

# SPONTAN® Achieves 100% Patient Satisfaction in Post-Prostatectomy ED Case Series

## 25 August 2025

## **Highlights**

- 100% patient satisfaction with SPONTAN® nasal spray in post-prostatectomy erectile dysfunction.
- All patients preferred SPONTAN over traditional oral ED therapies, citing spontaneity and ease of use.
- Large underserved market: ~8,500 radical prostatectomies annually in Australia<sup>1</sup> and hundreds of thousands globally.<sup>2</sup>
- Clinical validation at APCC, Asia-Pacific's premier prostate cancer forum, supports late-stage development and commercial pathway.

**LTR Pharma Limited (ASX:LTP) ("LTR Pharma" or "the Company")** today announced that a case series of four patients demonstrating the efficacy of SPONTAN® in treating erectile dysfunction following radical prostatectomy was presented at the <u>25th Asia-Pacific Prostate Cancer Conference</u> (APCC) in Sydney, 22-24 August 2025.

Melissa Hadley Barrett from <u>Make Hard Easy</u> and the <u>Restorative Health Clinic</u> presented the case series titled "Intranasal Vardenafil: A Novel PDE5 Therapy for Erectile Dysfunction in Men Post-Radical Prostatectomy" during the conference's clinical sessions.

The APCC is the region's premier forum for prostate cancer specialists, bringing together leading urologists, oncologists, radiation therapists and researchers from across Asia-Pacific and internationally. The conference serves as a critical platform for sharing breakthrough research and clinical innovations that shape treatment standards across the region, where prostate cancer represents approximately 14% of newly diagnosed cancers in men.

The case studies demonstrate compelling outcomes, with 100% reporting satisfaction with SPONTAN therapy and all preferring SPONTAN over traditional ED treatments. Patients particularly valued the spontaneity and ease of administration that SPONTAN provides.

### A Major Unmet Need

Erectile dysfunction is one of the most common and persistent side effects for men after radical prostatectomy, with oral PDE5 treatments often failing to deliver adequate outcomes. Studies show that 50% of men discontinue oral PDE5 inhibitors<sup>3</sup>, citing lack of spontaneity and poor tolerability.

Each year in Australia alone, ~8,500 men undergo radical prostatectomy, and globally, the patient population numbers in the hundreds of thousands annually. This represents a large, underserved treatment market where SPONTAN offers a differentiated and highly valued therapeutic option.





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

"These real-world clinical outcomes confirm that SPONTAN has the potential to transform treatment for prostate cancer survivors suffering from erectile dysfunction, a population where current therapies routinely fail. The fact that all patients in this independent case series not only achieved therapeutic success but also actively preferred our nasal spray technology over conventional treatments is tremendously encouraging. With a significant and growing global market of post-prostatectomy patients, these results strengthen our conviction that SPONTAN is positioned to become the first-line therapy in this underserved population, unlocking major commercial potential for LTR Pharma."

#### **Next Steps**

This patient case series adds to LTR Pharma's growing clinical validation package and supports the progression of SPONTAN through late-stage development and regulatory pathways in Australia, the US, and other key markets.

SPONTAN is already prescribed in Australia under the TGA's Special Access Scheme, providing patients with early access to this novel therapy. In parallel, LTR Pharma is preparing for the introduction of ROXUS, a variation of SPONTAN, in the US market under the personalised healthcare pathway, further advancing its global expansion strategy.

Together, these findings and initiatives de-risk SPONTAN's clinical development and position LTR Pharma to advance toward regulatory milestones and commercialisation.

1 Source: Australian Commission on Safety and Quality in Health Care, Australian Atlas of Healthcare Variation, 2012-13 hospital admissions data.

2 Source: PMC9974222, "Trends in surgical treatment for prostate cancer: Analysis of National Database," published in 2023

3 Carvalheira et al., "Dropout in the Treatment of Erectile Dysfunction with PDE5: A Study on Predictors and a Qualitative Analysis of Reasons for Discontinuation," 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 for 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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