ASX Announcement

SPL7013 COVID-19 nasal spray virucidal against SARS-CoV-2

- **New data generated at Scripps Research Institute in the US shows that Starpharma's antiviral nasal spray active (SPL7013) is virucidal, inactivating more than 99.9% of SARS-CoV-2, the virus that causes COVID-19**
- **Potent antiviral activity of SPL7013 against SARS-CoV-2 was evident when used either before or after exposure of cells to the virus meaning that the nasal spray could be used before or after exposure to the virus**
- **Starpharma is rapidly advancing development, regulatory, manufacturing and commercialisation activities and leveraging its extensive technical data set and approved status of SPL7013 to expedite approval with product now expected to be ready for market 1H CY2021**

Melbourne, Australia; 14 September 2020: Starpharma (ASX: SPL, OTCQX: SPHRY) today announced it has completed additional antiviral testing for SPL7013 against SARS-CoV-2 in studies conducted in the laboratory of internationally recognised virology researcher, Professor Philippe Gallay, at the renowned Scripps Research Institute in the US.

The latest results confirm that when SPL7013 is applied at the concentration of the SPL7013 COVID-19 nasal spray, it has potent virucidal activity, inactivating more than 99.9% of SARS-CoV-2, the virus that causes COVID-19.

These data expand on the previously announced (see previous ASX announcement - 25 August 2020) data showing that SPL7013 has potent antiviral activity and inhibits infection of host cells by SARS-CoV-2 when the compound is applied to the cells either before or after exposure to the virus. Earlier testing also showed that SPL7013 has a very favourable and high selectivity index[1] (up to ~2200), indicating potent antiviral efficacy with minimal cellular toxicity. The high selectivity index of SPL7013 compares very favourably with the selectivity index against SARS-CoV-2 reported in the literature of 279 for remdesivir and 55 for hydroxychloroquine.[2,3]

Dr Jackie Fairley, Starpharma CEO, commented: "We are delighted to be working with Professor Gallay to expedite the development of this important product. These latest data show that at clinically relevant concentrations (at the concentration of the SPL7013 COVID-19 nasal spray), SPL7013 inactivates more than 99.9% of SARS-CoV-2, which represents a compelling feature for the product. This potent virucidal action is consistent with the activity seen for SPL7013 in other viruses, including HIV and HSV."

Professor Gallay commented: "We have been working with Starpharma for a number of months now and are impressed with the antiviral data generated in our lab for SPL7013 against SARS-CoV-2. It is particularly exciting to see a product show such a potent and clear virucidal effect against this highly infectious virus, and for its antiviral activity to be present when SPL7013 is added either before or after exposure of cells to the virus."

---

[1] 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.

[2] Pizzorno, A., et al., 2020. *In vitro* evaluation of antiviral activity of single and combined repurposable drugs against SARS-CoV-2. *Antiviral Res.* 104878. Advance online publication. https://doi.org/10.1016/j.antiviral.2020.104878

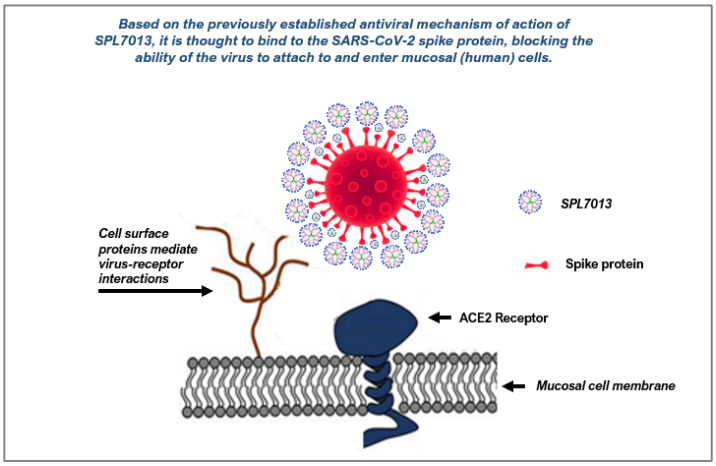
[3] Liu, J., et al., 2020. Hydroxychloroquine, a less toxic derivative of chloroquine, is effective in inhibiting SARS-CoV-2 infection in vitro. *Cell Discovery* 6(16). https://doi.org/10.1038/s41421-020-0156-0

