



LTR Pharma surpasses 2,000 SPONTAN® dispensed units under TGA Special Access Scheme

21 October 2026

Highlights

- **More than 2,000 bottles of SPONTAN® dispensed units in Australia** under the TGA Special Access Scheme and Authorised Prescriber pathways.
- **Over 120 established Prescribers of SPONTAN**, with dispensing across all six Australian states and the Australian Capital Territory.
- **Prescribing concentrated in men with an inadequate response to oral PDE5 inhibitors**, generating real-world evidence for the planned SPONTAN Phase III study.
- **Australian prescriber and patient experience informing the U.S. introduction of ROXUS®**, built on the same rapid-onset intranasal technology, following fulfilment of the first U.S. prescriptions in October 2026.

LTR Pharma Limited (ASX:LTP) ("LTR Pharma" or "the Company") is pleased to announce that, as at 20 October 2026, more than 2,000 bottles of SPONTAN®, the Company's rapid-onset intranasal vardenafil spray, have been dispensed in Australia under the Therapeutic Goods Administration (TGA) Special Access Scheme (SAS Category B) and Authorised Prescriber programs

More than 120 clinicians have now prescribed SPONTAN on more than one occasion, with dispensing across all six Australian states and the Australian Capital Territory. These milestones demonstrate adoption among Australian clinicians treatment men whose needs have not been adequately met by existing therapies, including oral PDE5 therapies (Viagra®, etc) and injections.

Special Access Scheme

The SAS allows a clinician to prescribe a medicine that is not yet registered in Australia for an individual patient, on a case-by-case basis, where registered treatments are unsuitable, ineffective or unavailable. By design, SAS prescribing is directed to patients whose clinical need has not been met by approved therapies.

Patient population

SAS prescribing of SPONTAN has been concentrated in men with moderate or difficult-to-treat erectile dysfunction. This includes men who have not responded adequately to oral PDE5 inhibitors such as sildenafil (Viagra®) and tadalafil (Cialis®) and men with erectile dysfunction following prostate cancer surgery.

In the real-world cohort study of 147 men, all participants had previously been treated with oral PDE5 inhibitors; 102 of the 147 sought SPONTAN after an inadequate response to oral therapy, and 87 of the 147 (59%) had



undergone prostatectomy. Overall, 100 of the 147 men (68%) reported improved erectile hardness and/or achieving penetration ([refer to the Company's ASX announcement dated 11 August 2026](#)).

Intranasal delivery

The final Phase II report ([refer to the Company's ASX announcement dated 1 October 2026](#)) confirmed a median time to peak blood concentration (Tmax) of 10 minutes for SPONTAN 5 mg compared with 60 minutes for oral vardenafil 20 mg ($p < 0.0001$).

Real-world evidence

De-identified data collection from SAS prescribing is ongoing. Real-world experience in these higher-need patients continues to inform the Company's planned SPONTAN Phase III study and its FDA 505(b)(2) programme, and the U.S. introduction of ROXUS®. The first patient-specific ROXUS prescriptions were fulfilled in the United States in October 2026 ([refer to the Company's ASX announcement dated 6 October 2026](#)).

LTR Pharma Executive Chairman, Lee Rodne, said:

"Surpassing 2,000 dispensed units and reaching more than 120 prescribing clinicians are meaningful milestones for SPONTAN in Australia. These figures demonstrate demand for an additional treatment option for men with erectile dysfunction, including those who have not responded adequately to oral therapies.

The experience gained through SAS use is informing our planned Phase III study and helping us support our U.S. partners as they introduce ROXUS. Our focus is on expanding clinician awareness and building on this progress."

- 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.

LTR Pharma Investor Centre

Stay informed with LTR Pharma's latest announcements and market updates by visiting our [Investor Centre](#) or scan the QR code.



For further information please contact:

Media enquiries
Haley Chartres
haley@hck.digital

Investor enquiries
Peter McLennan
investors@ltrpharma.com