

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.

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Disclosure

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

Forward Looking Statements

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