

# **Response to media article**

**Melbourne, Australia; 4 March 2022: Starpharma** (ASX: SPL, OTCQX: SPHRY) notes the media article published in The Age / Sydney Morning Herald this morning, titled 'Nasal spray not on Australian shelves', and provides the following information.

Starpharma confirms that it has submitted an application to Australia's Therapeutic Goods Administration (TGA) for its antiviral nasal spray as a medical device, which is in keeping with the approach taken in multiple other jurisdictions. The regulatory process for Starpharma's medical device application is ongoing. Starpharma does not normally comment on ongoing regulatory processes and was not anticipating the TGA to make public comment, given we are currently awaiting a response from the TGA, having provided additional information as recently as last week, including information related to the nasal spray mechanism of action and the appropriateness of its classification as a medical device.

Starpharma's submission for this product as a medical device is consistent with multiple other nasal sprays with antiviral indications that are registered by the TGA as medical devices and have been marketed in Australia for several years, including by multinational companies. These products are all similar to Starpharma's nasal spray and share the same fundamental mechanism of action against viruses. VIRALEZE<sup>™</sup> and these other antiviral nasal sprays are all registered as medical devices in Europe and multiple other regions.

We appreciate the TGA's important role in regulating the supply of therapeutic goods in Australia and look forward to working with the TGA to achieve registration of the nasal spray in Australia to make the product available to Australian consumers.

For further information in relation to Starpharma's antiviral nasal spray, please refer to <u>www.Starpharma.com</u>. Most recently, Starpharma <u>announced</u> impressive antiviral data against Omicron, where SPL7013 significantly outperformed other registered antiviral agents, including being approximately 30 times more potent than iota-carrageenan.

VIRALEZE<sup>™</sup> is registered in more than 30 countries, including Europe, Vietnam, India, New Zealand, and Saudi Arabia, and available in certain markets online.



## 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 respiratory viruses, DEP<sup>®</sup> drug delivery and VivaGel<sup>®</sup>. Starpharma has developed VIRALEZE<sup>™</sup>, an antiviral nasal spray that is registered for sale in the Europe, Vietnam, India, Saudi Arabia, and New Zealand, and available outside Australia in certain markets online. VIRALEZE<sup>™</sup> is not approved for sale or supply in Australia. SPL7013 is utilised in approved products - the VivaGel<sup>®</sup> condom and VivaGel<sup>®</sup> BV. VivaGel<sup>®</sup> products have been licensed in >160 countries, are registered in >45 countries and available for sale in the UK, Europe, Japan, South East Asia, South Africa, Australia and New Zealand.

As a leading company in dendrimer-based drug delivery, Starpharma's proprietary drug delivery platform technology, DEP<sup>®</sup>, 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.