

SPL7013 in VIRALEZE™ virucidal against influenza A and B

- The broad-spectrum antiviral agent in VIRALEZE™ nasal spray, SPL7013, achieved 95% and 99.7% reduction of virus infectivity against the two most significant influenza viruses, A and B, respectively
- Influenza A and B viruses are responsible for seasonal epidemics of influenza, and influenza A viruses are known to cause flu pandemics
- SPL7013 demonstrated irreversible virucidal properties against both types of influenza virus
- This virucidal action of SPL7013 against influenza virus is in contrast to other antiviral agents used in marketed nasal sprays that were tested in this experiment, including hydroxypropyl methyl cellulose (HPMC) and iota-carrageenan, neither of which demonstrated virucidal activity
- These new virucidal findings in influenza A and B further demonstrate the potent broad-spectrum activity of SPL7013
- These results in influenza virus are consistent with previous data for SPL7013, demonstrating virucidal activity against multiple viruses, including variants of SARS-CoV-2, Delta, Alpha, Beta, Gamma, Kappa, and Omicron, as well as other respiratory viruses that cause the common cold
- VIRALEZE™ is registered in more than 30 countries, including in Europe, the UK, Middle East, and Asia, and Starpharma is actively pursuing registration of the product in multiple other markets

Melbourne, Australia; 18 May 2022: Starpharma (ASX: SPL, OTCQX: SPHRY) today announced that SPL7013, the antiviral agent in VIRALEZE™ nasal spray, achieved 95% and 99.7% reduction in viral infectivity against two significant types of influenza virus, A and B, respectively, in virucidal assays¹. The virucidal assays conducted at the Scripps Research Institute in the US assessed the irreversible nature of the effect of a compound against viruses.

In addition to testing the virucidal activity of SPL7013, the Scripps testing assessed the activity of two antiviral agents used in widely available nasal sprays - hydroxypropyl methyl cellulose (HPMC) and iota-carrageenan. In contrast to the potent and rapid effect of SPL7013, HPMC and iota-carrageenan did not exhibit virucidal effect in this experiment, even after 30 minutes.

The antiviral activity of SPL7013 in other pandemic-causing influenza A viruses has previously been reported by Starpharma, with SPL7013 demonstrating potent antiviral activity against H1N1 (Swine Flu) and H3N2 (Avian Flu) ([announced 3 March 2021](#)).

These new virucidal findings are consistent with the previously reported activity of SPL7013 against multiple variants of SARS-CoV-2, including Delta, Alpha, Beta, Gamma, and Omicron, as well as other respiratory viruses that cause the common cold. The broad-spectrum antiviral and virucidal activity of SPL7013 (VIRALEZE™), which encompasses all of the pandemic-causing respiratory viruses, highlights the opportunities for VIRALEZE™ in combatting seasonal flu epidemics as well as pandemic preparedness.

¹ Both within 5 minutes. Noting the maximal possible reduction of virus infectivity in these assays was 96% for influenza A and 99.8% for influenza B.

The rapid virucidal effect of SPL7013 against multiple respiratory viruses, including influenza viruses and multiple variants of SARS-CoV-2, is a positive and differentiating feature of VIRALEZE™ compared with other antiviral compounds used in marketed nasal sprays. The excellent stability of SPL7013 and room temperature storage of VIRALEZE™ are also significant advantages for the product.

Dr Jackie Fairley, CEO of Starpharma, commented:

“Influenza is one of the most common respiratory infections globally, resulting in high rates of morbidity and mortality. Starpharma is pleased to share these new results in influenza for SPL7013, the agent in VIRALEZE™. Of particular note is the superior performance of SPL7013, which demonstrated highly potent and rapid virucidal activity in influenza A and B compared to other antiviral agents used in widely available nasal sprays.”

Experimental Details

In the virucidal assays, SPL7013 (1, 3 and 10 mg/mL), iota-carrageenan (1.2 mg/mL) or HPMC (10 mg/mL) were incubated with influenza A (H1N1 pandemic strain) or influenza B (Victoria) strains before virus was pelleted to separate and neutralise the compound in solution. The treated virus was then re-suspended and added to MDCK cells for quantitation of infectious virus by plaque assay (plaque forming units [pfu]/mL). Virus controls, which were not exposed to test compounds, were run in parallel.

SPL7013 at 10 mg/mL (the concentration of SPL7013 in VIRALEZE™) achieved up to 95% and 99.7% reduction in infectious virus compared with virus control against influenza A and B, respectively (see Table 1).

Table 1. Percent reduction* in infectious influenza A and B after incubation with SPL7013 at 10 mg/mL (concentration in VIRALEZE™)

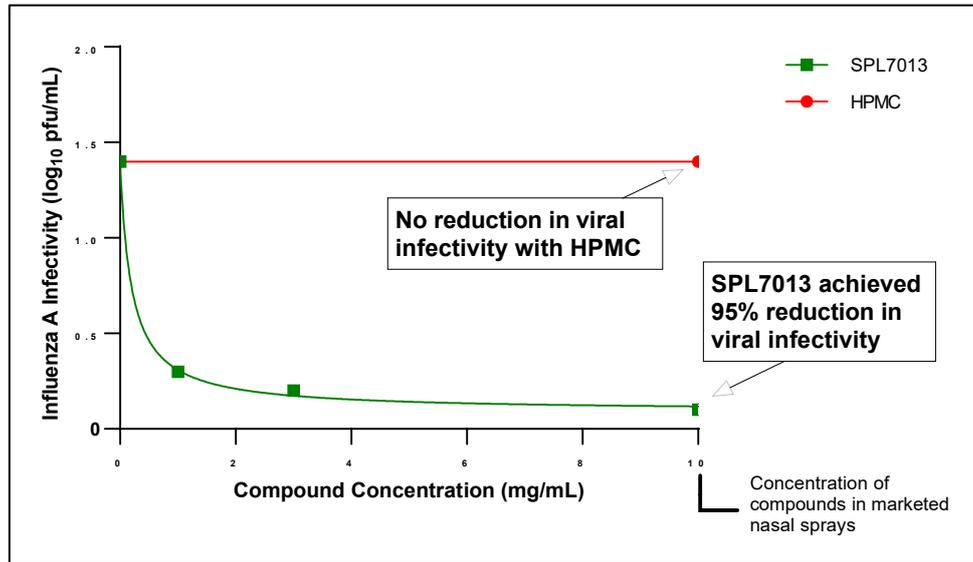
Virus:SPL7013 Incubation Time	Percent Reduction* in Infectious Influenza A vs Virus Control[^]	Percent Reduction* in Infectious Influenza B vs Virus Control[^]
1 minute	92.1%	99.4%
5 minutes	95.0%	99.7%
15 minutes	93.7%	99.6%
30 minutes	95.0%	99.4%

