ASX Announcement

VivaGel® BV treatment clinical submission under rolling NDA

Melbourne, Australia; 21 December 2017: Starpharma (ASX: SPL, OTCQX: SPHRY) today announced that it has completed the VivaGel® BV treatment clinical section of the NDA clinical module, which will be submitted to the FDA under Starpharma's rolling submission on Friday 22 December 2017 (US time).

The clinical module of the NDA is the fourth of five modules to be submitted and accounts for a major part of the overall submission. The FDA has also completed a preliminary review of the proposed clinical datasets and has confirmed that the intended format and presentation of that data is acceptable.

Included in the BV treatment section is data from Starpharma's two phase 3 treatment clinical trials of VivaGel® BV conducted in 2012. Efficacy data from these trials complies with the revised FDA guidance for the treatment of bacterial vaginosis (BV) issued in mid-2016. The revised FDA guidance recommends that the primary efficacy endpoint for products for treatment of BV should be assessed 7–14 days after commencing treatment. This timing aligns with the data from Starpharma's 2012 BV treatment efficacy trials, which showed highly statistically significant clinical cure of BV when patients were assessed 2–5 days after end of treatment (9-12 days after commencing treatment).

Starpharma's NDA submission for VivaGel® BV is for both BV indications - BV treatment and prevention of recurrent BV (rBV). As previously announced, the first three of five modules of the NDA were submitted in November, and it's expected that the final clinical data and remaining module will be submitted in the near future. Based on experience with other products granted Fast Track status, review time is expected to be approximately 6-8 months. The VivaGel® BV NDA submission and review process benefits from FDA's Fast Track status and Qualified Infectious Disease Product (QIDP) designation which are designed to accelerate the regulatory process and secure rapid approval and early market access for products that address unmet medical needs.

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 in the near future. Starpharma is actively engaged in licensing negotiations for commercial rights to VivaGel® BV across multiple regions. A number of term sheets and draft contracts are currently under discussion with parties, including major global and regional companies as well as companies specialising in women's health. These negotiations have been impacted positively by Fast Track status and QIDP designation, successful phase 3 rBV results and most recently, TGA approval, which is also relevant for many markets outside Australia.

Dr Jackie Fairley, Starpharma CEO, commented: "We are pleased with the significant progress of our rolling NDA submission and look forward to its completion soon. We anticipate that the prevention of rBV data along with the final module will be submitted in the New Year, by which time the volume of the NDA is likely to exceed 100,000 pages. This submission is a major milestone for the Company and we're also excited to see such good progress on the commercial negotiations for this breakthrough product for BV."

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. In Australia the product will be marketed by Aspen Pharmacare.

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 having it recurrently. 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 rBV making VivaGel® BV a first-in-class therapy supported by large, randomised clinical studies.

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 late stage women's health products based on VivaGel® (SPL7013, astodrimer sodium), a proprietary dendrimer. VivaGel® formulated as a water based gel and delivered vaginally - VivaGel® BV - has EU regulatory approval for topical treatment and rapid relief of bacterial vaginosis (BV) and has recently completed clinical development for the prevention of recurrent BV. Starpharma has signed 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. The VivaGel® condom is available in Australia and Canada under the Lifestyles® Dual Protect™ brand and Starpharma also has a number of license agreements to market the VivaGel® condom in other regions, including China and Japan.

DEP®: The other major part of Starpharma's pharmaceuticals business is its proprietary DEP® drug delivery platform. Starpharma has both partnered and internal DEP® programs in Drug Delivery. A number of dendrimer-enhanced, or DEP® versions of existing drugs are under development by the Company. The most advanced of these is DEP® docetaxel, a dendrimer-enhanced version of docetaxel (Taxotere®), which is in clinical development in patients with solid tumours. In preclinical studies DEP® docetaxel has shown significant tumour-targeting and superior anti-cancer effects across a range of important cancer types including breast, prostate, lung and ovarian tumour, when compared to Taxotere® (docetaxel). In the partnered area, AstraZeneca has signed a licensing agreement with Starpharma for the use of its DEP® drug delivery platform in the development and commercialisation of a number of AstraZeneca oncology compounds.

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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.