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ASX Announcement

VIRALEZE SPL7013 highly active in UK variant of coronavirus

- **New antiviral testing at the Scripps Research Institute has confirmed SPL7013 (VIRALEZE™ active) has potent antiviral activity against the UK (B.1.1.7) SARS-CoV-2 coronavirus mutant/variant strain**
- **SPL7013 demonstrated potent antiviral activity against the UK variant at clinical concentrations, achieving >98% reduction of infectious virus**
- **The UK variant of SARS-CoV-2 is classified a 'variant of concern' by UK public health authorities, the US Centers for Disease Control and Prevention (CDC) and the European Centre for Disease Prevention and Control (ECDC)**
- **A SARS-CoV-2 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**[1,2]
- **The UK variant of concern has been reported to be up to 90% more transmissible than preceding strains, and its spread led to a surge in COVID-19 cases and deaths in the UK; this variant has been reported to be responsible for more than 98% of recent SARS-CoV-2 infections in England**[3]
- **The broad-spectrum antiviral activity of VIRALEZE™ is a compelling feature for the product, particularly as new SARS-CoV-2 coronavirus variants/strains continue to emerge**
- **VIRALEZE™ antiviral nasal spray is available in the UK at LloydsPharmacy and other independent pharmacies, and is also available via www.viraleze.co**

Melbourne, Australia; 1 June 2021: Starpharma (ASX: SPL, OTCQX: SPHRY) today announced new data confirming that SPL7013, the active in VIRALEZE™ antiviral nasal spray, has potent antiviral activity against the UK (B.1.1.7) SARS-CoV-2 variant of concern (hCoV-19/England/204820464/2020) in laboratory studies, achieving more than 98% reduction in infectious virus in antiviral assays.

This antiviral testing of SPL7013 was conducted in the laboratory of virologist Professor Philippe Gallay at The Scripps Research Institute in the US. Previous studies at the same laboratory have demonstrated potent antiviral activity of SPL7013 against the US strain of SARS-CoV-2.[4]

The level of activity of SPL7013 against this UK variant in the current assay was equivalent to that achieved by SPL7013 against the US strain of SARS-CoV-2 (2019-nCoV/USA-WA1/2020) in the same assay (i.e., >98% reduction in infectious virus vs virus control). This finding indicates that there is no loss of potency for SPL7013 against the UK variant compared with earlier strains of the virus.

A key benefit of the product is its broad-spectrum activity, and retention of activity in multiple coronavirus variants. This is thought to be due to its mechanism of action, which is not reliant on specific binding sites within the spike protein. The active in VIRALEZE™ acts by blocking the interaction between the SARS-CoV-2 viral 'spikes' and the human cells the virus is seeking

[1] https://www.cdc.gov/coronavirus/2019-ncov/variants/variant-info.html#Concern
[2] https://www.ecdc.europa.eu/en/covid-19/variants-concern
[3] Davies, N.G., et al. Estimated transmissibility and impact of SARS-CoV-2 lineage B.1.1.7 in England. *Science* 2021;372(6538):eabg3055 (https://doi.org/10.1126/science.abg3055)
[4] 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)

to infect. This lack of reliance on specific binding sites within the spike protein could represent a key advantage for the breadth of activity of SPL7013 against multiple variants.

The broad-spectrum antiviral activity of VIRALEZE™ is a compelling feature for the product to be used alongside other prevention strategies and complementary to vaccines, particularly as health authorities respond to the emergence of new SARS-CoV-2 coronavirus variants.

The US CDC, European CDC, and health authorities in the UK and elsewhere currently identify a number of strains of SARS-CoV-2 that are classified as variants of concern or interest, including:

- UK (B.1.1.7)
- South Africa (B.1.351)
- Japan/Brazil (P.1)
- India (B.1.617.2)

These variants arise from mutation of the SARS-CoV-2 virus in the community and the names "UK", "South Africa" and "Japan/Brazil" represent where they were first isolated. They are classified as 'variants of concern' due to certain attributes such as having a higher level of transmissibility, causing more severe disease (e.g., increased hospitalisations or deaths) and/or reduced effectiveness of current treatments or vaccines.

Testing of SPL7013 against the Japan/Brazil and South Africa variants is also underway. The India (B.1.617.2) variant, which is currently linked to outbreaks in the UK and Australia, is planned to be tested when virus availability permits.

With these latest data, SPL7013 has now been shown in laboratory studies to have potent antiviral activity against all four SARS-CoV-2 strains tested to date: UK (B.1.1.7) (hCoV-19/England/204820464/2020), USA (2019-nCoV/USA-WA1/2020), Europe (Slovakia/SK-BMC5/2020), and Australia (hCoV-19/Australia/VIC01/2020).

Concerns have been reported regarding the first generation of vaccines and certain SARS-CoV-2 variants that may render those vaccines less effective ('vaccine escape')[5,6], and data from vaccination trials have shown variability in reducing transmission or preventing severe illness. Accordingly, protective measures such as mask wearing, social distancing, and good hygiene will continue to play an important role in combating the global pandemic.

VIRALEZE™ complements these other prevention strategies, including vaccines, and has special relevance where social distancing is not possible such as crowded environments like travel, sporting and social events. In May, Starpharma announced a partnership between VIRALEZE™ and Harlequins, a professional rugby union team in the UK. Starpharma is also in discussion with multiple other sporting teams (including Olympic) interested in using the product to keep their players and athletes safe.

