First patient, first dose in the SPONTAN® Pivotal Clinical Study

19 March 2024

Highlights:

- **First patients dosed in the SPONTAN® erectile dysfunction (ED) pivotal clincial study.**
- **Recruiting 18 patients in a single site clinical study.**
- **SPONTAN's unique nasal delivery technology rapidly delivers ED medication for faster onset.**

LTR Pharma Limited (**ASX:LTP**) ("LTR Pharma", "the Company"), today announced that the first patients have successfully completed the first dosing in the Company's pivotal bioequivalence clinical study of SPONTAN® nasal spray.

Erectile dysfunction (ED) is a condition in which a person is unable to get or keep an erection firm enough for satisfactory sexual intercourse. ED can be a short-term or long-term problem, contributing to relationship breakdowns and mental health issues. LTR Pharma is focused on improving men's health through clinical development and commercialisation of an innovative nasal spray treatment for Erectile Dysfunction ("ED"), called SPONTAN®.

The Study will evaluate the relative bioavailability of SPONTAN, a novel and proprietary PDE5 nasal spray treatment for ED. This first-in-kind nasal spray will be compared to oral administration of Vardenafil, a widely used PDE5 oral tablet and is designed to highlight the innovative nature of SPONTAN in the field of ED treatment.

LTR Pharma Chairman, Lee Rodne, said: *"The Study is off to a great start, and we are grateful to the participants interested in entering the study. SPONTAN nasal spray represents a potential paradigm shift in the treatment for erectile dysfunction and is a promising disruptor to the global blockbuster PDE5 market, offering a discreet and efficient treatment alternative. We are excited to bring this key innovation to men worldwide."*

Study design and overview

The study is an 18-patient single-dose, randomised, open-label, 2-treatment, 2-period crossover study of SPONTAN nasal spray (5 mg Vardenafil) compared to Vardenafil tablets (10 mg Vardenafil) in healthy adult male subjects under fasting conditions. The duration of involvement for each participant is approximately 4 weeks (including screening). The study has been specifically designed to meet the FDA and other markets future requirements.

With the study results expected in mid-2024, LTR Pharma is optimistic about SPONTAN nasal spray's ability to significantly impact the erectile dysfunction treatment landscape.

- ENDS -

This announcement has been approved by the Board of Directors.

About LTR Pharma

LTR Pharma is focused on improving men's health, physically and mentally, through the commercialisation of an innovative nasal spray treatment for Erectile Dysfunction. ED is a pressing health issue for millions of men that can negatively impact self-esteem and relationships, across multiple age brackets. LTR Pharma's lead product SPONTAN® is set apart from existing ED therapies by its mechanism of action – intranasal delivery technology of a PDE5 inhibitor. The nasal cavity is a highly vascular part of the body supporting even and rapid absorption of the drug, empowering it to work within 10 minutes or less. LTR Pharma is proudly aiming to restore greater control over the timing, spontaneity, and enjoyment of sexual experiences.

For further information please contact:

Haley Chartres
Media Relations
haley@hck.digital

Jane Morgan
Investor Relations
jm@janemorganmanagement.com.au