LTR Pharma Completes Extractables Study Milestone for SPONTAN®

30 June 2025

Highlights

- **Extractables study completed with co-development partner Aptar Pharma**
- **All identified compounds below ICH[1] safety thresholds**
- **Leachables study initiated to support FDA regulatory submission under real-world storage conditions**
- **Required milestone for FDA 505(b)(2) regulatory submission**

LTR Pharma Limited (ASX:LTP) ("LTR Pharma" or "the **Company")** is pleased to announce the completion of extractables studies for SPONTAN®, its intranasal spray for erectile dysfunction, and the commencement of leachables studies as part of its regulatory development program.

Study Results

The extractables study, conducted under the supervision of Aptar Pharma, evaluated the bottle and pump components of SPONTAN's container closure system. The study confirmed that all detected compounds were below ICH safety thresholds - the internationally recognised standards adopted by the FDA and regulatory authorities worldwide for pharmaceutical impurities. Identified compounds will be monitored in the ongoing leachables study.

The FDA requires Extractables and Leachables (E&L) studies for all pharmaceutical products to ensure packaging materials do not compromise product safety or efficacy. For nasal spray products, these studies must meet specific regulatory thresholds due to direct tissue exposure.

Development Progress

The leachables study has commenced under Aptar Pharma's management, evaluating the potential migration of the compounds from packaging into SPONTAN under real-world storage conditions. SPONTAN utilises industry-standard bottle and pump components used in multiple FDA-approved nasal spray products.

The study will run for at least 24 months to support shelf-life requirements. Consistent with FDA practice for nasal sprays, the Company can submit its application once sufficient robust data is available, with study completion continuing post-approval as standard.

Both extractables and leachables data are required for the Chemistry, Manufacturing and Controls (CMC) section of our planned New Drug Application. With extractables complete and meeting safety thresholds, we continue progressing through the regulatory pathway.

LTR Pharma Executive Chairman, Lee Rodne, said:

"The completion of our extractables study and commencement of the leachables phase keep our regulatory program on schedule. Working with Aptar Pharma provides us with their established expertise in nasal spray device development and FDA submissions. These studies are necessary steps in our development pathway, and we look forward to progressing through each regulatory milestone."

Regulatory Context

The E&L studies form part of LTR Pharma's comprehensive regulatory strategy following its FDA pre-IND meeting, where the FDA confirmed the proposed development pathway. With extractables results meeting regulatory requirements, the Company now progresses to the leachables phase for comprehensive regulatory submission data.

The Company continues to progress SPONTAN through established regulatory pathways while building commercial foundations through its Australian early access programmes and planned US market entry with ROXUS®. Completing E&L studies advances SPONTAN through the regulatory path, with clinical and manufacturing milestones ahead.

- ENDS –

This announcement has been approved by the Board of Directors.

About LTR Pharma

LTR Pharma is an emerging pharmaceutical company committed to developing and commercialising innovative therapies that address significant unmet medical needs. The Company is leveraging its proprietary intranasal drug delivery platform to enable rapid, non-invasive treatment options across multiple therapeutic areas.

LTR's lead products, SPONTAN® and ROXUS®, are fast-acting intranasal sprays for the treatment of erectile dysfunction, enabling onset of action in 10 minutes or less. Building on this proven technology, the Company is now advancing OROFLOW®, a novel intranasal spray under development for the treatment of Oesophageal Motility Disorders (OMD) – a debilitating group of conditions affecting swallowing function.

Through strategic partnerships, LTR Pharma is expanding its pipeline and global footprint to deliver differentiated, patient-centric treatments that enhance quality of life.

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1 ICH: International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use.