

Starpharma awarded \$1M MRFF funding for COVID-19 spray

- **\$1 million awarded to Starpharma by the Medical Research Future Fund (MRFF) to expedite development and commercialisation of its novel SPL7013 nasal spray for COVID-19**
- **Starpharma was selected by an expert international panel as one of only five recipients for this COVID-19 specific MRFF funding for *projects capable of achieving substantial and rapid impact in the global response to the COVID-19 pandemic within 12 months***
- **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**

Melbourne, Australia; 3 September 2020: Starpharma (ASX: SPL, OTCQX: SPHRY) today announced the award of \$1 million in matched funding by the Australian Government's Medical Research Future Fund (MRFF) Biomedical Translation Bridge (BTB) Program to expedite development and commercialisation of its COVID-19 antiviral nasal spray based on Starpharma's proprietary dendrimer, SPL7013.

Starpharma was awarded the \$1 million non-dilutive funding in a highly competitive COVID-specific MRFF funding round. Starpharma's product was selected for support by an expert international panel as one of only five recipients for this COVID-19 specific MRFF funding which required projects to be capable of achieving *substantial and rapid impact in the global response to the COVID-19 pandemic within 12 months*.

Starpharma's patented SPL7013 nasal spray has the potential to prevent both acquisition and transmission of SARS-CoV-2 and, due to its broad-spectrum antiviral activity, could also play a role for other respiratory viruses and future pandemic preparedness. Feedback from clinicians and healthcare providers indicates a strong interest in a preventative product for COVID-19 as an additional line of defence, in addition to conventional PPE and vaccines. The product would have application for the general population, including those in the frontline of this crisis, such as doctors, nurses and those exposed to crowded and high-risk environments, such as public transport, airlines and aged care.

Over and above its potent antiviral effects, SPL7013 has a number of advantages, including being the active component in approved and marketed VivaGel[®] products sold in UK, Europe, Asia, Canada, Australia, and New Zealand, and already manufactured at commercial scale, allowing for rapid market entry. Starpharma plans to expedite approval of a SPL7013 nasal spray by leveraging its existing regulatory approvals and extensive clinical and nonclinical data for related products containing SPL7013. The company will also leverage its existing supply chains and manufacturing relationships to expedite access to the product.

Since initiating the SPL7013 nasal spray development program in April, Starpharma has already undertaken extensive development activities for the product. To date, SPL7013 has been reformulated into several nasal spray formulations, a manufacturer has been identified, and pilot manufacture has been undertaken. In addition, work has commenced on compiling regulatory documentation in preparation for submission. Starpharma has also commenced confidential commercialisation discussions, having shared product details and supporting technical data with a number of interested pharmaceutical companies, covering a range of geographic markets.

Starpharma recently reported data confirming potent antiviral activity of SPL7013 against SARS-CoV-2, the coronavirus that causes COVID-19 ([see previous ASX announcement - 25 August 2020](#)). The selectivity index of SPL7013 for SARS-CoV-2 in these assays was very high (selectivity index up to ~2200), indicating potent antiviral efficacy compared 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 (Veklury[®], the approved treatment for severe COVID-19), 55 for hydroxychloroquine and 172 for chloroquine. The potent activity and high selectivity index for SPL7013 means that a final formulated product will have a concentration of SPL7013 that is several thousand-fold higher than the concentration shown to exert an antiviral effect on SARS-CoV-2.

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. This broad spectrum activity means that the SPL7013 nasal spray may also have potential application in other respiratory diseases and for future pandemic preparedness.

Dr Jackie Fairley, Starpharma CEO, commented: “We are very pleased that the SPL7013 COVID-19 nasal spray has been selected for this grant, especially from such a large and competitive field of applicants. This is an important initiative aimed at accelerating Australian innovations to address the global COVID-19 pandemic and we thank the Government for continuing to fund programs like these that drive the local development of novel, innovative therapies for patients globally. The selection of Starpharma’s program recognises its near-term potential and the global relevance of the SPL7013 COVID-19 nasal spray, with differentiated features that are complementary to other preventative strategies, like vaccines. We are proud of our contribution to the Australian biomedical industry response to combat COVID-19”.

Whilst Starpharma’s 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, nebulised or injection.

In addition to Starpharma’s COVID-19 nasal spray, Starpharma has also applied its proprietary drug delivery technology to create a DEP[®] version of antiviral drug remdesivir. DEP[®] remdesivir is a slow release, soluble nanoparticle that offers the potential to extend the use of remdesivir into non-hospital settings such as aged care ([see previous ASX announcement – 1 September 2020](#)).

About Biomedical Translation Bridge Program

Delivered by MTPConnect, the Australian Government’s Biomedical Translation Bridge (BTB) program is a \$22.3 million Medical Research Future Fund initiative that provides \$1 million in matching funding to nurture the translation of new therapies, technologies and medical devices through to the proof of concept to turn innovative medical ideas into reality.

Starpharma acknowledges the support of MTPConnect and their partner UniQuest in this 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, 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.