[^]virus without exposure to SPL7013

*Noting the maximal possible reduction of virus infectivity in these assays was 96% for influenza A and 99.8% for influenza B

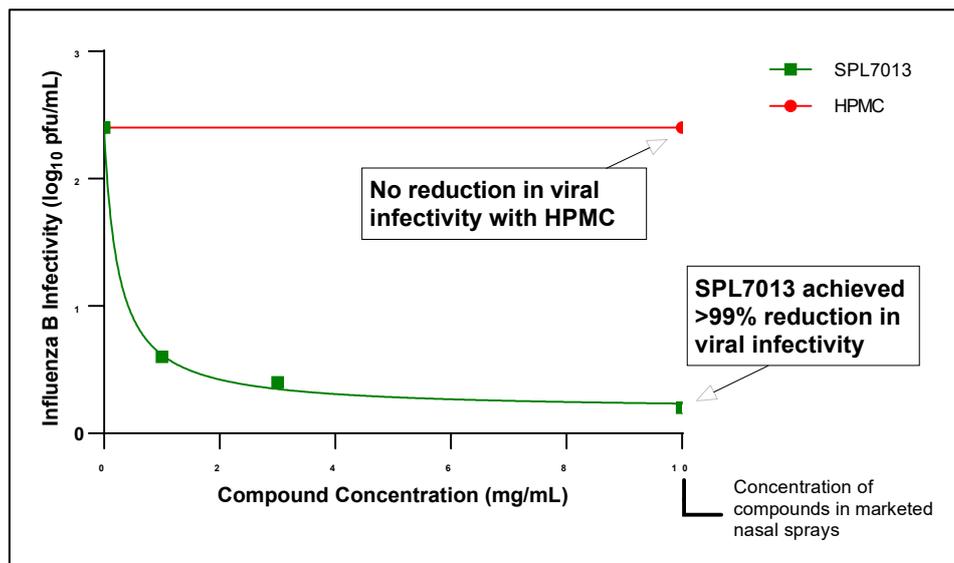
In contrast, iota-carrageenan and HPMC, which are antiviral components of widely marketed nasal sprays, did not reduce influenza A or B virus infectivity irreversibly, even after 30 minutes' incubation with virus (see Figures 1 and 2 for comparison of SPL7013 with HPMC).

Figure 1. Infectivity of influenza A virus (\log_{10} pfu/mL) following incubation with SPL7013 or HPMC (mg/mL)



Graph shows influenza A infectivity following 30 mins' incubation of virus with SPL7013 (0, 1, 3 or 10 mg/mL) or HPMC (0 or 10 mg/mL); Curves calculated using GraphPad Prism 9.3.1

Figure 2. Infectivity of influenza B virus (\log_{10} pfu/mL) following incubation with SPL7013 or HPMC (mg/mL)



Graph shows influenza B infectivity following 30 mins' incubation of virus with SPL7013 (0, 1, 3 or 10 mg/mL) or HPMC (0 or 10 mg/mL); Curves calculated using GraphPad Prism 9.3.1

VIRALEZE™ Antiviral Nasal Spray

VIRALEZE™ is a broad-spectrum antiviral nasal spray. The antiviral agent in VIRALEZE™, referred to as SPL7013, has been shown to have potent antiviral and virucidal activity in multiple respiratory viruses, including virucidal activity in multiple variants of SARS-CoV-2, including Omicron and Delta, as well as influenza viruses A and B, in laboratory studies. VIRALEZE™ is applied in the nose to provide a physical barrier - between viruses and the nasal mucous membrane - that traps and blocks virus.

VIRALEZE™ is now registered as a medical device in more than 30 countries, including in Europe, the UK, Asia, and the Middle East, and available in certain markets online. Product claims may differ by market. VIRALEZE™ is partnered with LloydsPharmacy in the UK, ADMENTA Italia Group in Italy, HealthCo/TBL in Vietnam, and E&N in countries in the Middle East. VIRALEZE™ is not approved for sale or supply in Australia.

VIRALEZE™ was developed with the support of \$1 million in funding by the Australian Government's Medical Research Future Fund (MRFF) Biomedical Translation Bridge (BTB) Program, with support from UniQuest.

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 respiratory viruses, DEP® drug delivery and VivaGel®. Starpharma has developed VIRALEZE™, an antiviral nasal spray that is registered for sale in >30 countries, including in Europe, Asia, and the Middle East, and available outside Australia in certain markets online. VIRALEZE™ is not approved for sale or supply in Australia. SPL7013 is utilised in approved products - the VivaGel® condom and VivaGel® BV. VivaGel® products have been licensed in >160 countries, are registered 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 & Co., Inc., 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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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.