starpharma

ASX Announcement

NDA submission for VivaGel® BV in the US

Melbourne, Australia; 21 November 2017: Starpharma (ASX: SPL, OTCQX: SPHRY) today announced that its US New Drug Application (NDA) submission for VivaGel® BV for both treatment and prevention of BV has been lodged with the FDA through a rolling submission process.

VivaGel® BV has been granted Fast Track status and Qualified Infectious Disease Product (QIDP) designation, which allows for rolling submission of the NDA and ensures priority regulatory review by the FDA.

FDA Fast Track status is designed to accelerate the regulatory process and secure rapid approval and early market access for products that address unmet medical needs. The QIDP designation applies to certain new antibacterial products and provides other significant commercial advantages such as an additional five years' market exclusivity.

The rolling NDA submission for VivaGel® BV is for both BV indications - BV treatment and prevention of recurrent BV (rBV). The NDA will feature data from the phase 3 trials for rBV reported in August 2017, as well as earlier trial data on BV treatment. The complete NDA will comprise five main data modules. The current submission includes three of the five main modules. Further modules are currently being finalised and will be submitted in the near future and then FDA review is expected to take approximately 6-8 months.

In parallel with these regulatory activities, Starpharma is currently actively engaged in both global and regional negotiations for commercial rights to VivaGel® BV, with a number of term sheets under discussion, and facilitated by a leading global healthcare investment bank. Filing of the NDA is an important milestone for the commercialisation of the product and, together with the benefits of Fast Track priority review and QIDP designation, this achievement will impact positively on commercial negotiations.

Dr Jackie Fairley, Starpharma CEO, commented: "We are delighted to be submitting our NDA for VivaGel® BV. Starpharma is one of very few Australian companies to have achieved an NDA submission. It is very satisfying strategically that we have retained the commercial rights to VivaGel® BV, while developing the product from discovery through to the successful phase 3 trials and NDA submission – in doing so we've maximised its commercial value."

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 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.