LTR Pharma surpasses 1,000 SPONTAN® prescriptions under TGA Special Access Scheme

17 December 2025

Highlights

- More than 1,000 SPONTAN® prescriptions issued under the TGA Special Access Scheme
- Growing prescriber network with continued uptake in complex ED cases, including post-prostate cancer patients
- Real-world insights informing US commercial strategy ahead of ROXUS® launch in H1 CY2026

LTR Pharma Limited (ASX:LTP) ("LTR Pharma" or "the Company") is pleased to announce that more than 1,000 SPONTAN® prescriptions have now been issued in Australia under the Therapeutic Goods Administration (TGA) Special Access Scheme (SAS Category B).

SPONTAN is being prescribed for patients with unmet clinical needs, including men who have not achieved adequate benefit from traditional oral PDE5 inhibitor therapies (e.g., Viagra®, Cialis®). Under SAS, clinicians may request access to SPONTAN where approved treatments are unsuitable, ineffective, or unavailable. The number of healthcare providers prescribing SPONTAN continues to grow, reflecting expanding clinical awareness and utilisation across Australia.

Clinicians have expressed interest in SPONTAN's intranasal delivery route, which avoids first-pass metabolism through the digestive tract and liver, and minimises gastric irritation. Intranasal administration provides a different pharmacokinetic profile compared with oral PDE5 inhibitors, and SAS prescribing has frequently occurred in patients with more complex or difficult-to-treat forms of erectile dysfunction, such as post-prostate cancer patients, where response rates to oral PDE5 tablets (e.g., Viagra®, Cialis®) are typically reduced.

LTR Pharma Scientific Advisory Board member, Professor Eric Chung, said:

"As clinicians, we frequently encounter patients who have not responded adequately to oral ED therapies or prefer a faster onset of action to allow for sexual spontaneity. SPONTAN's intranasal delivery system offers a meaningful alternative for these patients, and reaching 1,000 prescriptions under SAS reflects growing clinical demand for new and alternative treatment options in this space."

De-identified data collection from SAS prescribing is ongoing, with insights from real-world use informing the Company's regulatory and commercial planning.

LTR Pharma Executive Chairman, Lee Rodne, said:

"Reaching over 1,000 prescriptions is an important milestone for SPONTAN®, demonstrating continued clinician interest and patient uptake through the SAS program. The real-world experience being generated in these higher-need patient populations provides LTR with valuable insights into the treatment landscape. It informs our broader clinical and commercial strategy, including preparations for the introduction of ROXUS® in the United States."

- 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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For further information please contact:

Media enquiries
Haley Chartres
haley@hck.digital

Investor enquiries
Peter McLennan
investors@ltrpharma.com