ASX Announcement

VIRALEZE™ UK COVID-19 Clinical Study Completes Recruitment

Melbourne, Australia; 25 September 2023: Starpharma (ASX: SPL, OTCQX: SPHRY) today announces that it has completed recruitment for the post-market clinical study of its broad-spectrum antiviral barrier nasal spray, VIRALEZE™, in patients with COVID-19 in the UK. Recruitment proceeded rapidly and the study successfully enrolled ~200 patients with laboratory-confirmed COVID-19.

Developed by Starpharma, VIRALEZE™ is an antiviral nasal spray that creates a barrier within the nasal cavity to physically trap and block cold/respiratory viruses. VIRALEZE™ forms a physical moisture barrier between viruses and the nasal mucous membrane that traps and blocks viruses.

Study Overview

The randomised, double-blinded, placebo-controlled clinical study of VIRALEZE™ assesses SARS-CoV-2 viral load in the nasal cavity of patients with COVID-19 while using VIRALEZE™. The primary endpoint of the clinical study is the level of a patient's viral load over a seven-day treatment period.

The study is also collecting additional information on the ability of VIRALEZE™ to prevent disease progression and worsening of symptoms, and shorten the duration of symptoms in patients with COVID-19. This will build on existing human data for the product.

This study has been led by Dr Stephen Winchester, Consultant Virologist, at St Peter's Hospital NHS Foundation Trust in the UK, which has also successfully completed other studies of nasal sprays in people with COVID-19. The VIRALEZE™ clinical trial design was based on other clinical studies of topical nasal sprays and followed extensive specialist clinical advice and literature review. In non-clinical studies conducted at Scripps Research, treatment with VIRALEZE™ achieved a greater reduction in viral load in mice challenged with SARS-CoV-2 omicron virus than these other nasal sprays.

This post-market clinical study of VIRALEZE™ will generate valuable clinical data on the antiviral performance of VIRALEZE™ in patients with COVID-19. The resulting data will support ongoing marketing and commercial activities, building on the extensive in-market experience with the product. The study will also provide additional clinical safety and efficacy data to satisfy the new European medical device regulations, which will apply to products of this category from mid-2024. Starpharma and its commercial partners have registered VIRALEZE™ in more than 35 countries, including the UK and Europe.

Dr Jackie Fairley, CEO, Starpharma, commented:

"We are pleased with the high level of interest in the VIRALEZE™ post-market clinical study. Many people in the UK and elsewhere are still grappling with COVID-19, as evidenced by the rapid recruitment, and new strains are continuing to emerge. A broad-spectrum antiviral barrier nasal spray, such as VIRALEZE™, has the potential to play an important role globally. We look forward to sharing the results once available. We extend our sincere appreciation to Dr Winchester and the Research and Development team at St Peter's Hospital in the UK, as well as the participants for their valuable contribution to this study."

Starpharma will release the results of this post-market clinical study following data and statistical analyses, and anticipates this will be during Q4 CY23.

VIRALEZE™ Antiviral Nasal Spray

Developed by Starpharma, VIRALEZE™ is a topical nasal spray that physically traps and blocks multiple cold/respiratory viruses in the nasal cavity. VIRALEZE™ is applied in the nose where it forms a physical moisture barrier between viruses and the nasal mucous membrane that traps and blocks virus.

Starpharma and its commercial partners have registered VIRALEZE™ in more than 35 countries, including the UK and Europe, and it is available in certain markets online. Product claims may differ by market. Starpharma markets VIRALEZE™ via commercial arrangements in countries in Europe, Asia, and the Middle East. VIRALEZE™ is not approved for use or supply in Australia.

About Starpharma

Starpharma Holdings Limited (ASX: SPL, OTCQX: SPHRY) is a world leader in dendrimer technology for medical applications. As an innovative Australian biopharmaceutical company, Starpharma is focused on developing and commercialising novel therapeutic products that address significant global healthcare needs. Starpharma boasts a strong portfolio of products, partnerships, and intellectual property.

Starpharma's innovative technology is based on proprietary polymers called dendrimers, which are precise, synthetically manufactured, nanoscale molecules. The unique properties of dendrimers – including their size, structure, high degree of branching, polyvalency, and water solubility – are advantageous in medical and pharmaceutical applications.

Starpharma uses its dendrimer technology to develop novel therapeutics and to improve the performance of existing pharmaceuticals. Starpharma's portfolio includes multiple clinical-stage oncology products, which utilise its Dendrimer Enhanced Product ('DEP®') drug delivery technology, and marketed products, including VIRALEZE™ and VivaGel® BV, which utilise SPL7013, a proprietary dendrimer with antimicrobial properties.

Starpharma's DEP® drug delivery platform is being used to enhance the effectiveness of existing and novel therapies and to reduce drug-related toxicities through controlled and specified drug delivery.

In addition to Starpharma's internal DEP® programs, Starpharma has multiple DEP® partnerships with international biopharmaceutical companies, including AstraZeneca (oncology), MSD (Antibody-Drug Conjugates), Chase Sun (anti-infectives), and other world-leading pharmaceutical companies. Due to the broad applicability and optionality of Starpharma's DEP® platform, partnered DEP® programs have the potential to generate significant future milestones and royalties.

Starpharma's topical antiviral nasal spray, VIRALEZE™, is now registered in more than 35 countries*, including Europe, the UK, and Asia. Starpharma's novel non-antibiotic vaginal gel, VivaGel® BV, for the treatment of bacterial vaginosis (BV) and prevention of recurrent BV, is registered in more than 50 countries, including in the UK, Europe, Southeast Asia, South Africa, Australia and New Zealand.

For more information about Starpharma, visit www.starpharma.com or connect with Starpharma on LinkedIn.

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Disclosure
This ASX Announcement was authorised for release by the Chair, Mr Rob Thomas.

Forward Looking Statements

This document contains certain forward-looking statements, relating to Starpharma's business, which can be identified by the use of forward-looking terminology such as "promising", "plans", "anticipated", "will", "project", "believe", "forecast", "expected", "estimated", "targeting", "aiming", "set to", "potential", "seeking to", "goal", "could provide", "intends", "is being developed", "could be", "on track", "outlook", or similar expressions, or by express or implied discussions regarding potential filings or marketing approvals, or potential future sales of product candidates. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no assurance that any existing or future regulatory filings will satisfy the FDA's and other authorities' requirements regarding any one or more product candidates nor can there be any assurance that such product candidates will be approved by any authorities for sale in any market or that they will reach any particular level of sales. In particular, management's expectations regarding the approval and commercialization of the product candidates could be affected by, among other things, unexpected trial results, including additional analysis of existing data, and new data; unexpected regulatory actions or delays, or government regulation generally; our ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry, and general public pricing pressures; and additional factors that involve significant risks and uncertainties about our products, product candidates, financial results and business prospects. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected. Starpharma is providing this information as of the date of this document and does not assume any obligation to update any forward-looking statements contained in this document as a result of new information, future events or developments or otherwise. Clinical case studies and other clinical information given in this document are given for illustrative purposes only and are not necessarily a guide to product performance and no representation or warranty is made by any person as to the likelihood of achievement or reasonableness of future results. Nothing contained in this document nor any information made available to you is, or shall be relied upon as, a promise, representation, warranty or guarantee as to the past, present or the future performance of any Starpharma product.