ASX Announcement

VIRALEZE™ Post-Market Clinical Study in COVID-19 Patients

Melbourne, Australia; 8 December 2022: Starpharma Holdings Limited (ASX: SPL, OTCQX: SPHRY) today announces that it has commenced recruitment in the UK for a post-market clinical study of its broad-spectrum antiviral barrier nasal spray, VIRALEZE™, in patients with COVID-19, following receipt of the necessary regulatory and ethics approvals.

The post-market study will generate valuable clinical data on the antiviral performance of VIRALEZE™ in a controlled setting in non-hospitalised participants with COVID-19. The resulting data will support ongoing marketing and commercial activities and will build on the extensive in-market experience with the product. The post-market study will also generate additional clinical safety and efficacy data, which are relevant to the new European medical device regulations applicable to products of this category from mid-2024.

The study will assess the SARS-CoV-2 viral load in the nasal cavity of recently diagnosed COVID-19 patients while using either VIRALEZE™ or a placebo nasal spray. The primary endpoint is viral load over a 7-day treatment period, expressed as "area under the curve" (AUC). The study will also examine the ability of VIRALEZE™ to prevent disease progression and worsening of symptoms, and to shorten the duration of symptoms in patients with COVID-19; and build on the existing safety and tolerability data.

The randomised, double-blinded study will enrol 160 adults with laboratory-confirmed COVID-19. During the treatment period, participants will use either VIRALEZE™ or a placebo nasal spray 4 times daily for 7 days and swabs will be collected to assess SARS-CoV-2 viral load in the nasal cavity.

The selection of this clinical trial design follows extensive specialist clinical advice and literature review. The trial design is based on other similar clinical studies of topical nasal sprays. In nonclinical 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 clinical study is being conducted at St Peter's Hospital, in the UK, which has conducted previous studies of nasal sprays in patients with COVID-19. Other sites, including in other countries, may be added, if required.

Starpharma CEO, Dr Jackie Fairley, commented: "Following on from the SARS-CoV-2 data generated for VIRALEZE™ at Scripps Research, which are being presented at the international virology conference RespiDART in Mexico this week, Starpharma is pleased to commence this clinical study in patients, which will support ongoing marketing and commercialisation activities for VIRALEZE™ in multiple markets around the world."

VIRALEZE™ Nasal Spray

VIRALEZE™ is a 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.

VIRALEZE™ is registered as a medical device in more than 30 countries, including the UK and Europe, and 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.

This announcement is intended for investors and market participants only.

About Starpharma

Starpharma Holdings Limited (ASX:SPL, OTCQX:SPHRY) is a global biopharmaceutical company and a world leader in the development of new pharmaceutical and medical products based on proprietary polymers called dendrimers, with programs for DEP® drug delivery, respiratory viruses and VivaGel®.

Starpharma's proprietary drug delivery platform technology, DEP®, is being used to improve pharmaceuticals, to reduce toxicities and enhance their performance. There are numerous internal and partnered programs underway to develop DEP® versions of existing drugs, particularly in the area of anti-cancer therapies.

DEP® partnerships include oncology programs with AstraZeneca, with MSD in the area of Antibody Drug Conjugates (ADCs), with Chase Sun in the area of anti-infectives, and other world leading pharmaceutical companies. Partnered DEP® programs have the potential to generate significant future milestones and royalties.

Starpharma has developed VIRALEZE™, an antiviral nasal spray that is registered in a number of countries, including in Europe and the UK. VIRALEZE™ is not approved for use or supply in Australia. SPL7013 is also utilised in the following products - VivaGel® condom and VivaGel® BV. VivaGel® products have been licensed in >160 countries and are registered in >45 countries, including the UK, Europe, Japan, Southeast Asia, South Africa, Australia and New Zealand.

Starpharma.com | Twitter | LinkedIn

Media: Sumit Media
Grant Titmus
Mob: +61 419 388 161
grant@sumitmedia.com.au

Starpharma Holdings Limited
Dr Jackie Fairley, Chief Executive Officer
Nigel Baade, CFO and Company Secretary
+61 3 8532 2704
investor.relations@starpharma.com
4-6 Southampton Crescent
Abbotsford Vic 3067

Disclosure
This ASX Announcement was authorised for release by the Chairman, 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.