Starpharma commences pivotal phase 3 VivaGel® trials for bacterial vaginosis treatment

Key points:

- Two pivotal phase 3 trials launched for the treatment of bacterial vaginosis (BV)
- Special Protocol Assessment (SPA) already received from the FDA which confirms the design of the planned studies is acceptable to support a New Drug Application (NDA) and marketing approval of VivaGel®
- Trials to be completed in 2012
- Preparation of NDA submission and out-licensing discussions to follow

**Melbourne Australia; 22 March 2012:** Starpharma Holdings Limited (ASX:SPL, OTCQX:SPHRY) today announced the commencement of two concurrent pivotal phase 3 clinical trials of VivaGel® for the treatment of bacterial vaginosis (BV), following receipt of ethics approval.

Approximately 30 international sites, primarily in the US, will be involved in the two trials. Each trial will enrol approximately 220 participants. Trial results are anticipated before the end of 2012.

These trials will complete the development program for VivaGel® for the treatment of BV. Following the results, the Company expects to prepare and submit a New Drug Application (NDA) to the US Food and Drug Administration (FDA) concurrently with partnering discussions for the marketing rights of VivaGel® for the treatment of BV.

Starpharma announced in January 2012 that the FDA had provided formal agreement to its Special Protocol Assessment (SPA) submission for the trials. Agreement under an SPA is a declaration from the FDA that the proposed phase 3 trials' design, clinical endpoints, and statistical analyses are acceptable for FDA approval once successfully completed.

These phase 3 trials are designed to confirm the results of a similarly designed phase 2 BV study that was completed in 2011. It demonstrated that VivaGel® was safe and effective for the treatment of BV. In that trial, VivaGel® met the primary endpoint of the trial, demonstrating significant efficacy for treatment of BV with a very high level of statistical significance (P=0.0002). The primary endpoint for these two phase 3 trials is the same as the phase 2 study.

Dr Jackie Fairley, Chief Executive Officer of Starpharma, said: "The commencement of these pivotal phase 3 studies is a landmark achievement in the development of VivaGel®.
The use of VivaGel® for the management of BV is an exciting prospect, with the potential to improve the quality of life for many millions of women around the world. The fact that VivaGel® is not a conventional antibiotic and also has the potential for use in the prevention of recurrent BV will represent a major advance in the management of this highly problematic condition.

BV is the most common vaginal infection worldwide, and the most common cause of vaginal irritation, discharge and malodour. It is particularly prevalent in the US, where it affects an estimated one-third of the adult female population. The condition is implicated in pelvic inflammatory disease and pre-term birth, and also leads to an increased risk of sexually transmitted infections, including HIV. Clinicians and patients in this field have indicated there is a clear need for new treatment options for BV.

The market for topical treatments of BV is approximately $300-$350 million. However, existing treatments are considered suboptimal with relatively low cure rates, high rates of recurrence, unpleasant side-effects, and high levels of bacterial resistance. VivaGel® is a non-antibiotic gel that is applied to the vagina with an applicator. It is not absorbed into the bloodstream (as antibiotics are), and does not result in the side effects often associated with these antibiotics. Clinical trials of VivaGel® have shown a very high level of patient acceptability.

“This is an important milestone for Starpharma - and the biopharmaceutical industry in Australia - as it represents one of only very few examples of where a new chemical entity drug (NCE) has been discovered by Australian scientists and developed by an Australian company through to pivotal phase 3 trials,” Dr Fairley added.

VivaGel® is also being developed for the prevention of recurrence of BV, and as a topical microbicide for the prevention of STIs such as HIV, genital herpes and human papillomavirus (HPV). VivaGel® has also been licensed as a condom coating to Ansell and Okamoto.

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**ABOUT STARPHARMA**

Starpharma Holdings Limited (ASX:SPL, OTCQX:SPHRY) 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 uses. Starpharma has three core development programs: VivaGel® portfolio, drug delivery and agrochemicals with the Company developing a number of products internally and others via commercial partnerships. In addition, products for diagnostics and laboratory reagents are already on market through licence arrangements with partners including Siemens Healthcare and Merck KGaA.

