** Design, endpoints and the geriatric cohort were agreed at the 2025 Pre-IND meeting; the final report characterises the core requirements of the planned 505(b)(2) submission.
- **Lower dose, predictable exposure.** Rapid absorption at a quarter of the oral dose, with no accumulation, consistent elimination and lower metabolite exposure than the oral tablet.

Next Steps: With the pharmacokinetic dataset complete, the U.S. development programme moves to the submission-enabling workstreams scheduled for 2H CY2026, comprising CMC package finalisation, human factors validation, leachables and non-clinical toxicology. The pivotal Phase III study is targeted to commence in 1H CY2027 and the FDA 505(b)(2). The dataset also supports ongoing discussions with potential U.S. licensing and commercial partners and engagement with the TGA and regulators in other key markets.

LTR Pharma Executive Chairman, Lee Rodne, said:

"We now hold a complete, independently reported dataset, designed to FDA specifications, confirming SPONTAN's rapid-onset profile and favourable safety, with comparable pharmacokinetics in men aged 65 and over. This is the evidence package U.S. licensing partners and regulators need to see. Our focus now is progressing SPONTAN's U.S. development programme, from preparations for the Phase III study through to our planned 505(b)(2) submission, while converting our partnering discussions into commercial outcomes for shareholders."

¹ Carvalheira et al., Journal of Sexual Medicine, May 2012

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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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For further information please contact:

Media enquiries
Haley Chartres
haley@hck.digital

Investor enquiries
Peter McLennan
investors@ltrpharma.com