

## VIRALEZE™ antiviral nasal spray registered in Europe

- **VIRALEZE™ has been successfully registered, to allow for its sale in Europe, including in the UK, and is on track for launch this quarter**
- **Starpharma's plan includes VIRALEZE™ to be initially launched online, available direct to consumers in the UK and Europe, followed by roll-out into pharmacies**
- **In parallel with the consumer roll-out of VIRALEZE™, Starpharma is also progressing discussions with B2B customers (e.g. aged care, healthcare, travel providers, etc.) and potential partners**

**Melbourne, Australia; 23 February 2021:** Starpharma (ASX: SPL, OTCQX: SPHRY) announced today it had received confirmation that the VIRALEZE™ antiviral nasal spray has been successfully registered for sale in Europe, including in the UK.

This registration allows for the marketing of VIRALEZE™ across the European Economic Area (EEA), which includes the 27 countries of the EU, the UK, plus the European Free Trade Association (EFTA) countries, with a combined population of approximately 520 million.

VIRALEZE™ is an easy to use antiviral nasal spray. It contains SPL7013 (astodimer sodium), which has been shown in laboratory studies to inactivate a broad spectrum of respiratory viruses, including >99.9% of coronavirus SARS-CoV-2 (the virus that causes COVID-19).

SPL7013 has been shown to be virucidal, rapidly inactivating >99.9% of SARS-CoV-2 within 60 seconds.

SPL7013 has also been shown to have activity against other important respiratory viruses including influenza viruses, respiratory syncytial virus (RSV), and other cold-causing coronaviruses in laboratory studies. VIRALEZE™ can be stored at room temperature and does not require cold storage or specialised transportation.

The European launch of VIRALEZE™ is on track and the product is expected to be available for sale online, direct to European and UK consumers next month. Preparations for launch are well advanced with the [manufacture of launch batches underway](#). A roll-out of VIRALEZE™ to European pharmacies is planned, and in parallel, Starpharma is undertaking discussions with B2B customers (e.g. aged care, health care, travel providers, etc.), as well as with potential commercial partners seeking sales and marketing rights.

Information on the product is available at <http://www.viraleze.co> and consumers can sign up for updates, including on product availability.

The European registration of VIRALEZE™ and the regulatory dossier will be used as the basis for obtaining further marketing approvals for the product as soon as practicable in other countries, including in Australia.

Dr Jackie Fairley, CEO of Starpharma commented: "Starpharma is pleased to have successfully developed a product that has the potential to assist with the fight against the global COVID-19 pandemic. We are delighted to have completed registration of VIRALEZE™ in the UK and Europe ahead of our original schedule and acknowledge the support of local and international specialist laboratories who have assisted Starpharma with

the development of VIRALEZE™. We have already undertaken substantial launch preparations, including manufacturing in Europe, to ensure VIRALEZE™ is available to consumers and businesses as early as possible. Starpharma is focussed on making the product as widely available as possible, with further registrations and roll-out planned.”

“We know from consumer research conducted with the Boston Consulting Group, that VIRALEZE™ has strong appeal for European consumers across all age groups. The spray is easy to use and convenient – and works rapidly, without being absorbed into the bloodstream. If you are about to walk into the supermarket, you would use it. The same is true for public transport, elevators, planes, bars and restaurants,” added Dr Fairley.

VIRALEZE™ topical antiviral nasal spray is complementary to other prevention measures such as PPE and vaccines and has special relevance where social distancing is not possible such as crowded environments and certain workplaces.

*Starpharma acknowledges the \$1 million in funding for the development of VIRALEZE™ provided by the Australian Government’s Medical Research Future Fund (MRFF) Biomedical Translation Bridge (BTB) Program, with support from UniQuest. Delivered by MTPConnect, the Australian Government’s BTB program is a \$22.3 million MRFF initiative that provides up to \$1 million in matched funding to nurture the translation of new therapies, technologies and medical devices through to proof of concept to turn innovative medical ideas into reality.*

#### **About VIRALEZE™ - easy to use antiviral nasal spray**



VIRALEZE™ is an easy to use antiviral nasal spray, which can be stored at room temperature and does not require refrigeration.

VIRALEZE™ is an easy to use antiviral nasal spray. It contains SPL7013 (astodimer sodium), which has been shown in laboratory studies to inactivate a broad spectrum of respiratory viruses, including >99.9% of coronavirus SARS-CoV-2 (the virus that causes COVID-19).

SPL7013 has been shown to be virucidal, inactivating >99.9% of SARS-CoV-2 within one minute. SPL7013 has also been shown in laboratory studies to have activity against other important respiratory viruses including influenza viruses, respiratory syncytial virus (RSV), and other human coronaviruses. Based on the effectiveness of VIRALEZE™ against multiple viruses, including drug-resistant strains, the product is expected to retain activity against the SARS-CoV-2 strains being reported in the UK, South Africa and elsewhere. VIRALEZE™ can be stored at room temperature. The product does not require cold storage or specialised transportation.

The nasal cavity is the primary site where SARS-CoV-2 (COVID-19) becomes established, before spreading to the lungs<sup>^</sup>. “Spike” proteins on the surface of these viruses that come into contact with VIRALEZE™ are trapped by SPL7013. This interaction is ‘virucidal’ – the virus is irreversibly blocked and can no longer infect mucosal cells, thereby providing a physical barrier to respiratory viruses in the nasal cavity. These “blocked” viruses are then eliminated naturally through the nasal mucus. <sup>^</sup>Hou et al., 2020, Cell 182, 429–446

SPL7013 is included in products licensed in >160 countries, approved in >40 countries and available for sale in the UK, Europe, South East Asia, Australia and New Zealand.

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#### **About Starpharma**

Starpharma Holdings Limited (ASX:SPL, OTCQX:SPHRY) 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 COVID-19, DEP® drug delivery and VivaGel®. Starpharma has developed VIRALEZE™, an antiviral nasal spray for COVID-19, which is complementary to vaccines and other preventative measures such as distancing and PPE. VIRALEZE™ is registered in the UK/Europe, with launch of product expected in Q1 CY2021. SPL7013 is utilised in approved products - the VivaGel® condom and VivaGel® BV. VivaGel® BV has been licensed in >160 countries, is approved in >40 countries and available in for sale in the UK, Europe, South East Asia, Australia and New Zealand.

As a leading company in dendrimer based drug delivery, Starpharma's proprietary drug delivery platform technology, DEP<sup>®</sup>, which is being used to improve pharmaceuticals, to reduce toxicities and enhance their performance. There are numerous internal and partnered programs underway to develop DEP<sup>®</sup> versions of existing drugs, particularly in the area of anti-cancer therapies. DEP<sup>®</sup> partnerships include oncology programs with AstraZeneca, with Merck 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<sup>®</sup> programs have the potential to generate significant future milestones and royalties.

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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. 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.