ASX Announcement

SPL7013 shows potent antiviral activity in RSV expanding use for nasal spray

- **New data generated demonstrates Starpharma's antiviral nasal spray active (SPL7013) has potent antiviral activity against Respiratory Syncytial Virus (RSV)**
- **RSV is a common and very contagious virus that affects the lungs and airways, infecting an estimated 64 million people and causing 160,000 deaths each year globally**[1]
- **SPL7013 was effective against RSV when used either before or after exposure of cells to the virus, indicating that the nasal spray would be effective if used before and/or after exposure to the virus**
- **This data, generated at a US specialist virology testing laboratory, expands the antiviral spectrum of SPL7013 from previously announced respiratory viruses, including SARS-CoV-2 (the coronavirus causing COVID-19) and influenza**
- **Starpharma has formulated SPL7013 into a preventative nasal spray, VIRALEZE™ - on track to be commercially available in H1 2021**

Melbourne, Australia; 19 November 2020: Starpharma (ASX: SPL, OTCQX: SPHRY) today announced it has completed additional testing showing potent antiviral activity of SPL7013 against human respiratory syncytial virus (RSV). RSV is a common and very contagious virus that affects the lungs and airways. RSV is most problematic in the young and the elderly and those with weakened immune systems, or chronic heart and lung disease, including asthma.[2] More than 177,000 adults are hospitalized and 14,000 of them die due to RSV infection in the US annually.[3] RSV is also one of the viruses responsible for the common cold.

Despite extensive efforts over many years, there are few strategies available to prevent or treat RSV infection. There are no vaccines for RSV, and few therapeutics available to treat RSV infections. Like influenza, RSV frequently mutates making vaccine development particularly challenging.[4]

The data demonstrating the antiviral activity of SPL7013 against RSV further expands the antiviral spectrum of SPL7013 in respiratory viruses, which already includes SARS-CoV-2 (the coronavirus that causes COVID-19) and H1N1 influenza. Starpharma is also testing SPL7013 against other respiratory viruses with the intention to add these to the product claims as data becomes available.

SPL7013 has been formulated into a preventative antiviral nasal spray, VIRALEZE™, which is now in the late stages of development and on track to be commercially available in H1 2021, with first launches expected to occur in Europe and other regions to follow. VIRALEZE™ is an easy to use preventative nasal spray, which can be stored at room temperature and will not require refrigeration. Recent consumer research for VIRALEZE™ conducted in Europe indicates strong, wide-ranging appeal, particularly in regard to the broad spectrum antiviral activity including COVID-19 and influenza.

[1] https://www.niaid.nih.gov/diseases-conditions/respiratory-syncytial-virus-rsv
[2] https://www.cdc.gov/rsv/factsheet-older-adults.html
[3] https://www.cdc.gov/rsv/about/index.html
[4] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5217795/

The expanded range of viruses against which SPL7013 is active further strengthens the product proposition for VIRALEZE™ as well as its potential use in the management of both endemic viral respiratory diseases and preparedness for future pandemics.

Dr Jackie Fairley, Starpharma CEO, commented: "We are pleased to announce the expanded use of SPL7013 in RSV. RSV is a common virus which has significant morbidity and mortality for the elderly and those with chronic disease. What these results confirm, is that SPL7013 has broad spectrum antiviral activity, and that VIRALEZE™ could play an important role for future pandemic preparedness. The rapid development and commercialisation of SPL7013 as VIRALEZE™ antiviral nasal spray is on track, with the product set to be available in some markets as early as 1H CY2021".

"SPL7013 is virucidal, inactivating more than 99.9% of SARS-CoV-2, which causes COVID-19. For every additional virus, like RSV, in which SPL7013 shows activity - builds the commercial opportunity for the product both in endemic respiratory viral infections and potentially for use in future pandemics", added Dr Fairley.

About Respiratory Syncytial Virus (RSV)

RSV is a common and very contagious virus, that affects the lungs and airways. RSV is most problematic in the young and the elderly and those with weakened immune systems, or chronic heart and lung disease, including asthma.[5] It is one of the leading causes of death of infants worldwide, but is also important in older adults and adults with chronic medical conditions. RSV has been associated with long term respiratory conditions such as chronic bronchitis, asthma, obstructive pulmonary disease and idiopathic pulmonary fibrosis. It can also result in serious disease in older adults especially those who are frail or have other health problems such as chronic bronchitis and COPD.[6] RSV is also one of the most frequent causes of the common cold and can infect people of all ages.

