SPONTAN® Achieves Manufacturing Validation For Pivotal Clinical Study

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Highlights:

- **LTR Pharma has achieved manufacturing validation for its upcoming pivotal clinical study for its lead product, SPONTAN®.**
- **Essential criteria for a pivotal FDA clinical study have been met – including stability testing, quality control checks, product purity and packaging integrity.**
- **Patient recruitment for its bioequivalence study is due to commence this month.**

LTR Pharma Limited (**ASX:LTP**) ("LTR Pharma", "the Company"), a Company focused on improving men's health through clinical development and commercialisation of an innovative nasal spray treatment for Erectile Dysfunction ("ED"), SPONTAN®, is pleased to provide an update on the Company's preparation for the product's upcoming bioequivalence clinical study.

LTR Pharma, in conjunction with its Contract Manufacturing Organisation (CMO), has now successfully completed pivotal stability and quality control milestones for SPONTAN®. By testing the chemical stability of SPONTAN over three specified periods, whilst assessing packaging integrity and confirming purity of the active ingredients, LTR Pharma has now met key U.S. Food and Drug Administration (FDA) requirements to be considered a pivotal study.

Achieving this status signifies adherence to the highest product quality and regulatory standards and is an important step to support the start of clinical batch manufacturing and commencement of SPONTAN's pivotal clinical study.

LTR Pharma Chairman, Lee Rodne, said: *"This achievement has been underpinned by a comprehensive suite of quality control checks as mandated by the FDA. Each check was meticulously designed to evaluate the chemical stability of SPONTAN over specified time periods, assess the integrity of its packaging, and verify the purity of our nasal spray formulation. Completion of these critical steps signifies our Company's commitment to adhering to the highest standards of product quality and regulatory compliance. We are optimistic about the potential impact of SPONTAN in the market and look forward to sharing our progress as we move closer to initiating the clinical trial."*

Patient recruitment for SPONTAN's bioequivalence study is due to commence this month. The trial is a randomized, open-label, single-dose, two-treatment cross-over study that looks at how the body processes Vardenafil after giving it to 18 healthy adult men in the form of SONTAN Nasal Spray and Vardenafil Tablets.

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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.

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