Patient Recruitment Commences for SPONTAN® Pivotal Clinical Study

19 February 2024

Highlights:

- **LTR Pharma has commenced patient recruitment for the SPONTAN® clinical study .**
- **SPONTAN is designed to be a world-first, fast acting, on-demand Nasal Spray treatment for Erectile Dysfunction (ED).**
- **The study will be conducted in Sydney in partnership with Southern Star Research and Scientia Clinical Research.**
- **Data from the study to be used in SPONTAN's FDA regulatory submissions.**

LTR Pharma Limited (**ASX:LTP**) ("LTR Pharma", "the Company"), a Company focused on improving men's health through clinical development and commercialisation of its novel treatment for Erectile Dysfunction ("ED") SPONTAN®, is pleased to announce patient recruitment has now commenced for its pivotal bioequivalence clinical study for this innovative nasal spray treatment ("the Study").

The Study will assess the relative bioavailability of Vardenafil following administration of SPONTAN nasal spray, when compared to oral delivery of Vardenafil tablets – a widely used PDE5 inhibitor. The Company's Contract Research Organisation (CRO) partner, Southern Star Research, will manage various aspects of the Study, including monitoring, data management, safety, and pharmacokinetic analysis.

LTR Pharma Scientific and Clinical Advisor, Professor Eric Chung said: *"On behalf of LTR Pharma, we are excited to welcome appropriately screened and suitable participants to participate in the Study – and look forward to building a clear picture of data that helps to inform measured regulatory and clinical access pathways for novel treatments in the treatment of ED."*

Current oral PDE5 tablets are gold standard treatments but have a high discontinuation rate with consumers. SPONTAN is designed to overcome the issues with oral PDE5 tablets and to be a fast acting-on demand treatment for ED, potentially transforming men's lives and their relationships worldwide.

LTR Pharma, in partnership with its appointed clinical research facility, Scientia Clinical Research, is now welcoming healthy adult males to volunteer their time to be part of the Study. The Study site will be active in Sydney and overseen by Scientia Clinical Research personnel.

The Study design is a single-dose, randomised, open-label, 2-treatment, 2-period crossover study of SPONTAN nasal spray (5 mg Vardenafil consisting of a single 2.5 mg spray in each nostril) 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).

Pending successful completion of the Study, in accordance with the Study's protocols including where all relevant expected data has been obtained, the Company will use the Study data in its new drug applications ("NDA") with the FDA and the TGA for relevant regulatory approvals.

LTR Pharma is in the process of clinical and commercial scale up, having announced earlier this month that its appointed Contract Manufacturing Organisation (CMO), has now met key US Food and Drug Administration (FDA) requirements for the Study to be considered a pivotal trial– and essential GMP manufacturing requirements too.

LTR Pharma Chairman, Lee Rodne, said: *"Commencing recruitment for our upcoming bioequivalence clinical study for our lead product, SPONTAN, is a significant achievement for our Company and in keeping with the clearly mandated clinical and commercial milestones that we communicated during our recent IPO campaign. This Study will form a critical piece of the data package we plan to submit to the FDA and TGA – supporting our plans for expedited regulatory approval for SPONTAN in key initial markets. We believe SPONTAN has the potential to disrupt the global blockbuster PDE5 market and we are excited to bring this innovation to men worldwide. I encourage all members of the public who meet the essential recruitment criteria to get involved."*

Southern Star Research Managing Director, David Lloyd, said: *"This clinical trial is an exciting project for Southern Star Research and we appreciate the opportunity to work with LTR Pharma and Scientia Clinical Research. We are looking forward to the results, as the market potential and unmet patient needs are significant."*

The global ED market is forecast to increase to $5.94 billion by 2028, growing at a CAGR of 7.1%. The number of men with ED in the US is approximately 30 million. In Australia, over 60% of males suffer from ED once they reach the age of 45 years or older.*

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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.

*Source: Frost and Sullivan Report, The Erectile Dysfunction Medicines Market, September 2023

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