Dr Jackie Fairley, CEO of Starpharma, commented: *"Given the constantly evolving public health challenges presented by SARS-CoV-2 variants, we are delighted to see that VIRALEZE™ retains potent activity against the important UK variant. SPL7013 has consistently shown high levels of antiviral activity, not only against multiple COVID-19 variants, but also against a broad spectrum of other respiratory viruses, including influenza, making VIRALEZE™ an ideal product to use alongside vaccines and other measures."*

[5] Woodley, M. Current COVID vaccines could be ineffective by next year: epidemiologists. *newsGP*, March 2021 (https://www1.racgp.org.au/newsgp/clinical/current-covid-vaccines-could-be-ineffective-by-nex)
[6] Neuzil, K.M. Interplay between emerging SARS-CoV-2 variants and pandemic control. *N Engl J Med* 2021;384:1952-1954 (https://doi.org/10.1056/nejme2103931)

Internationally recognised virology researcher, Professor Philippe Gallay, at the renowned Scripps Research Institute in the US, commented: *"We are impressed with the antiviral activity of SPL7013, and that it retains potent activity against the SARS-CoV-2 UK variant B.1.1.7.*

"It is particularly exciting to see a product with this level of antiviral activity against a variant of concern that is much more transmissible than earlier SARS-CoV-2 strains. The latest data are consistent with our previous data showing antiviral and virucidal effects of SPL7013 against the US strain of this highly infectious virus, and suggest a mechanism of action that is not affected by mutations in the virus spike proteins."

These new data on the UK (B.1.1.7) SARS-CoV-2 variant provide further confirmation of the broad-spectrum antiviral properties of SPL7013, and are in addition to previously announced data for other pandemic causing coronaviruses, SARS-CoV and MERS-CoV, and other respiratory viruses, including respiratory syncytial virus (RSV) and influenza virus subtype, H1N1 or "Swine Flu".

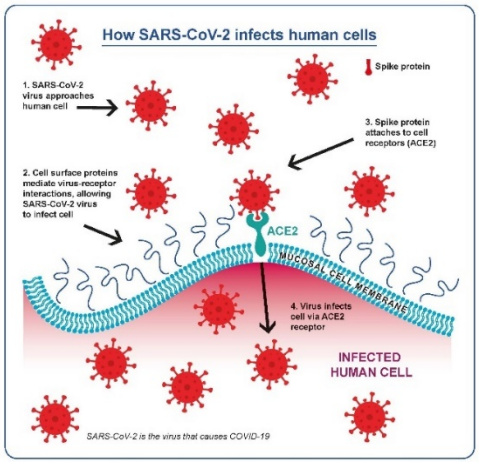
Extensive data on the antiviral and virucidal activity of astodrimer sodium (SPL7013) against SARS-CoV-2 was recently published in the prestigious international scientific journal, Antiviral Research.[4]

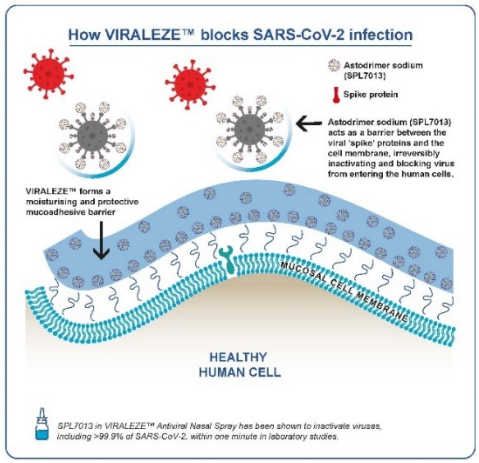
Starpharma is pursuing avenues to provide rapid access to VIRALEZE™ in a number of countries where outbreaks have occurred. Starpharma is exploring expedited registration where applicable. The Company is also progressing other regulatory activities for a number of markets, including Australia. Starpharma will make further announcements upon registration and launch of the product in other countries/regions.

For more information on VIRALEZE™ visit www.viraleze.co.

How VIRALEZE™ works

VIRALEZE™ is the only nasal spray containing a specifically designed antiviral active that has previously been shown in virucidal assays in laboratory studies to irreversibly inactivate more than 99.9% of SARS-CoV-2 within one minute.[4] VIRALEZE™ targets the area in the nasal cavity where respiratory viruses that cause colds, flu, and more severe respiratory illness, such as COVID-19, first attach and start to multiply. The active in VIRALEZE™ acts by blocking the interaction between the SARS-CoV-2 viral 'spikes' and the human cells the virus is seeking to infect.





Experimental details

In this experiment, SPL7013 at concentrations ranging from 0.0015 to 30 mg/mL was added to Vero E6 cells in triplicate 1 hour prior to, at the time of, or 1 hour after exposure of cells to SARS-CoV-2 UK (B.1.1.7) strain, hCoV-19/England/204820464/2020, or US strain, 2019-nCoV/USA-WA1/2020. After 6 hours, virus and compound were removed, and cells were left for multiple virus replication cycles. Supernatant was removed and assayed for the amount of infectious virus by plaque assay (plaque forming units/mL) and ELISA (amount of virus nucleocapsid, ng/mL). Virus controls, which were not exposed to SPL7013, were run in parallel. At concentrations ≥10 mg/mL, >98% reduction in infectious virus compared with virus control, by both plaque assay and ELISA, and for both UK and US strains, was observed when SPL7013 was added 1 hour prior to infection. Up to >98% reduction of infectious virus was also achieved when SPL7013 was added at the time of, or 1 hour after exposure of cells to the viruses.

About VIRALEZE™ Antiviral Nasal Spray

VIRALEZE™ Antiviral Nasal Spray was developed by Starpharma (ASX: SPL) and is registered for sale in Europe. It is an easy-to-use antiviral nasal spray containing 1% w/w astodrimer sodium (SPL7013), shown in laboratory studies to inactivate respiratory viruses, including >99.9% of coronavirus SARS-CoV-2.[4]

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.[4]
- 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.

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 available in the UK through LloydsPharmacy and in Europe 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.

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", 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.