ASX Announcement

VivaGel® BV US FDA Appeal Outcome

Melbourne, Australia; 19 February 2024: Starpharma (ASX: SPL, OTCQX: SPHRY) today announces that it has completed the formal dispute resolution process with the US Food and Drug Administration (FDA) in relation to VivaGel® BV. The FDA has maintained its position that they require additional clinical efficacy data to be generated for the regulatory approval of VivaGel® BV for bacterial vaginosis (BV) in the US. The formal dispute resolution process involved multiple submissions, meetings, detailed analyses, and the preparation of regulatory precedents relating to recent product approvals. Starpharma was supported through this process by highly experienced regulatory advisers, key opinion leaders, and biostatistical and legal advisers, including several who were ex-FDA.

VivaGel® BV is approved in more than 45 countries globally for both treatment and prevention of BV, including the UK, Europe, Southeast Asia, Australia and New Zealand. Starpharma's dual strategy, in response to the FDA's original complete response to the New Drug Application (NDA), involved pursuing formal dispute resolution and considering the need to generate additional clinical data. Starpharma and its clinical and regulatory advisers maintain that the existing clinical data show extensive and robust evidence for the clinical benefit of VivaGel® BV for the treatment and prevention of BV. The FDA raised no approvability issues with the safety, toxicology, manufacturing or quality aspects of VivaGel® BV.

Currently, the VivaGel® BV NDA remains open (Fast Track and QIDP status); however, Starpharma is not planning to pursue additional clinical studies for VivaGel® BV on its own at this time. Starpharma remains committed to leveraging the VivaGel® BV development program and will work to maximise the commercial opportunities for VivaGel® BV in the more than 45 markets where it is already approved. The decision by the FDA does not alter the approval status in the countries where VivaGel® BV is already registered.

***Starpharma's Chief Executive Officer, Cheryl Maley**, commented: "Naturally, this is not the outcome Starpharma was hoping for. Throughout the dispute resolution process with the FDA, Starpharma has carefully considered and taken account of numerous factors that could affect the outcome of the appeal, including complex regulatory and legal advice, a constantly evolving regulatory landscape, and relatively recent approvals of products used as regulatory precedents.*

"VivaGel® BV has achieved approval in more than 45 other countries and has been launched in multiple markets, including Australia, where the product is the top-selling topical BV treatment. The Company's more immediate focus is on growing the product's sales in countries where it is already approved.

"Whilst we explore opportunities to enter the US market in the future, Starpharma will not prioritise conducting another VivaGel® BV clinical trial. The Company's primary focus remains on the commercialisation of the clinical-stage DEP® candidates, our partnerships, and advancing the application of DEP® in high-value novel therapeutic areas, such as DEP® antibody-drug conjugates (ADCs) and DEP® radiotheranostics."

About Starpharma

Starpharma Holdings Limited (ASX: SPL, OTCQX: SPHRY) is a world leader in dendrimer technology for medical applications. As an innovative Australian biopharmaceutical company, Starpharma is focused on developing and commercialising novel therapeutic products that address significant global healthcare needs. Starpharma boasts a strong portfolio of products, partnerships, and intellectual property.

Starpharma's innovative technology is based on proprietary polymers called dendrimers, which are precise, synthetically manufactured, nanoscale molecules. The unique properties of dendrimers – including their size, structure, high degree of branching, polyvalency, and water solubility – are advantageous in medical and pharmaceutical applications.

Starpharma uses its dendrimer technology to develop novel therapeutics and to improve the performance of existing pharmaceuticals. Starpharma's portfolio includes multiple clinical-stage oncology products, which utilise its Dendrimer Enhanced Product ('DEP®') drug delivery technology, and marketed products, including VIRALEZE™ and VivaGel® BV, which utilise SPL7013, a proprietary dendrimer with antimicrobial properties.

Starpharma's DEP® drug delivery platform is being used to enhance the effectiveness of existing and novel therapies and to reduce drug-related toxicities through controlled and specified drug delivery.

In addition to Starpharma's internal DEP® programs, Starpharma has multiple DEP® partnerships with international biopharmaceutical companies, including AstraZeneca (oncology), MSD (Antibody-Drug Conjugates), Chase Sun (anti-infectives), and other world-leading pharmaceutical companies. Due to the broad applicability and optionality of Starpharma's DEP® platform, partnered DEP® programs have the potential to generate significant future milestones and royalties.

Starpharma's topical nasal spray, Viraleze™, is registered in more than 35 countries*, including Europe, the UK, and Asia. Starpharma's novel non-antibiotic vaginal gel, VivaGel® BV, for the treatment of bacterial vaginosis (BV) and prevention of recurrent BV, is registered in more than 50 countries, including in the UK, Europe, Southeast Asia, South Africa, Australia and New Zealand.

For more information about Starpharma, visit www.starpharma.com or connect with Starpharma on LinkedIn.

* Note: VIRALEZE™ is not approved for use or supply in Australia.

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Disclosure
This ASX Announcement was authorised for release by Chair, 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.