

VIRALEZE UK update

Melbourne, Australia; 21 June 2021: Starpharma (ASX: SPL, OTCQX: SPHRY) advises that its UK retail partner, LloydsPharmacy, has received correspondence from the UK Medicines and Healthcare products Regulatory Agency (MHRA) in relation to specific promotional claims made for VIRALEZE[™] antiviral nasal spray. The correspondence relates to promotional claims, including references to SARS-CoV-2 and COVID-19, and the interrelationship between these product claims and its categorisation. The MHRA correspondence does not question or relate to the safety or quality of VIRALEZE[™], but relates to allowable promotional claims.

Starpharma, LloydsPharmacy and their expert advisers are engaging with the MHRA to resolve the matter as quickly as possible. While Starpharma disagrees with the MHRA's position, Starpharma and LloydsPharmacy have agreed to temporarily pause sales of VIRALEZE[™] in the UK during this time. Starpharma has generated extensive data, including published data, in relation to the broad-spectrum antiviral activity and the mechanism of action for VIRALEZE[™] supporting the product and its promotional claims. During development and prior to the launch of VIRALEZE[™], Starpharma obtained expert regulatory advice and input from an EU regulatory body in relation to the product and its claims.

This temporary pause in promotion and sales is specific to the UK and does not impact other markets, including in Europe and India where the product is registered for sale. VIRALEZE[™] continues to be available in multiple countries via <u>www.viraleze.co</u>.

Starpharma is rapidly progressing commercial and supply arrangements for the Indian market, for both the private (consumer) and Government markets. Starpharma also continues to prioritise regulatory activities for VIRALEZE[™] for a number of other important markets. VIRALEZE[™] is not yet approved in Australia.

About VIRALEZE[™] Antiviral Nasal Spray

VIRALEZE[™] Antiviral Nasal Spray was developed by Starpharma (ASX: SPL) and is registered for sale in Europe and India. It is an easy-to-use antiviral nasal spray containing 1% w/w astodrimer sodium (SPL7013), shown in laboratory studies to inactivate a broad spectrum of respiratory viruses, including multiple variants of SARS-CoV-2.¹

VIRALEZE[™] binds to and irreversibly inactivates a broad spectrum of respiratory viruses. Inactivated viruses are blocked from attaching to cells inside your nose and taking hold. In addition to providing a protective antiviral barrier, VIRALEZE[™] provides a moisturising layer to help keep nasal tissue hydrated, protecting it from dryness and damage.

SPL7013 is included in products that are already approved in >45 countries and available for sale in the UK, Europe, Japan, South East Asia, South Africa, Australia, and New Zealand.

VIRALEZE[™] is intended to be used alongside vaccines, masks, and physical distancing.

¹ Paull J.R.A., et al. Virucidal and antiviral activity of astodrimer sodium against SARS-CoV-2 *in vitro*. *Antiviral Res* 2021;191:105089 (https://doi.org/10.1016/j.antiviral.2021.105089)

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 COVID-19, DEP[®] drug delivery and VivaGel[®]. Starpharma has developed VIRALEZE[™], an antiviral nasal spray for COVID-19, which is complementary to vaccines and other preventative measures such as distancing and PPE. VIRALEZE[™] is registered for sale in the UK/Europe and India, and available in the UK through LloydsPharmacy and in certain markets via <u>www.viraleze.co</u>. VIRALEZE[™] is not yet 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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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", "extended", "estimated", "targeting", "ainting, "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.