

VIRALEZE COVID-19 nasal spray study to commence in January

- Starpharma has now received all necessary approvals to commence its study for VIRALEZE™ with enrolment to commence in early January 2021
- VIRALEZE™ expected to be ready for market in Q1 CY2021 with EU regulatory dossier >90% complete

Melbourne, Australia; 22 December 2020: Starpharma (ASX: SPL, OTCQX: SPHRY) today announced that it has received all necessary approvals to commence its clinical study for VIRALEZE™. The study will commence enrolment of healthy volunteers in Perth in early January 2021 and is expected to be completed in Q1 2021. This study is being undertaken to support commercialisation activities for VIRALEZE™, and is not a requirement to achieve EU product registration.

The double-blind, placebo-controlled, safety, tolerability and pharmacokinetic study of VIRALEZE™ nasal spray will be conducted in 40 healthy volunteers, who will use the product four times a day for 14 days.

Starpharma continues to aggressively pursue an expedited regulatory approval pathway for the product, leveraging the extensive data already available for SPL7013 in VIRALEZE™, and the product will be registered via the CE mark route. The EU regulatory dossier is more than 90% complete and VIRALEZE™ is on track to be registered, and ready for market in Q1 CY2021 ([as previously announced on 10 December 2020](#)).

Dr Jackie Fairley, CEO of Starpharma commented: “We continue to make excellent progress towards the launch of this important product, including manufacturing campaigns of VIRALEZE™ early in the new year. Starpharma is working hard to bring this product to market as quickly as possible, in the first quarter of 2021. The worsening situation of COVID-19 in Europe in particular clearly highlights the need for preventative strategies for use alongside PPE and vaccines. Not surprisingly, our recent consumer research in Europe indicates strong demand for VIRALEZE™.”

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.

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), and stops infection when applied to 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.