



ASX ANNOUNCEMENT

VivaGel[®] Demonstrates Efficacy in Bacterial Vaginosis

Melbourne Australia; 23 May 2011: Starpharma Holdings Limited (ASX:SPL, OTCQX:SPHRY) today announced successful results of a major phase 2 clinical study that demonstrated efficacy of VivaGel[®] for the treatment of bacterial vaginosis (BV).

Key Points:

- *VivaGel[®] meets primary endpoint, demonstrating significant efficacy for treatment of BV*
- *VivaGel[®] expected to avoid many shortcomings of existing therapies*
- *Trial results support new patent filing which extends VivaGel[®] protection to at least 2032*
- *Planning underway for Phase 3 trials for VivaGel[®] for BV treatment*
- *BV prevention trial of VivaGel[®] to commence Q3 2011*
- *Addressable global market for BV treatment and prevention potentially exceeds \$1B*

VivaGel[®] meets primary endpoint, demonstrating significant efficacy for treatment of BV

The study showed that treatment with VivaGel[®] (containing 1% of the active, SPL7013), once daily for seven days, resulted in 74% of patients achieving Clinical Cure of BV 2 to 5 days after completion of therapy compared with just 22% in the placebo group (P=0.0002).

Moreover, 2 to 3 weeks after completion of therapy, 46% of patients achieved Clinical Cure of BV compared with just 12% for the placebo (P=0.006) indicating that VivaGel[®] provided lasting cure in a significant proportion of the women. Both results were highly statistically significant and cure at both time points is considered by clinicians to be important in the clinical management of BV.

The main symptoms of BV are unpleasant vaginal discharge and odour. In Starpharma's study, vaginal BV discharge as assessed by the investigator was cured following treatment in 89% of the VivaGel[®] treated patients. Unpleasant vaginal odour was cured in 78% of the VivaGel[®] treated patients.

Dr Jackie Fairley, Chief Executive Officer of Starpharma, said: "Starpharma's objective is to develop an efficacious BV product that avoids the side-effects and other shortcomings of conventional antibiotics."

"This Phase 2 study was a crucial test of the product and these exciting results confirm the significant commercial potential of VivaGel[®] for BV. As well as the great outcome for the acute treatment opportunity, we are also very encouraged by the implication of these results for the additional application of VivaGel[®] for prevention of BV recurrence."

"It is particularly pleasing to see such high rates of resolution of symptoms and excellent patient acceptability", she said.

Existing treatments for BV, such as the conventional antibiotics metronidazole and clindamycin, have published Clinical Cure rates of between 35% and 65% when assessed 2-3 weeks after completion of therapy. Unfortunately, existing products have significant shortcomings in terms of side-effects or tolerability, high levels of antibiotic resistance and in some cases incompatibility with condoms.

In contrast, whilst having comparable efficacy, VivaGel[®] is well tolerated, is not absorbed (and so is free from systemic effects), can be used with condoms, and has the real potential to be used for prolonged periods to prevent recurrence of BV.

Clinical Cure 2 to 3 weeks after completion of treatment is currently the US FDA's preferred endpoint for assessing cure of BV. In addition to cure of BV achieved with VivaGel[®] at that time, acceptability of the product was very high with 83% of patients using 1% VivaGel[®] extremely satisfied, very satisfied or satisfied with the product when taking all aspects of the treatment into account, compared with just 35% of patients using the placebo.

Professor George Kinghorn, of the Department of Genitourinary Medicine at the Royal Hallamshire Hospital, Sheffield, UK, a leading expert in BV and Medical Advisor to Starpharma on this Phase 2 study, commented: "These significant efficacy results are very promising and indicate that VivaGel[®] is a potentially useful alternative acute treatment for BV that is different from the systemic and topical antibiotic agents that are the current mainstay of treatment."

The study was a double-blind, randomized, placebo controlled, dose ranging Phase 2 study and was conducted at sites in the US under an Investigational New Drug (IND) application with the US FDA. The study enrolled 132 women who were randomized to receive VivaGel[®] (0.5%, 1% or 3% SPL7013), or placebo. The incidence of adverse events, including genitourinary adverse events, was similar across all placebo gel and VivaGel[®] groups. No severe (grade 3) adverse events were observed in the VivaGel[®] groups. Two severe adverse events were observed in the placebo.

Additional details and results from the study are provided in the Appendix to this announcement.

