SPONTAN® achieves 470% faster absorption in completed pivotal study

14 October 2024

Highlights:

- **SPONTAN® achieves 470% faster absorption than oral vardenafil tablets (12 min vs 56 min)**
- **Dose-normalised bioavailability of 111.8% relative to oral tablets**
  - **Clinically relevant comparable bioavailability**
- **Delivers 155.6% higher peak concentration despite using only half the dose**
- **Favourable safety profile positions SPONTAN as a potential market disruptor in the global ED market**

LTR Pharma Limited (**ASX:LTP**) ("**LTR Pharma**", "the **Company**") is pleased to announce the completion of the data evaluation phase of the SPONTAN® pivotal clinical study (the Study) evaluating the pharmacokinetics and safety profile of SPONTAN, its novel intranasal formulation of vardenafil for the treatment of erectile dysfunction (ED) (see ASX Announcement dated 7 June 2024 with an overview of initial Study results).

Key results from the randomized, open-label, cross-over study demonstrate that SPONTAN Nasal Spray (5 mg vardenafil) achieved a significantly faster time to maximum plasma concentration (Tmax) compared to the oral tablet (10 mg vardenafil). SPONTAN achieved a mean Tmax of 12 minutes versus 56 minutes for the oral tablet. This rapid onset offers patients greater spontaneity and convenience compared to traditional oral ED medications.

Moreover, SPONTAN displayed a comparable bioavailability to the oral tablet on a dose-normalized basis. Despite the lower 5 mg dose, the nasal spray showed 111.8% dose-normalized bioavailability relative to the oral tablet. Additionally, SPONTAN's maximum plasma concentration (Cmax) was comparable on a dose-normalized basis, reaching 155.6% of the oral tablet's Cmax. The half-life ($t½$) of vardenafil was similar for both formulations, with SPONTAN demonstrating a mean half-life of 4.15 hours, compared to 4.23 hours for the oral tablet.

SPONTAN was well-tolerated, with no serious adverse events (SAEs) reported. All treatment-emergent adverse events (TEAEs) were mild to moderate and transient. The overall safety profile of SPONTAN is consistent with the known safety profile of vardenafil.

LTR Pharma Chief Medical Officer, Professor Geoffrey Strange, said: *"These results are highly encouraging from a clinical perspective. The rapid onset of action and pharmacokinetic profile of SPONTAN® have the potential to address significant unmet needs in erectile dysfunction treatment. The speed of absorption, coupled with the excellent bioavailability and safety profile, offers patients a more spontaneous and convenient therapeutic option. These data have been supported by positive anecdotal efficacy feedback from patients to prescribers of SPONTAN under the Special Access Scheme. Together, these data, support our belief that SPONTAN® may represent a meaningful advancement in ED management."*

Comparative Pharmacokinetic Results

Parameter	SPONTAN Nasal Spray (5 mg)	Vardenafil Oral Tablet (10 mg)	SPONTAN Comparison (Dose-Normalised)
Tmax (mean)	12 minutes	56 minutes	78% faster, p-value <.0001
C_{max}/D (ng/mL/mg)	1.9864	1.2769	155.6% (dose-normalised)
AUC_{0-t}/D (h*ng/mL/mg)	3.8921	3.4815	111.8% (dose-normalised)
Half-life (t½)	4.15 hours	4.23 hours	Comparable

Study Outline

The Study involved 18 healthy adult males under fasting conditions and utilised a cross-over design to compare the pharmacokinetics of SPONTAN Nasal Spray and vardenafil oral tablets. Blood samples were taken at multiple time points over 24 hours to evaluate vardenafil concentrations. The study's secondary endpoint assessed the safety and tolerability of SPONTAN compared to the oral formulation. Please refer to the Company's ASX Announcement dated 7 June 2024 for a comprehensive clinical study overview.

Regulatory Pathway and Commercialisation Strategy

The data will enhance LTR Pharma's ongoing global partnering and licensing discussions. Additionally, the data will support our engagement with key regulatory bodies, including the US Food and Drug Administration (FDA), Australia's Therapeutic Goods Administration (TGA), and other key markets.

LTR Pharma Chairman, Lee Rodne said: *"These study results mark a significant milestone for LTR Pharma. SPONTAN's pharmacokinetic profile and rapid onset of action demonstrate its potential to disrupt the global ED market. We are now well-positioned to accelerate our commercialisation strategy, including advancing regulatory discussions and exploring strategic partnerships. This success reinforces our commitment to delivering innovative solutions that can significantly improve patients' lives while creating value for our shareholders."*

-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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