ASX Announcement

Regulatory progress for VivaGel® BV in the US

Melbourne, Australia; 23 May 2019: Starpharma (ASX: SPL, OTCQX: SPHRY) has received formal feedback from the recent meeting held with the US FDA in relation to the approval for two related bacterial vaginosis (BV) indications - BV treatment and the prevention of recurrent BV in the United States.

The FDA feedback highlights that there are several potential options for obtaining approval especially given that Starpharma's application/NDA includes two related bacterial vaginosis (BV) indications. In their feedback and at the meeting, the FDA acknowledged the important unmet medical need in BV, and the potential for VivaGel® BV to fill that unmet need and confirmed its interest in working with Starpharma to achieve approval in the US.

For prevention of recurrent BV, there are no approved therapies, and for treatment of BV, VivaGel® BV would be the first non-antibiotic BV treatment. As a result, the product has both Qualified Infectious Disease Product (QIDP) and Fast Track status for both indications.

Starpharma is currently working through the various options to obtain approval for both indications, recognising that an approval for one indication would have a positive impact on approval for the other indication. Starpharma's focus is naturally to pursue the most expeditious and efficient path to approval. In assessing these options, Starpharma continues to liaise with the FDA and work closely with its team of expert FDA consultants, statisticians and legal advisors, including several who previously held senior management positions within the FDA. As part of this process Starpharma is seeking expert regulatory/legal advice on the avenues available for review of some of the conclusions reached by FDA. Other options include generating confirmatory clinical data through an additional BV treatment trial. Should it be determined that a new clinical trial is the best strategy, Starpharma would be in a position to commence a BV treatment trial quickly. By way of background, a previous Starpharma BV treatment trial in the US was completed in less than 4 months and cost less than US$4M.

Starpharma CEO Dr Jackie Fairley said: "We are pleased that the FDA interactions continue to be constructive and focussed on the path to approval. The FDA's feedback also clearly highlights the recognition of the significant unmet medical need that could be fulfilled by VivaGel® BV."

"Having received formal feedback, we are now thoroughly investigating the possible options with a view to pursuing the optimal approval strategy to secure access to the US market as soon as possible. Along with our expert advisors we, continue to believe in the strength of the extensive data package for VivaGel® BV which has supported multiple approvals around the world, including Europe and Australia and we look forward to the upcoming European launch of the product."

VivaGel® BV is a novel non-antibiotic therapy for BV already available for sale in pharmacies in Australia and approved for sale in Europe with expected launch mid-year. VivaGel® BV has been licensed in more 160 countries around the world and regulatory processes, which are independent of the FDA, are also underway in many countries around the world.

BV is a highly recurrent condition that causes unpleasant vaginal odour and discharge symptoms that have significant medical and social impacts for women. The condition is twice as common as thrush and affects 1 in 3 women in the US.

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 available for sale in Australia for bacterial vaginosis (BV) and a new drug application has been submitted to 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, with DEP® irinotecan due to commence clinical trials shortly. 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

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