ASX Announcement

Starpharma completes US New Drug Application for VivaGel® BV

- **NDA rolling submission for VivaGel® BV now complete**
- **US FDA review under QIDP/Fast Track priority review**
- **VivaGel® NDA covers two indications for BV – treatment and prevention**
- **Late-stage global licensing negotiations for VivaGel® BV**

Melbourne, Australia; 30 April 2018: Starpharma (ASX: SPL, OTCQX: SPHRY) today announced that its rolling new drug application (NDA)[i] for VivaGel® BV including two indications, for the treatment of bacterial vaginosis (BV) and prevention of BV, has been completed, and the final module of the NDA will be submitted to the US Food and Drug Administration (FDA) on Monday 30 April 2018 (US time).

The review of the VivaGel® BV NDA by the FDA has already commenced and will be conducted as a priority review based on the Fast Track status of the product. The NDA review is expected to take approximately 6-8 months from the completed submission.

Fast Track status is intended to accelerate the regulatory process and secure rapid approval and early market access for products that address unmet medical needs. VivaGel® BV was also granted Qualified Infectious Disease Product (QIDP) designation, which applies to certain important new antibacterial products. As well as making the product eligible for Fast Track status, QIDP designation provides other significant commercial advantages such as an additional 5 years' market exclusivity. Starpharma also has a Special Protocol Agreement in place from the FDA for VivaGel® BV which provides binding FDA agreement on the phase 3 trial design.

VivaGel® BV offers the potential to fill a currently unmet medical need with respect to both the treatment and prevention of BV. Compared with existing therapies, none of which are approved for prevention of BV, VivaGel® BV is characterised by an absence of problematic drug interactions, an absence of need for food or alcohol restrictions, reduced risk of side effects, and a lack of effect in promoting harmful antibiotic resistance. VivaGel® BV acts via a novel mechanism of action, whereby it affects BV-related biofilms, which have been linked to persistence and recurrence of the condition. The product is well suited to longer-term use, given the lack of absorption of the product into the bloodstream and resulting lack of systemic side effects attributable to the product.

Independent market research in the US has highlighted that the VivaGel® BV product profile is very appealing to BV patients, payers and clinicians alike, and in particular, its rapid action and novel (non-antibiotic) mechanism were highly valued. Clinical investigators involved in the conduct of the VivaGel® BV trials have often commented on the desirability and benefits of VivaGel® BV for their patients. Dr Belvia Carter, from Tennessee, USA, commented that her patients described the effects of VivaGel® BV as "miraculous". An extract of the market research is available via http://www.starpharma.com/news/365.

Dr Jackie Fairley, Starpharma CEO, commented: "Completion of our NDA filing is an exciting milestone for Starpharma, and a great story for Australian innovation. We look forward to VivaGel® BV being available for patients in the US, where the rate of BV is particularly high, with one in three women suffering from this troubling and recurring condition. In parallel with these regulatory activities, Starpharma's licensing negotiations for commercial rights to

[i] New Drug Application - Starpharma's VivaGel® BV NDA submission exceeds 110,000 pages.

VivaGel® BV are now well-advanced across multiple regions, including the US. Draft contracts are currently under advanced negotiation with parties, including major global and regional companies as well as companies specialising in women's health.

“The combined value of the BV treatment and prevention markets globally is estimated to be more than US$1.75 billion annually and VivaGel® BV stands to be the first and only product approved for the prevention of recurrent BV. As a treatment, VivaGel® BV also offers patients and clinicians important advantages over existing therapies, which have troublesome side effects.”

VivaGel® BV is already approved for sale in Europe and Australia. In Australia, VivaGel® BV is licensed to Aspen Pharmacare, who will launch the product under the Fleurstat brand in the near future.

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 2032. 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. VivaGel® BV is already approved in Europe and Australia and is expected to be first available in Australian pharmacies, under the brand name Fleurstat in 2018.

About Bacterial Vaginosis (BV)

Bacterial vaginosis is the most common cause of vaginal infection for women of childbearing age, and affects around 30% of women in the US. It is a highly recurrent condition with 50-60% 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). Smoking, the use of some hygiene products and several other risk factors are linked to a higher risk of developing BV. 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, making VivaGel® BV a first-in-class therapy for this condition.

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 a number of products internally and others via commercial partnerships.

VivaGel®: Starpharma’s portfolio includes women’s health products based on VivaGel® (SPL7013, astodrimer sodium), a proprietary dendrimer. VivaGel® BV is approved for marketing in the EU and Australia for bacterial vaginosis (BV). Starpharma has a license agreement with Aspen Pharmacare Australia Pty Ltd for the sales and marketing of VivaGel® BV in Australia and New Zealand. Starpharma has also developed an antiviral condom which uses VivaGel® in the lubricant, which is available in Australia and Canada under the Lifestyles® Dual Protect™ brand. Starpharma has a number of license agreements to market the VivaGel® condom in other regions, including China and Japan (Okamoto).

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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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.