Addressable global market for BV treatment and prevention potentially exceeds \$1B

The global market for topical BV treatments alone is estimated at approximately US\$350M. Starpharma's modeling suggests the addressable global market for prevention of recurrence of BV is potentially in excess of \$1 billion, due to the long term usage associated with such a product.

Trial results support new patent filing which extends VivaGel[®] protection to at least 2032

On the basis of the data from this phase 2 study, Starpharma has filed a new patent application relating to BV that will, once granted, expand and extend patent protection for VivaGel[®] to at least 2032.

Planning underway for Phase 3 trials for VivaGel[®] for BV treatment

Based on the results of this phase 2 study, Starpharma will undertake further discussions with regulatory authorities, with a view to initiating phase 3 registration trials of VivaGel[®] for the treatment of BV in late 2011 or early 2012.

BV prevention trial of VivaGel® to commence Q3 2011

As previously announced Starpharma is also well advanced in its planning of studies to determine the efficacy of VivaGel® for this second BV indication and expects to commence this trial in Q3 2011. The very high early cure rate observed in this study is an important observation that is highly relevant to and supportive of the application of VivaGel® for prevention of BV recurrence.

About Bacterial Vaginosis

BV is the most common vaginal infection worldwide and is particularly prevalent in the US, where it affects an estimated one-third of the adult female population. Similar to imbalances between “good” and “bad” bacteria in the gut, an imbalance in the vaginal microbiota between good bacteria - which help maintain a normal healthy vagina - and harmful bacteria, leads to BV with symptoms including vaginal irritation, discharge and odour that are unpleasant and disrupt and interfere with a woman’s relationships and general quality of life. The condition also has more serious consequences, being implicated in pelvic inflammatory disease and associated with an increased risk of pre-term birth. BV also significantly increases the risk of some sexually transmitted infections, including HIV.

Several studies have found an association between BV and acquisition of HIV, with one study indicating that more than 30% of HIV infections in women could be prevented if BV was successfully treated. Therefore, treatment of BV with VivaGel® could have a positive indirect impact in reducing HIV acquisition.

Other Applications of VivaGel®

VivaGel® is also being developed as a topical microbicide for the prevention of HIV and genital herpes and as a condom coating. Prevention of human papillomavirus is also under assessment.

ABOUT STARPHARMA

Starpharma Holdings Limited (ASX:SPL, OTCQX:SPHRY) is a world leader in the development of dendrimer technology for pharmaceutical, life-science and other applications. SPL has two operating companies, Starpharma Pty Ltd in Melbourne, Australia and DNT, Inc in the USA. Products based on SPL’s dendrimer technology are already on the market in the form of diagnostic elements and laboratory reagents through licence arrangements with partners including Siemens and Merck KGaA.

The Company’s lead pharmaceutical development product is VivaGel® (SPL7013 Gel), a vaginal microbicide designed to treat and prevent BV, and to prevent the transmission of STIs, including HIV and genital herpes. Starpharma has licence agreements with Reckitt Benckiser (LSE:RB) and Okamoto Industries in Japan to develop a VivaGel® coated condom. Reckitt Benckiser manufactures and sells Durex® condoms, the market-leading condom brand worldwide and Okamoto is the leading company in the Japanese condom market.

Starpharma also has agreements in place with Lilly, Elanco, Stiefel Laboratories (a GSK Company), and Siemens Healthcare as well as many research collaborations with some of the world’s leading organisations in the fields of pharmaceuticals, drug delivery, cosmetics and agrochemicals.

Dendrimer: A type of precisely-defined, branched nanoparticle. Dendrimers have applications in the medical, electronics, chemicals and materials industries.

American Depositary Receipts (ADRs): Starpharma's ADRs trade under the code **SPHRY** (CUSIP number 855563102). Each Starpharma ADR is equivalent to 10 ordinary shares of Starpharma as traded on the Australian Securities Exchange (ASX). The Bank of New York Mellon is the depositary bank. Starpharma's ADRs are listed on International OTCQX, a premium market tier in the U.S. for international exchange-listed companies, operated by OTC Markets Group Inc. (www.otcmarkets.com).

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.