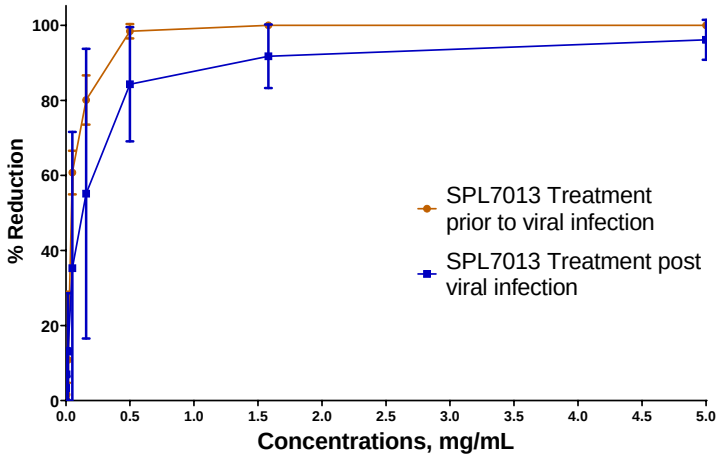
Study results

Antiviral testing of SPL7013 against RSV was conducted by a US-based, specialised antiviral testing laboratory.

As with other viruses including coronavirus (SARS-CoV-2), SPL7013 showed potent antiviral activity against RSV when applied to the cells before or after exposure to the virus (Figure 1).

In addition, the selectivity index[7] was also very high (up to 790), indicating potent antiviral efficacy with minimal cellular (off-target) toxicity.

Figure 1: Inhibition of human respiratory syncytial virus infection when SPL7013 is used to treat cells prior to and post-infection



[5] https://www.cdc.gov/rsv/factsheet-older-adults.html
[6] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5217795/pdf/zcm277.pdf
[7] Selectivity index is a ratio of antiviral activity to cellular toxicity. The higher the selectivity index, the theoretically safer and more effective a compound would be in humans.

Given its mechanism of action, SPL7013 has activity against a broad spectrum of viruses. In addition, in previous antiviral testing, SPL7013 has been shown to be active against multiple drug-resistant strains of viruses including HIV and HSV (herpes simplex virus), and to not select for virus resistant to SPL7013. Therefore, SPL7013 is also expected to be active even if virus mutates, which is an advantage over traditional vaccine approaches which can be overcome by mutations (e.g. annual strain updates required for influenza vaccines).

Previous announcements in relation to Starpharma's antiviral nasal spray include:

- SPL7013 COVID-19 nasal spray virucidal against SARS-CoV-2
- SPL7013 nasal spray for COVID-19 – development update
- Starpharma awarded $1M MRFF funding for COVID-19 spray

About Starpharma

Starpharma Holdings Limited (ASX: SPL, OTCQX:SPHRY), located in Melbourne Australia, is an ASX 300 company and is a world leader in the development of dendrimer products for pharmaceutical, life science and other applications.

Starpharma's underlying technology is built around dendrimers – a type of synthetic nanoscale polymer that is highly regular in size and structure and well suited to pharmaceutical and medical uses. Starpharma has two core development programs: VivaGel® portfolio and DEP® drug delivery with the Company developing several products internally and others via commercial partnerships.

VivaGel®: Starpharma's women's health product - VivaGel® BV is based on SPL7013, astodrimer sodium, a proprietary dendrimer. VivaGel® BV for bacterial vaginosis (BV), is available for sale under the brand names Betafem® BV Gel (UK), Betadine BV™ (Europe), Betadine™ BV Gel (Asia) and Fleurstat BVgel (Australia and New Zealand) and a new drug application has been submitted to the US FDA. Starpharma has licensed the sales and marketing of VivaGel® BV to ITF Pharma for the US; Mundipharma for Europe, Russia, CIS, Asia, the Middle East, Africa and Latin America; and to Aspen Pharmacare for Australia and New Zealand. Starpharma also has licence agreements to market the VivaGel® condom (an antiviral condom which includes VivaGel® in the lubricant) in several regions, including Australia, Europe, Canada, China and Japan (Okamoto). The VivaGel® condom has been launched in Japan under Okamoto's 003 brand, and in Australia and Canada under the LifeStyles Dual Protect® brand. The VivaGel® condom is approved in Europe.

DEP® - Dendrimer Enhanced Product®: Starpharma's DEP® drug delivery platform has demonstrated reproducible preclinical benefits across multiple internal and partnered DEP® programs, including improved efficacy, safety and survival. Starpharma has three internal DEP® products – DEP® docetaxel, DEP® cabazitaxel and DEP® irinotecan - in clinical development in patients with solid tumours. Starpharma's partnered DEP® programs include a multiproduct DEP® licence with AstraZeneca, which involves the development and commercialisation of two novel oncology compounds, with potential to add more. In June 2019 Starpharma signed a Development and Option agreement with AstraZeneca for a DEP® version of one of AstraZeneca's major marketed oncology medicines.

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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.