

VIRALEZE antiviral nasal spray registered for sale in India

- VIRALEZE™ has been registered for sale nationally in India
- VIRALEZE™ is a broad spectrum antiviral nasal spray that contains astodrimmer sodium (SPL7013) which is virucidal, irreversibly inactivating >99.9% of SARS-CoV-2 (the virus that causes COVID-19) within one minute¹
- The active in VIRALEZE™ is also highly active against multiple strains and variants of SARS-CoV-2, including the [Alpha variant](#) and further testing is underway with other Variants of Concern²
- Consumers in India can already purchase VIRALEZE™ via www.viraleze.co for personal use and this registration will expand this access
- Commercial discussions with commercial partners in India for distribution into both the private (consumer) and Government markets are well advanced
- Starpharma is also progressing discussions for B2B sales with a number of companies in India

Melbourne, Australia; 11 June 2021: Starpharma (ASX: SPL, OTCQX: SPHY) today announced it had received confirmation that VIRALEZE™ antiviral nasal spray has been registered for sale nationally in India via the Central Drugs Standard Control Organisation (CDSCO), which is part of the Indian Ministry of Health and Family Welfare. Consumers in India can currently purchase VIRALEZE™ via www.viraleze.co, and discussions to finalise local distribution arrangements with potential commercial partners into both the private (consumer) and Government markets are well advanced. Starpharma is also progressing product supply preparations for the Indian market.

India has a population of more than 1.3 billion and the ongoing COVID-19 crisis in the country has seen the death toll surpass 359,000 people, and more than 29 million cases.³ At the peak of the crisis, there were more than 400,000 cases being reported per day, the highest of any country since the pandemic began.

VIRALEZE™ is an easy-to-use antiviral nasal spray, which can be stored at room temperature and does not require cold storage or specialised transportation. It contains SPL7013 (astodrimmer sodium), which has been shown in laboratory studies to inactivate a broad spectrum of respiratory viruses, including >99.9% of coronavirus SARS-CoV-2 (the virus that causes COVID-19). SPL7013 has been shown to be virucidal, rapidly inactivating >99.9% of SARS-CoV-2 within 60 seconds⁴ with potent antiviral activity shown in multiple strains and variants of the virus.

The active in VIRALEZE™ has also been shown to be highly active against multiple strains and variants of SARS-CoV-2, including the [Alpha variant](#), a Variant of Concern, which is the

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

² A Variant of Concern is a variant of the virus for which there is evidence of certain attributes including increased transmissibility, more severe disease, and reduced vaccine-induced protection from severe disease (<https://www.cdc.gov/coronavirus/2019-ncov/variants/variant-info.html#Concern> and <https://www.ecdc.europa.eu/en/covid-19/variants-concern>)

³ [India Population \(2021\) - Worldometer \(worldometers.info\)](https://www.worldometers.info/) [India COVID-19 Crisis | UNICEF Australia Emergency Appeal](#) [India: WHO Coronavirus Disease \(COVID-19\) Dashboard With Vaccination Data | WHO Coronavirus \(COVID-19\) Dashboard With Vaccination Data](#)

⁴ Paull J.R.A., et al. Virucidal and antiviral activity of astodrimmer sodium against SARS-CoV-2 *in vitro*. *Antiviral Res* 2021;191:105089 (<https://doi.org/10.1016/j.antiviral.2021.105089>)

second most common variant reported in India⁵ and has been responsible for COVID-19 cases in ~135 countries to date⁶. Further testing is underway with other Variants of Concern.

VIRALEZE™ antiviral nasal spray complements other COVID-19 prevention strategies, including vaccines. It has special relevance in areas of high population density, and where social distancing is not possible and in high-risk environments like travel, hotel quarantine, and sporting events (e.g. Cricket matches, Olympics etc).

Dr Jackie Fairley, CEO of Starpharma, commented: *“India continues to record hundreds of thousands of COVID-19 cases every day. Starpharma has worked extremely hard to achieve expedited registration of VIRALEZE™ in India given the significant need, and we are pleased that Indian consumers are able to access the product immediately through our webstore www.viraleze.co. We are also well advanced in progressing negotiations for distribution arrangements with potential local commercial partners to enable greater access to the product”.*

Starpharma is also progressing regulatory activities for a number of markets, including Australia. The Company will make further announcements upon registration and launch of the product in other countries/regions.

Information on the product is available at www.viraleze.co and consumers can sign up for updates, including on product availability.

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 astodimer sodium (SPL7013), shown in laboratory studies to inactivate respiratory viruses, including >99.9% of coronavirus SARS-CoV-2.^{Error! Bookmark not defined.}

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™ can be used alongside vaccines, masks, and physical distancing.

Advantages of VIRALEZE™



- Broad-spectrum, works against multiple strains of SARS-CoV-2 and multiple respiratory viruses.
- Potent antiviral activity against multiple strains of SARS-CoV-2.
- Virucidal, irreversibly and rapidly inactivating >99.9% of coronavirus/SARS-CoV-2 within one minute.¹
- Ability to inactivate virus either before or after exposure.
- Contains a well-tolerated, already marketed active, which is not absorbed into the bloodstream.
- Provides a moisturising and protective barrier to help keep nasal tissue hydrated.
- Room temperature storage, easy and convenient for regular use.

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.

⁵ <https://aci.health.nsw.gov.au/covid-19/critical-intelligence-unit/sars-cov-2-variants>

⁶ https://cov-lineages.org/global_report_B.1.1.7.html

About Starpharma

Starpharma Holdings Limited (ASX:SPL, OTCQX:SPHY) 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 is available in the UK through LloydsPharmacy and elsewhere via www.viraleze.co. 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.