starpharma

ASX Announcement

VIRALEZE™ COVID-19 nasal spray to be ready for market Q1CY21

- **EU regulatory dossier >90% complete and VIRALEZE™ now on track to be registered, and ready for market in Q1 CY2021, earlier than previously announced**
- **Initial launch batches of VIRALEZE™ scheduled for manufacture in January 2021; Starpharma is also building inventory of components and raw material to support rapid roll-out**
- **Launch and marketing preparations well advanced, including discussions with pharmacy chains, B2B customers, qualitative and quantitative consumer market research; partnering discussions are continuing in parallel**
- **VIRALEZE™ clinical study in healthy volunteers to commence in January 2021, for completion in Q1 CY2021**
- **SPL7013 has been shown to be virucidal, inactivating more than 99.99% of SARS-CoV-2 and Scripps Research Institute mechanistic studies have confirmed potent inhibition of viral 'spike protein' binding (>90%)**
- **The broad spectrum antiviral activity of VIRALEZE™ is a compelling differentiating feature and Starpharma is continuing to build additional efficacy data in other respiratory viruses to further broaden the product claims for VIRALEZE™**

Melbourne, Australia; 10 December 2020: Starpharma (ASX: SPL, OTCQX: SPHRY) today announced significant commercial and regulatory progress has been made for VIRALEZE™ nasal spray with the EU regulatory dossier more than 90% complete and VIRALEZE™ now on track to be registered, and ready for market in Q1 CY2021. This timing is earlier than previously announced.

VIRALEZE™ will be marketed as an antiviral nasal spray for SARS-CoV-2 (the coronavirus that causes COVID-19) as well as other important respiratory viruses (influenza and RSV). VIRALEZE™ is expected to form part of a range of preventative measures such as masks and other PPE, and is complimentary to COVID-19 vaccines to further reduce risk of infection.

Starpharma's pre-launch commercialisation activities for VIRALEZE™ are well advanced with input from Boston Consulting Group (BCG), focussing initially on direct to consumer and B2B (business-to-business) channels to facilitate the most rapid entry to market. Starpharma is continuing partnering discussions in parallel. Europe will be the first geographic region for the VIRALEZE™ launch. Starpharma plans to leverage the European registration to roll-out VIRALEZE™ into other markets including Australia as quickly as possible.

As part of the go-to-market planning for VIRALEZE™, BCG conducted qualitative and quantitative consumer research in Europe during November. The research from ~1,500 consumers confirmed that the product proposition for VIRALEZE™ is highly appealing, and that consumers would use the product in a wide range of settings including in crowded areas such as shopping centres, elevators, workplaces and public transport.

The research showed a high number of respondents (~60%) liked VIRALEZE™ and that this translated to very high purchase intent – higher than 80% in millennials, with the following features of VIRALEZE™ driving strong purchase intent:

- Broad spectrum antiviral activity (COVID-19, influenza, RSV, and further viral testing ongoing)
- Inactivates >99.99% of SARS-CoV-2 (the coronavirus that causes COVID-19) – with testing completed in strains from multiple geographies
- Preventative spray (VIRALEZE™ inactivates virus before, and after, exposure to cells)
- Handy and convenient product (easy to use and does not need refrigeration or special handling, to be available OTC)

Starpharma's launch preparations are well advanced with initial launch batches of VIRALEZE™ scheduled for January 2021 and the Company is also building stocks of raw material and components. Starpharma's internationally accredited manufacturer already supplies marketed VivaGel® products and has expertise in nasal sprays.

Starpharma is leveraging the extensive data already available for the active (SPL7013) in VIRALEZE™. VIRALEZE™ will be approved via the CE mark route. The Company is also conducting a clinical study in healthy volunteers to be completed in Q1 CY21 to support commercialisation activities for VIRALEZE™, noting that this study is not a requirement for registration.

Dr Jackie Fairley, CEO of Starpharma commented: "We know from the positive market research that VIRALEZE™ has the ability to restore confidence and encourage people to resume everyday professional and recreational activities. Our market research also shows that the compelling features and convenience of VIRALEZE™ are highly appealing to consumers".

"The distribution challenges of COVID-19 vaccines are well documented including the timing of wide-spread availability and adoption. Even after a vaccine becomes widely available, social distancing, PPE and other measures will continue to be important and VIRALEZE™ complements other prevention strategies, including vaccines. In November, the World Health Organisation stated that someone died every 17 seconds from COVID-19 in Europe[1]. It is with the greatest urgency that Starpharma is working to make this product ready for market as quickly as possible in 1Q CY2021".

Further validation of the product in the form of antiviral mechanism of action studies for SPL7013 completed at the prestigious Scripps Research Institute confirm that SPL7013 achieves potent inhibition of SARS-CoV-2 'spike protein' binding (>90%) to the cell target. Blocking and targeting of spike proteins is the approach taken in the development of many COVID-19 vaccines including by Moderna and Pfizer.

About VIRALEZE™

VIRALEZE™ is an antiviral nasal spray for coronavirus and other viruses such as influenza and respiratory syncytial virus (RSV). VIRALEZE™ is an easy to use preventative nasal spray, which can be stored at room temperature and does not require refrigeration.

VIRALEZE™ contains SPL7013, a broad spectrum antiviral, which is the active in products approved in more than 40 countries and on market in the UK, Europe, Asia, Australia and New Zealand.

[1] https://www.smh.com.au/world/europe/someone-in-europe-is-dying-every-17-seconds-from-covid-19-who-says-20201120-p56gaq.html

SPL7013 has been shown in laboratory studies to be virucidal, inactivating more than 99.99% of SARS-CoV-2 (the coronavirus that causes COVID-19), when applied to the cells before or after exposure to the virus.

The broad spectrum antiviral activity of VIRALEZE™ is a compelling differentiating feature and means that the product could have an important role in future pandemics.

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 is developing VIRALEZE™, an antiviral nasal spray for COVID-19 which is complementary to vaccines and other preventative measures such as distancing and PPE. VIRALEZE™ also has potential use in future pandemics and is afforded expedited development because it is repurposing an already-marketed, broad-spectrum antiviral dendrimer, SPL7013. 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®, 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® versions of existing drugs, particularly in the area of anti-cancer therapies. DEP® partnerships include programs with AstraZeneca and other world leading pharmaceutical companies, which 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.