



ASX ANNOUNCEMENT

VivaGel® BV phase 3 trials for prevention of BV completed

- **Two pivotal VivaGel® BV phase 3 trials for the prevention of recurrent bacterial vaginosis now complete**
- **Topline results expected Q2 CY2017**
- **Final data collation, blinded QC reviews, and bio-statistical programming underway**
- **Special Protocol Agreement (SPA) in place with FDA for study design**
- **QIDP designation and Fast Track status granted to accelerate FDA review and approval**
- **US Marketing application for BV Treatment in preparation with submission expected in the near future with Prevention of BV to follow**
- **Global licensing activities for VivaGel® BV underway**

Melbourne, Australia; 30 March 2017: Starpharma Holdings Ltd (ASX: SPL, OTCQX: SPHRY) today announced completion of its international, multicentre, phase 3 clinical studies evaluating VivaGel® BV for the prevention of recurrent bacterial vaginosis (rBV). Starpharma expects topline results of the trials to be available in the second quarter of 2017.

The two pivotal phase 3, double-blind, randomised, placebo-controlled trials compare the rate of BV recurrence in women using VivaGel® BV to the rate of recurrence in women using a placebo gel during a 16 week treatment period with the primary endpoint measured as patients complete the treatment period. The trials were conducted at sites across the US, Europe, Canada, Mexico and Asia. Topline results of the trials will be available late in Q2 CY17 following data collation, routine blinded QC and bio-statistical programming of the extensive data set.

Starpharma has been granted a Special Protocol Agreement (SPA) by the FDA which provides the company with binding FDA agreement on the trial design including the primary endpoint. The achievement of an SPA significantly reduces the US regulatory risk associated with clinical development, by specifying upfront the FDA's agreement with the trial design and providing certainty in the trial data required to support marketing approval.

Starpharma Chief Executive Officer, Dr Jackie Fairley, said: "The completion of these pivotal phase 3 trials is a significant milestone for Starpharma. The market for prevention of BV recurrence is estimated to be worth more than US\$1 billion and there are currently no approved products. As we look forward to the release of results in the next quarter, we are in parallel preparing our US FDA marketing applications, and are engaged in active negotiations for commercial rights to VivaGel® BV. The granting of QIDP designation and Fast Track status by the FDA for both treatment of BV and prevention of rBV in January are also important developments, attracting significant commercial interest."

Bacterial vaginosis affects around 30% of women in the US with around 50-60% suffering from the recurrent form. VivaGel® BV will address a significant unmet medical need for rBV in a market with a value estimated to be in excess of US\$1 billion and where there are currently no approved products.

VivaGel® BV is already approved in Europe for the treatment and relief of BV symptoms and regulatory reviews including by the TGA are well advanced. VivaGel® BV has been licensed in Australia and New Zealand to Aspen Pharmacare and extensive licensing discussions are also underway globally.

Next steps

- **Trial Results:** The extensive data set from the trials will now undergo data collation, routine blinded QC review, and bio-statistical programming, which, based on the size and duration of the trial, is expected to take around 10-12 weeks. Until this time, data will remain blinded. Results are expected to be announced late in the second quarter of CY2017.
- **US Marketing Application:** Starpharma is already well advanced in the compilation of a VivaGel® BV marketing application (New Drug Application) for submission to the FDA. It is expected that an application will be made in the near future for the treatment of BV, with the rBV indication to follow.

The VivaGel® BV marketing applications will benefit from QIDP designation and Fast Track status granted by the FDA earlier this year, each carrying significant benefits for regulatory approval and commercialisation for both indications. Benefits include priority regulatory review and an additional five years' of market exclusivity. The Fast Track designation enables more frequent interactions with the FDA and expedited review, leading to faster approval, and facilitates earlier market access for patients.

- **Partnering:** Starpharma has licensed VivaGel® BV to Aspen Pharmacare for Australia and New Zealand and also has advanced negotiations underway with a number of parties for other regions, including Europe. Global negotiations have been positively impacted by the recent developments in the US including revision to the FDA draft guidance for BV treatment, Fast Track status and the grant of QIDP designation for both indications.

About VivaGel® BV

VivaGel® BV is a water based gel for topical treatment and rapid relief of bacterial vaginosis (BV). It is based on Starpharma's SPL7013, astodrimmer sodium, a proprietary dendrimer that blocks certain bacteria involved in BV and also has potent antiviral activity against certain viruses (HIV, HSV, HPV, Zika).

The VivaGel® BV treatment product, which is already approved in Europe, targets an area of significant unmet medical need in a high-value market (est. US\$750M) and has been licensed to Aspen Pharmacare with preparations underway for launch. A second VivaGel® BV product is in phase 3 clinical development for the prevention of recurrent BV which is another high value market (est. US\$1B) for which there are currently no clinically approved products.

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.

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 three core development programs: VivaGel® portfolio, DEP® drug delivery, and agrochemicals with the Company developing a number of products internally and others via commercial partnerships.

Starpharma's lead products are based on VivaGel® (SPL7013, astodimer sodium), a proprietary dendrimer. VivaGel® formulated as a water based gel and delivered vaginally now has EU regulatory approval for topical treatment and rapid relief of bacterial vaginosis (BV) and is under 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 signed separate license agreements with Ansell Limited (ASX:ANN), Okamoto Industries, Inc., (TSE: JP3192800005), Sky and Land (China) and Koushan Pharmed (Iran) to market a value-added, VivaGel® condom. The VivaGel® condom is available for purchase in Australia and shortly in Canada under Ansell's Lifestyles® Dual Protect™ brand. Ansell manufactures and sells leading condom brands worldwide, including LifeStyles®, Manix®, ZERO® and SKYN®. Okamoto is the market leader for condoms sold in Japan, which is the world's second largest condom market.

In the wider pharmaceutical field, Starpharma has both partnered and internal programs in Drug Delivery. A number of dendrimer-enhanced, or DEP® versions of existing drugs are under development. 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). AstraZeneca has signed a licensing agreement with Starpharma for the use of its DEP® drug delivery platform in the development and commercialisation of an AstraZeneca oncology compound, with potential for follow on compounds directed at a defined family of targets.

In agrochemicals Starpharma has a series of partnerships with leading industry players including global leader Adama (formerly Makhteshim Agan) as well as internal programs including an enhanced version of glyphosate (the active ingredient in Roundup®).

For more information please visit: www.starpharma.com

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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.