

## **SPL7013 shows significant activity against SARS-CoV-2 (coronavirus)**

- **Starpharma's antiviral dendrimer, SPL7013, has been shown to have significant activity against SARS-CoV-2<sup>1</sup> (coronavirus), which causes COVID-19**
- **SPL7013 is the active component in Starpharma's range of marketed VivaGel<sup>®</sup> products<sup>2</sup> (VivaGel<sup>®</sup> BV and the VivaGel<sup>®</sup> condom), already sold in Australia, UK, Europe, Canada, Japan and South East Asia**
- **Given that products containing SPL7013 are already approved in the above markets, the existing preclinical and clinical data on file creates the opportunity to fast-track the development and commercialisation of SPL7013-based product(s) for COVID-19**

**Melbourne, Australia; 15 April 2020:** Starpharma (ASX: SPL, OTCQX: SPHRY) today announced that its proprietary VivaGel<sup>®</sup> active, astodimer sodium (SPL7013), has been shown in laboratory studies to have significant antiviral activity against the coronavirus that causes COVID-19 (coronavirus disease). SPL7013 inhibited the infection of cells with the SARS-CoV-2 virus and the finding was validated by replicate testing against a positive control compound, remdesivir (Gilead), which is considered a leading candidate for the treatment of COVID-19. The finding was also significant given that SPL7013 was reported to be the best performing test compound against SARS-CoV-2 in the laboratory's assay to date. With these positive results, Starpharma is evaluating product concepts and formulation options for SPL7013, which may have potential applications in the prevention and management of COVID-19.

Given SPL7013 is already approved as the active component of two marketed VivaGel<sup>®</sup> products (VivaGel<sup>®</sup> BV and the VivaGel<sup>®</sup> condom) and these products have regulatory approval in Europe, Canada, Japan, Australia and South East Asia, Starpharma anticipates it should be possible to fast-track certain aspects of the development path for products targeted at COVID-19. The Company will now commence additional short-term preclinical studies, and in parallel, will confirm the pathway with regulatory authorities. A new patent has also been filed following receipt of these coronavirus results. Starpharma retains rights to COVID-19 related products resulting from these findings and as such they would be the subject of new commercial licences and would not impact existing VivaGel<sup>®</sup> licences.

The SARS-CoV-2 antiviral testing of SPL7013 was conducted under contract by Melbourne-based 360Biolabs, which has developed SARS-CoV-2 assays to support antiviral discovery and development. SPL7013 is one of the first agents tested by 360Biolabs to demonstrate significant SARS-CoV-2 activity.

The VivaGel<sup>®</sup> active (SPL7013) has previously been shown to have potent antiviral activity against a wide range of viruses, including HIV, herpes simplex, hepatitis B, HPV, Zika virus and adenovirus. 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.

Dr Jackie Fairley, Starpharma CEO, commented: "Following the emergence of the coronavirus pandemic in February, Starpharma instigated testing of SPL7013 via a specialist

<sup>1</sup> Severe acute respiratory syndrome coronavirus 2, or SARS-CoV-2, is the virus that causes COVID-19.

<sup>2</sup> VivaGel BV<sup>®</sup> is marketed by Mundipharma as Betafem<sup>®</sup> BV Gel (UK), Betadine BV<sup>™</sup> (Europe), Betadine<sup>™</sup> BV Gel (Asia) and by Aspen Pharmacare as Fleurstat BVgel (Australia and New Zealand). The VivaGel<sup>®</sup> condom was launched by Okamoto as VivaGel<sup>®</sup> Zero Zero Three (003) (Japan) and by LifeStyles under the Dual Protect<sup>®</sup> brand and is pending launch by LifeStyles under the Absolute<sup>™</sup> Dual Protection brand in Europe.

antiviral testing laboratory in Melbourne. We are very pleased to find that the compound is highly active against the coronavirus that causes COVID-19 and we are now exploring a number of product opportunities, including a potential preventative application to reduce the risk of infection. Such a product could provide additional personal protection including for those in the frontline of this crisis, such as doctors, nurses and other essential workers, and is in keeping with Starpharma's strategy to expand commercial applications of our dendrimers. We are very pleased to be in a position to potentially help with the effort in overcoming the current global COVID-19 pandemic."

### About 360biolabs

360biolabs ([www.360biolabs.com](http://www.360biolabs.com)), is a commercially-focused, ISO-accredited laboratory that offers specialised clinical virology testing, and which has access to specialist Physical Containment (PC) 3 biological facilities. Starpharma thanks Melbourne Health, the Doherty Institute and VIDRL (Victorian Infectious Diseases Reference Laboratory) for providing a sample of SARS-CoV-2 to 360biolabs to facilitate testing.

### About VivaGel® active (SPL7013)

SPL7013 is one of Starpharma's proprietary dendrimers that is already a component of two approved products, VivaGel® BV for bacterial vaginosis and the VivaGel® antiviral condom. These products are approved and marketed in a range of regions/ countries including the UK, Europe, Japan, South East Asia, Canada, Australia and New Zealand.

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### 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, astodimer 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.