Dr Fairley added “Starpharma’s COVID-19 nasal spray has potential to be an important near-term preventative product, and given it is based on an already marketed active, its path to market is both faster and less complex than a completely new product. Another attractive feature of Starpharma’s SPL7013 COVID-19 nasal spray is that it is entirely complementary to other prevention measures such as PPE and vaccines. It also has special relevance where social distancing is not possible such as crowded environments and certain workplaces. The importance of having multiple preventative product strategies has been highlighted by the recent challenges with some vaccine trials. Starpharma’s topical antiviral nasal spray could play a role both prior to vaccines being available, and complementary to vaccines once available to further reduce risk.”

Starpharma is expediting the development of the SPL7013 nasal spray and has already completed reformulation, pilot product manufacture, selection of device and packaging components, identification of manufacturer and compiled regulatory documentation in preparation for submission (see previous ASX announcement - 25 August 2020). The company has also commenced commercial discussions across a range of distribution channels and customer groups (e.g. B2B, online platforms) and expects that the product will be ready for market in 1H CY2021.

SPL7013 Mechanism of antiviral action

SPL7013 inactivates viruses by blocking the interaction between viral surface proteins and the human cell receptor proteins. As for other viruses inhibited by SPL7013, SARS-CoV-2 infects human cells by using the characteristic viral surface proteins, or “spikes”, to attach to receptor proteins on the surface of human cells and SPL7013 blocks this interaction.



About Scripps Research Institute

Scripps Research Institute is ranked the most influential institution in the world for its impact on innovation. Scripps’ researchers lead breakthrough studies that address the world’s most pressing health concerns. In 2018, Scripps Research was ranked top stand-alone scientific institute in the United States for producing high-quality research by Nature Index, based on discoveries published in leading scientific journals.

About SPL7013 COVID-19 nasal spray

SPL7013 is a broad-spectrum antiviral with potent SARS-CoV-2 activity and is also the active in VivaGel® marketed products approved in UK, Europe, Asia, Canada, Australia, and New Zealand. SPL7013 acts early in the viral replication cycle and has virucidal activity against SARS-CoV-2 with antiviral activity evident when used either before or after exposure of cells to the virus. SPL7013 inactivates viruses by blocking the interaction between viral surface proteins and the human cell receptor proteins. SPL7013 has broad spectrum antiviral and virucidal effects, with activity demonstrated against a range of viruses, including HIV, herpes simplex virus (HSV), human papillomavirus (HPV), adenovirus, H1N1 influenza virus, hepatitis B virus (HBV) and Zika virus.

Given the broad antiviral activity, a SPL7013 nasal spray also has potential for application beyond SARS-CoV-2 for other common respiratory viruses, and could be useful in pandemic preparedness in the future. The SPL7013 nasal spray has the potential to complement vaccine strategies to further reduce risk by preventing acquisition and transmission of SARS-CoV-2, and play an important role in reducing transmission for the broader population and especially for frontline workers in the health, aged care and other industries such as travel. Whilst the initial focus is on a nasal spray as the most rapid path to market, the company also notes that SPL7013 could be applied via other routes of administration, such as ocular, nebulized (inhaled) or injection. The SPL7013 active is patented by Starpharma in major markets, and a specific patent application has been filed for the COVID-19 nasal spray. Starpharma recently announced the award of $1 million in matched funding by the Australian Government's Medical Research Future Fund Biomedical Translation Bridge Program.

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.

Starpharma.com | Twitter | LinkedIn

Media:
WE Communications
Rebecca Wilson
Mob: +61 417 382 391
rwilson@we-worldwide.com

Arthur Chan
+61 2 9237 2805
arthurc@we-worldwide.com

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.