Starpharma's lead product is VivaGel® (SPL7013 Gel), a gel-based formulation of a proprietary dendrimer. VivaGel® is under clinical development for the treatment and prevention of bacterial vaginosis (BV) and also as a vaginal microbicide to prevent the transmission of sexually transmitted infections including HIV and genital herpes.

Starpharma has also signed separate licence agreements with Ansell Limited (ASX:ANN) and Okamoto Industries Inc (TSE) to market a value-added, VivaGel®-coated condom. Ansell manufactures and sells leading condom brands worldwide, including Lifestyles®, ZERO® and SKYN®. Okamoto is the market leader for condoms sold in Japan, the world’s second largest condom market.

In the wider pharmaceutical and life science fields, Starpharma has both partnered and internal programs in Drug Delivery. Most recently Starpharma announced pre-clinical results in its Docetaxel (Taxotere®) program demonstrating significant improvements in that agent's anticancer efficacy and the enhancement of solubility offering potential safety benefits as well. The company is also exploring dendrimer opportunities in agrochemicals in a series of industry partnerships as well as with internal programs including an enhanced version of glyphosate (the active ingredient in Roundup®).
FOR FURTHER INFORMATION

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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 health authorities’ requirements regarding any one or more product candidates nor can there be any assurance that such product candidates will be approved by any health 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 clinical trial results, including additional analysis of existing clinical data, and new clinical 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.
APPENDIX – CLINICAL TRIAL SUMMARY

**Official Title:** A double-blind, multicenter, randomized, placebo controlled study to assess the efficacy and safety of SPL7013 Gel (VivaGel®) for the treatment of bacterial vaginosis

**Identifying Codes:** Starpharma Protocol Numbers: SPL7013-015 and SPL7013-016

**Primary Objective:** To assess the efficacy of 1% SPL7013 Gel compared with placebo gel for the treatment of bacterial vaginosis (BV)

**Primary Endpoint:** Clinical Cure at the Test of Cure (TOC) (Day 21-30) visit defined as resolution of clinical findings (i.e. Amsel criteria) from the Baseline visit (Day 1).

**Secondary Objectives:** To determine the safety and tolerability of 1% SPL7013 Gel

**Secondary Endpoints:**
- Clinical Cure at the End of Treatment (EOT) (Day 9-12) visit
- Nugent Cure, defined as a Nugent score of 0-3, at the TOC visit
- Nugent Cure at EOT visit
- Incidence of adverse events

**Study Design:** Double-blind, multicentre, randomised, placebo-controlled, phase 3 studies.

After screening eligible participants will be randomized to receive either 1% SPL7013 Gel or hydroxyethyl cellulose (HEC) placebo gel at a dose of 5g administered vaginally at bedtime for 7 consecutive days. Participants will be assessed for BV (both by Amsel criteria and Nugent score) at screening/Baseline, after last application (End-of-Treatment, EOT, Day 9-12) and at the final study visit approximately 2-3 weeks after last dose (Test-of-Cure, TOC, Day 21-30).

**Planned Sample Size:** Approximately 220 women will be enrolled in each trial in a 1:1 randomisation ratio (active:placebo).

**Sites:** SPL7013-015 and SPL7013-016 will be conducted at a total of approximately 30 international sites, primarily in the US.

**Key Inclusion Criteria:**
- Post-menarchal females, aged 12 years or more
- diagnosis of BV by Amsel criteria (i.e. all four of the following symptoms: presence of white to grey homogeneous discharge; positive whiff test indicating an amine (fishy) odor with addition of potassium hydroxide; vaginal pH greater than 4.5; and presence of clue cells ≥ 20% of total epithelial cells)
- Nugent score of ≥ 4
- otherwise healthy, as determined by medical history, physical examination
- normal Pap smear at or documented within 24 months of screening