SPONTAN® pivotal clinical study completes recruitment and dosing

25 March 2024

Highlights:

- **Recruitment and dosing are now complete in the SPONTAN® erectile dysfunction (ED) pivotal clinical study.**
- **Data analysis has now commenced, with data read-out expected in mid 2024.**
- **Data will be utilised for pre-submission meetings with the FDA and Australia's early access scheme for intial sales.**
- **SPONTAN is a world-first, fast-acting, on-demand nasal spray treatment for ED.**

LTR Pharma Limited (**ASX:LTP**) ("LTR Pharma", "the Company") today announced that all patients recruited for its pivotal bioequivalence clinical study of SPONTAN® nasal spray ("the Study") have now received their second and final dose, completing the recruitment and dosing stage of the clinical study.

SPONTAN's unique nasal delivery technology bypasses the digestive system and is designed to overcome the issues of oral tablets for ED by having a significantly faster onset of action within 10 minutes.

The Study is evaluating the relative bioavailability of SPONTAN, a novel and proprietary PDE5 (Vardenafil) 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. With recruitment and dosing now complete, the Study progresses to the data evaluation phase, with data read-out expected in mid-2024.

The Study is a critical milestone in the Company's strategic, expedited path to commercialisation. Data collected from the Study will used to support the pre-submission meetings with the FDA and prescriptions of SPONTAN via the early access scheme in Australia.

LTR Pharma Chairman, Lee Rodne, said: *"With recruitment and dosing now complete, we thank the participants and our partners for contributing to this critical study. We are the first and only nasal spray coming to market for the treatment of Erectile Dysfunction and are extremely excited to bring this key innovation to men worldwide. We are now entering the data analysis phase. We believe SPONTAN represents a large paradigm shift in the treatment for Erectile Dysfunction and is a disruptor to the global blockbuster PDE5 (Viagra, etc) market."*

Study design and overview

The Study is a 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 path to market and potential 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.

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