

LTP Secures Global Co-Development Agreement with Aptar Pharma

13 August 2024

Highlights:

- LTR Pharma (ASX:LTP) and Aptar Pharma have entered into a Co-Development Agreement for SPONTAN® for global markets.
- The primary goal is commercialisation of SPONTAN in the USA and other key markets.
- The Agreement will combine LTP's pharmaceutical development capabilities with Aptar Pharma's expertise in nasal spray technology, supporting a streamlined regulatory pathway and market access for SPONTAN.

LTR Pharma Limited (ASX:LTR) ("LTR Pharma", "the Company") is pleased to announce that it has entered into a Co-Development Agreement ("the Agreement") for SPONTAN for global markets.

The Agreement has been secured with Aptar Pharma <https://aptar.com/pharmaceutical/>, a global leader in drug delivery systems, services and active material science solutions. Aptar Pharma has supported numerous market authorisation holders in obtaining their combination drug-device product approvals incorporating Aptar's nasal delivery systems from regulatory agencies such as the U.S. Food and Drug Administration (FDA).

The Agreement will encompass joint development and expertise, combining LTR Pharma's pharmaceutical development capabilities with Aptar Pharma's expertise in nasal spray technology – including Aptar's VP7 model nasal spray components. The application for SPONTAN Nasal Spray will be filed in the US via the FDA's 505(b)(2) expedited regulatory pathway, which governs a change in route of administration of an already approved drug, here Levitra® (Vardenafil) tablets.

The Agreement grants LTR Pharma access to Aptar Pharma's comprehensive range of regulatory, analytical testing, and human factor services, which will considerably strengthen the FDA application process for SPONTAN.

A shared goal will be to focus on imminent market establishment and expansion, targeting commercialisation in the USA, and other key global markets – together with a long-term strategic alliance for ongoing innovation for healthcare solutions.

LTR Pharma Chairman, Lee Rodne, said:

"We are delighted to enter into a Co-Development Agreement with Aptar Pharma – a respected and experienced partner in our imminent goal to obtain regulatory approval for SPONTAN and to expand its global market reach and impact. As part of this, we will gain access to Aptar's expertise in the VP7 nasal spray system and related specialised services to support our FDA application process. This vastly de-risks the FDA application process and elevates the profile of LTR Pharma as a long-term partner of a global market innovator, which we anticipate may create opportunities for other products with alternative indications in future."

Guillaume Brouet, Vice President Analytical Regulatory and Scientific Affairs Aptar Pharma, said:

"We look forward to working closely alongside the LTR Pharma team to support its SPONTAN Nasal Spray application. We have purpose-designed facilities and experienced personnel to ensure a successful partnership throughout this Co-Development- within an efficient timeframe."

LTP recently completed its clinical trial to compare the pharmacokinetics, safety, and tolerability of Vardenafil following administration of SPONTAN nasal spray and Levitra® tablets in healthy male adults. The trial showed that SPONTAN achieved a rapid absorption and faster onset of action compared to oral PDE5 inhibitors (i.e., vardenafil, sildenafil, tadalafil) and delivered a similar amount of drug (Cmax) at half the dose of the oral PDE5 tablet. Following the success of this clinical trial, medical providers have started prescribing SPONTAN in Australia under the Therapeutic Goods Administration (TGA) Special Access Scheme (SAS).

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This announcement has been approved by the Board of Directors.

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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.