ASX Announcement

US FDA requests further data for VivaGel® BV approval

- **FDA has advised Starpharma it requires confirmatory clinical data prior to approval**
- **Starpharma plans to meet with the FDA as soon as possible to discuss the additional data required for approval**
- **In parallel with FDA discussions, Starpharma and its non-US partners are committed to the active commercialisation of VivaGel® BV in non-US regions; VivaGel® BV is already approved in the EU and Australia, and has been licensed in most regions around the world, with launches planned in 2019**
- **Regulatory processes underway continue in other markets and are independent of FDA approval**

Melbourne, Australia; 27 December 2018: Starpharma (ASX: SPL, OTCQX: SPHRY) today received advice from the US FDA that it will require confirmatory clinical data prior to approving VivaGel® BV for treatment of bacterial vaginosis (BV) and the prevention of recurrent BV (rBV).

Starpharma is currently evaluating the details of FDA's advice but anticipates being able to address the issues raised through the generation of confirmatory clinical efficacy data. The company is requesting a meeting with the FDA as soon as practicable to discuss the data required and Starpharma is keen to secure approval with minimal delay. Encouragingly, the FDA did not identify any approvability issues in relation to the safety, manufacturing or quality of VivaGel® BV. Starpharma will also be discussing next steps with its US partner, ITF Pharma, and any potential impact on its US licence.

VivaGel® BV is already approved in the EU and Australia, and regulatory processes currently underway continue in other markets and are completely independent of FDA approval. Starpharma has licensed VivaGel® BV to Mundipharma for most non-US regions around the world. Initial launches for VivaGel® BV will proceed as planned in multiple Mundipharma regions (including Europe) and Australia during the first half of 2019.

Dr Jackie Fairley, CEO of Starpharma, said: "Clearly we are surprised and extremely disappointed with the FDA's requirement for confirmatory data in order to approve the NDA for VivaGel® BV considering the comprehensive nature of the data provided. However, we are greatly encouraged by the FDA's acknowledgement of the significant unmet medical need that would be fulfilled by the product, and they have expressed a desire to work with Starpharma to secure approval in order to make VivaGel® BV available to women in the US as soon as possible".

"Aside from VivaGel® BV, Starpharma will also continue to commercially exploit its deep portfolio of DEP® drugs, including DEP® docetaxel, DEP® cabazitaxel, DEP® irinotecan and a range of other internal and partnered programs, including the novel oncology agent AZD0466, which is being developed under licence by AstraZeneca".

"Importantly for the dendrimer component of VivaGel® BV, which is the first of its kind to be reviewed by the FDA under an NDA, no issues were raised in relation to the safety, manufacturing or quality of the product. We stand by the compelling data package submitted to the FDA, which has supported approvals in other major markets and is expected to enable

multiple additional approvals throughout non-US regions. Starpharma is committed to the active commercialisation of VivaGel® BV in these regions as well as commercialisation of our DEP® portfolio, in parallel with addressing the requirements for approval in the US.", concluded Dr Fairley.

In their advice, the FDA acknowledged the demonstrated efficacy benefits of VivaGel® BV although they have requested confirmatory data prior to approval. The FDA's acknowledgment of the significant unmet medical need for an approved product to manage rBV is consistent with the strong positive feedback from key opinion leaders, OBGYNs and patients in the US. Starpharma knows that BV patients, US clinicians and BV key opinion leaders will be disappointed with the FDA's decision on VivaGel® BV which will delay access to the product in the US. Starpharma looks forward to working with the FDA to address their additional requirements as soon as practicable.

About VivaGel® BV

VivaGel® BV is a patented, water-based vaginal gel for the treatment of bacterial vaginosis (BV) and prevention of recurrent BV. VivaGel® BV is a breakthrough product which specifically targets the organisms that cause BV, rapidly relieves symptoms and has a novel mechanism of action affecting biofilm. VivaGel® BV is a non-antibiotic therapy and is not absorbed into the bloodstream.

VivaGel® BV is protected by patents in the US and elsewhere with coverage out to at least 2030 with potential for extensions out to 2033. VivaGel® BV demonstrated compelling efficacy in phase 3 trials without the unpleasant side effects of current BV therapies and has been endorsed by clinicians and patients alike.

About Bacterial Vaginosis (BV)

BV is the most common cause of vaginal infection for women of childbearing age and affects one in three women in the US. It is a highly recurrent condition with almost two thirds of sufferers experiencing repeated episodes. BV is caused by an imbalance of naturally occurring bacterial flora (the usual bacteria found in a woman's vagina). Current therapies for BV are inadequate and have many unpleasant side-effects, there are also no approved products in the US for preventing recurrent BV.

About Starpharma

Starpharma Holdings Limited (ASX: SPL, OTCQX:SPHRY), located in Melbourne Australia, is an ASX 300 company and is a world leader in the development of dendrimer products for pharmaceutical, life science and other applications.

Starpharma's underlying technology is built around dendrimers – a type of synthetic nanoscale polymer that is highly regular in size and structure and well suited to pharmaceutical and medical uses. Starpharma has two core development programs: VivaGel® portfolio and DEP® drug delivery with the Company developing several products internally and others via commercial partnerships.

VivaGel®: Starpharma's women's health product - VivaGel® BV is based on SPL7013, astodrimer sodium, a proprietary dendrimer. VivaGel® BV is approved for marketing in the EU and Australia for bacterial vaginosis (BV) and a new drug application is under Fast Track review by the US FDA. Starpharma has licensed the sales and marketing of VivaGel® BV to ITF Pharma for the US; Mundipharma for Europe, Russia, CIS, Asia, the Middle East, Africa and Latin America; and to Aspen Pharmacare for Australia and New Zealand. Starpharma also has licence agreements to market the VivaGel® condom (an antiviral condom which includes VivaGel® in the lubricant) in several regions, including Australia, Europe, Canada, China and Japan (Okamoto). The VivaGel® condom has been launched in Australia and Canada under the Lifestyles® Dual Protect™ brand.

DEP® - Dendrimer Enhanced Product®: Starpharma's DEP® drug delivery platform has demonstrated reproducible preclinical benefits across multiple internal and partnered DEP® programs, including improved efficacy, safety and survival. Starpharma has two internal DEP® products – DEP® docetaxel and DEP® cabazitaxel - in clinical development in patients with solid tumours, and further DEP® products approaching clinical development. Starpharma's partnered DEP® programs include a multiproduct DEP® licence with AstraZeneca, which involves the development and commercialisation of two novel oncology compounds, with potential to add more.

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Media
WE Buchan Consulting
Rebecca Wilson
Mob: +61 417 382 391
rwilson@buchanwe.com.au

Starpharma
Dr Jackie Fairley, Chief Executive Officer
Nigel Baade, CFO and Company Secretary
+61 3 8532 2704
investor.relations@starpharma.com

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.