SPONTAN® Clinical Data Published in Prestigious European Journal Validates up to 5 Times Faster Onset Than Oral Tablets

20 August 2025

Highlights

- **Peer-reviewed publication validates up to 5x faster onset - strengthens regulatory pathway and physician adoption.**
- **Clinical data confirms dual-product platform - supports both SPONTAN® and ROXUS® commercialisation.**
- **Addresses US$3,7 billion ED market[1] - 50% of patients discontinue oral treatments[2] seeking better spontaneity.**

LTR Pharma Limited (ASX:LTP) ("LTR Pharma" or "the **Company")** is pleased to announce that clinical data from its Phase I pharmacokinetic study of SPONTAN® (SDS-089), the Company's lead intranasal vardenafil formulation for erectile dysfunction (ED), has been published in the peer-reviewed *European Journal of Pharmaceutical Sciences*.

The publication provides independent validation of SPONTAN's differentiated profile, showing peak plasma concentrations in approximately 10 minutes versus 45 minutes for conventional oral tablets. These are median values from the peer-reviewed study; mean Tmax was 12 minutes for SPONTAN and 56 minutes for tablets in the final study report, with mean values including all results and reflecting the overall average across participants.

The European Journal of Pharmaceutical Sciences is a leading international peer-reviewed journal that publishes high-impact research in pharmaceutical sciences and drug delivery. Publication in this journal requires rigorous peer review by independent scientific experts and represents significant third-party validation of clinical data quality. For pharmaceutical companies, peer-reviewed publications are critical for regulatory submissions and healthcare professional adoption. This publication adds substantial credibility to LTR's regulatory dossier as the Company advances towards full commercialisation.

The randomised, crossover study in 18 healthy male volunteers compared SPONTAN nasal spray (5mg vardenafil) with oral vardenafil tablets (10mg). Publication in this leading pharmaceutical sciences journal represents important third-party validation of LTR's innovative drug delivery platform and its potential to transform ED treatment.

Key Clinical Findings:

- **Ultra-rapid onset:** SPONTAN reached peak plasma concentration (Tmax) in a median of 10 minutes (range 9-15 min; mean 12 min) versus oral tablets at a median of 45 minutes (range 30-150 min; mean 56 min), based on the same study data.
- **Superior efficiency:** Despite half the dose, SPONTAN achieved higher bioavailability per milligram, with dose-normalised Cmax of 2.58 ng/mL/mg versus 1.67 ng/mL/mg for oral administration.
- **Comparable duration:** Similar half-life of approximately 4 hours for both formulations, supporting sustained therapeutic effect.
- **Manageable tolerability:** Safety profile consistent with the PDE5 inhibitor class, with no serious adverse events reported.

The clinical validation extends to the Company's broader intranasal vardenafil portfolio. While the study specifically evaluated SPONTAN, the pharmacokinetic data support the Company's intranasal delivery platform for vardenafil, which also includes ROXUS®. Both products leverage the same rapid-onset technology, providing LTR with multiple commercial opportunities in different market segments from a single validated drug delivery platform.

The publication notes that current oral PDE5 inhibitors face significant limitations, including delayed onset (30 minutes to 2 hours), reduced efficacy with food intake, and the need for careful timing around sexual activity. These factors contribute to discontinuation rates of approximately 4% per month, with lack of spontaneity cited as a primary reason for treatment abandonment.

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

"This peer-reviewed publication in a leading European journal provides robust scientific validation of SPONTAN's game-changing pharmacokinetic profile. The data clearly demonstrate that our intranasal delivery technology achieves the desired therapeutic levels in under 10 minutes – addressing the spontaneity challenge that drives part of the 50% of patients discontinuing oral ED treatments within their first year. From a clinical perspective, this represents a fundamental advancement in how PDE5 inhibitors can be administered, with the potential to significantly improve treatment adherence and patient satisfaction."

The study authors concluded that "intranasally delivered vardenafil is associated with more rapid onset of action with similar plasma concentrations" and that "this differential pharmacokinetic profile has potentially important clinical implications given the overall safety and efficacy profile of PDE5 inhibitors in the treatment of ED, especially in men seeking sexual spontaneity."

SPONTAN is currently available in Australia through the Therapeutic Goods Administration's Special Access Scheme. LTR Pharma is advancing regulatory submissions for the United States via the 505(b)(2) pathway and other key markets, with this publication strengthening the clinical evidence package for regulatory authorities.

The full publication is available at:
https://www.sciencedirect.com/science/article/pii/S0928098725002258?via%3Dihub

[1]Source: Frost and Sullivan Report, The Erectile Dysfunction Medicines Market, September 2023

[2]Source: Corona, G. et al. (2016). "First-generation phosphodiesterase type 5 inhibitors dropout: a comprehensive review and meta-analysis."

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This announcement has been approved by the Board of Directors.

About LTR Pharma

LTR Pharma is an emerging pharmaceutical company committed to developing and commercialising innovative therapies that address significant unmet medical needs. The Company is leveraging its proprietary intranasal drug delivery platform to enable rapid, non-invasive treatment options across multiple therapeutic areas.

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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