ASX Announcement

VIRALEZE™ well tolerated in multiple dose clinical study

- **VIRALEZE™ was very well tolerated, with no notable or serious adverse events reported, in clinical safety study**
- **Results of the clinical safety study confirm that that the dendrimer antiviral in VIRALEZE™, SPL7013, is not absorbed into the bloodstream following nasal application, consistent with extensive previous nonclinical and clinical data**

Melbourne, Australia; 17 August 2021: Starpharma (ASX: SPL, OTCQX: SPHRY) today announced results from its VIRALEZE™ clinical safety study demonstrating the product was safe and well tolerated in accordance with the primary endpoint, and also confirming that the dendrimer antiviral in VIRALEZE™, SPL7013, was not absorbed into the bloodstream following nasal application.

The randomised, double-blind, placebo-controlled, safety, tolerability and pharmacokinetic study of VIRALEZE™ was conducted in 40 healthy volunteers who used the product four times a day for 14 days. The product was well tolerated with no notable or serious adverse events reported, and no participants discontinued product use.

The study also confirmed that SPL7013 was not detected in the bloodstream following repeated nasal application. This finding is consistent with previous extensive nonclinical and clinical data showing lack of systemic absorption of SPL7013 following topical application to mucosal membranes.

Dr Jackie Fairley, CEO of Starpharma, commented: “We are pleased to report that VIRALEZE™ was very well tolerated in the study. This additional clinical data adds to the extensive body of evidence for SPL7013, demonstrating its extremely benign safety profile and confirming lack of systemic absorption of SPL7013 in VIRALEZE™. These data further support the suitability of VIRALEZE™ antiviral nasal spray for use in everyday situations as a preventative product where individuals may be at risk of exposure to respiratory viruses. An antiviral nasal spray like VIRALEZE™ is advantageous because respiratory viruses, including SARS-CoV-2, take hold by initially infecting mucosal cells in the nasal cavity, and VIRALEZE™ and SPL7013 form a barrier that traps and irreversibly inactivates viruses before they can infect cells.”

VIRALEZE™ is registered for sale in Europe and India, and available in certain markets via www.viraleze.co. VIRALEZE™ is not approved for sale or supply in Australia. Starpharma is currently negotiating distribution and marketing arrangements for VIRALEZE™ in a number of countries which include India, various European countries and other international regions.

About the study

The study was a randomised, double-blind, placebo-controlled clinical investigation of the safety, tolerability and pharmacokinetics of multiple applications of VIRALEZE™ antiviral nasal spray in healthy volunteers. The primary objective of the study was to assess the safety and tolerability of VIRALEZE™ containing 1% SPL7013 administered nasally four times a day for 14 days. The secondary objective was to determine the extent of absorption of SPL7013 following use of the spray.

The primary endpoint was safety, measured by frequency and severity of adverse events (AEs). The secondary endpoint was blood plasma levels of SPL7013 determined following single and repeated applications of the spray.

The study participants were 40 healthy volunteers aged 19 to 58 years; 30 participants received VIRALEZE™ and 10 received the placebo nasal spray 4 times a day for 14 days. Participants were closely monitored and followed up for 1 week after end of treatment.

The product was very well tolerated with no notable AEs reported, no serious AEs, and no AEs leading participants to stop or withdrawal from use of the product. The AEs that were reported were of lowest grade, or mild, intensity. All events that occurred in more than >5% of participants in the VIRALEZE™ group and considered potentially associated with treatment, were also reported at a similar or higher rate in participants in the placebo group. These were: transient tingling/nasal discomfort (VIRALEZE™ 10%; Placebo 10%), nasal congestion (VIRALEZE™ 6.7%; Placebo 20%), nose bleed (epistaxis) (VIRALEZE™ 10%; Placebo 10%) and headache (VIRALEZE™ 13.3%; Placebo 10%).

Compliance with the product use requirements was extremely high (mean 99.9% for VIRALEZE™ and 100% for placebo; or 99.9% across both VIRALEZE™ and placebo), indicating again the excellent tolerability of the product. There were no clinically significant findings or observations from detailed nasal cavity examinations, and no clinically significant abnormal findings from ECGs or vital sign monitoring.

The study also confirmed that SPL7013 was not detected in the plasma following repeated nasal application indicating there was no absorption into the bloodstream. This finding is relevant because it means that the potential for any systemic effects with VIRALEZE™ is negligible, which is not necessarily the case with all nasal sprays. These data are also consistent with previous extensive nonclinical and clinical data showing that SPL7013 is not absorbed into the bloodstream following topical application to mucosal membranes.

The study was conducted at Linear Clinical Research in Western Australia. Starpharma thanks the site staff and study participants for their contribution to and participation in the study.

VIRALEZE™ Antiviral Nasal Spray

VIRALEZE™ contains SPL7013, which has been shown in laboratory studies to inactivate a broad spectrum of respiratory/cold viruses, including multiple variants of SARS-CoV-2, influenza, RSV, SARS, and MERS. The product is an easy to use nasal spray which can be stored at room temperature. VIRALEZE™ is registered for sale in Europe and India. VIRALEZE™ is not registered for sale or supply in Australia.

SPL7013 is also included in products registered in >45 countries and available for sale in the UK, Europe, Japan, South East Asia, Australia and New Zealand.

Starpharma acknowledges the $1 million in funding for the development of VIRALEZE™ provided by the Australian Government's Medical Research Future Fund (MRFF) Biomedical Translation Bridge (BTB) Program, with support from UniQuest. Delivered by MTPConnect, the Australian Government's BTB program is a $22.3 million MRFF initiative that provides up to $1 million in matched funding to nurture the translation of new therapies, technologies and medical devices through to proof of concept to turn innovative medical ideas into reality.

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 respiratory viruses, DEP® drug delivery and VivaGel®. Starpharma has developed VIRALEZE™, an antiviral nasal spray that is registered for sale in the UK/Europe and India, and available in certain markets via www.viraleze.co. VIRALEZE™ is not approved for sale or supply in Australia. SPL7013 is utilised in approved products - the VivaGel® condom and VivaGel® BV. VivaGel® BV has been licensed in >160 countries, is approved in >45 countries and available for sale in the UK, Europe, Japan, South East Asia, South Africa, Australia and New Zealand.

As a leading company in dendrimer-based drug delivery, 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 Merck in the area of Antibody Drug Conjugates (ADCs), with Chase Sun in the area of anti-infectives and other world leading pharmaceutical companies. Starpharma's partnered DEP® programs have the potential to generate significant future milestones and royalties.

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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", 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.