FOR FURTHER INFORMATION

Media:

Buchan Consulting
Rebecca Wilson
Mob: +61 417 382 391
rwilson@bcg.com.au

Starpharma:

Dr Jackie Fairley
Chief Executive Officer
+61 3 8532 2704

www.starpharma.com

Ben Rogers
Company Secretary
+61 3 8532 2702

ben.rogers@starpharma.com

APPENDIX – CLINICAL TRIAL RESULTS SUMMARY

- Official Title:** A double-blind, multi-center, randomized, placebo controlled, dose-ranging study to determine the efficacy and safety of SPL7013 Gel (VivaGel®) administered vaginally in the treatment of bacterial vaginosis
- Identifying Codes:** Starpharma Protocol Number: SPL7013-013
- Primary Objective:**
- To determine the clinical efficacy of 0.5%, 1% and 3% SPL7013 Gel compared to placebo gel in the treatment of BV
- Primary Endpoint:** Clinical Cure as defined by no abnormal discharge, as described by the Amsel's criterion for vaginal discharge, and fulfilling no more than one of the other three Amsel's criteria.
- Secondary Objectives:**
- To explore the microbiological and overall efficacy of 0.5%, 1% and 3% SPL7013 Gel compared to the HEC placebo gel
 - To determine the safety and tolerability of SPL7013 Gel in the study population
 - To determine patient perceived symptom resolution and acceptability of SPL7013 Gel in the study population
- Study Design:** Multi-centre, randomised, dose-ranging, placebo-controlled, Phase 2 study.
Participants (N=132) were randomized to receive 0.5%, 1% or 3% SPL7013 Gel or HEC placebo gel at a dose of 5g each night administered vaginally for 7 consecutive days. Participants were assessed for BV (both clinically by Amsel's criteria and microbiologically by Nugent score¹) at screening, baseline (or combined screening / baseline), 2-5 days after last application (Day 9-12, End of Treatment [EOT]) and at the final study visit approximately 2-3 weeks after last dose (Day 21-30, Test of Cure [TOC]).
- Sites:** The study was conducted at six sites in the US.
- Key Inclusion Criteria:**
- female, aged 18–45 years
 - diagnosis of BV by Amsel's criteria (*i.e.* all four of the following symptoms: presence of white to grey homogeneous discharge; positive whiff test indicating an amine (fishy) odour with addition of potassium hydroxide; vaginal pH greater than 4.5; and presence of clue 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

RESULTS All results presented here are of the Modified Intent to Treat [MITT] population, except where indicated. Results of the Per Protocol population closely matched those of the MITT group. Statistical significance was achieved if $P < 0.048$ compared with placebo (pairwise P-value comparing each SPL7013 Gel concentration to placebo using a Cochran Mantel-Haenszel test controlling for study centre).

Participants: A total of 132 participants aged 18-45 years were randomized to receive 3% (N=32), 1% (N=33) or 0.5% SPL7013 Gel (N=34) or HEC placebo gel (N=33). A total of 84%, 88%, 94% of patients in the 3%, 1%, 0.5% SPL7013 Gel groups, respectively, completed treatment compared with 88% in the placebo group.

Clinical Cure:	3% SPL7013 Gel	1% SPL7013 Gel	0.5% SPL7013 Gel	HEC Placebo
EOT	63% (P=0.0015)*	74% (P=0.0002)*	55% (P=0.0098)*	22%
TOC	28% (P=0.1583)	46% (P=0.006)*	23% (P=0.2478)	12%

* Statistically significant result compared with placebo

The primary endpoint of the study was met, *i.e.* Clinical Cure of BV, as defined above.

At EOT, 74% of participants in the 1% SPL7013 Gel group compared with just 22% in the placebo group achieved Clinical Cure ($P=0.0002$). Statistically significant Clinical Cure was also achieved in both the 0.5% and 3% SPL7013 Gel groups compared with placebo. At TOC, 2-3 weeks after cessation of treatment, 46% of patients receiving 1% SPL7013 Gel achieved Clinical Cure, compared with just 12% in the placebo group (statistically significant, $P=0.006$).

Signs and symptoms of BV, as assessed objectively by the study investigators, were significantly improved with SPL7013 Gel treatment compared with placebo. For example, at EOT, vaginal BV discharge was cured following treatment in 89% of the 1% SPL7013 Gel treated patients compared with just 37% of patients using placebo. Unpleasant vaginal odour was cured in 78% of the 1% SPL7013 Gel treated patients compared with just 22% of patients using placebo.

Microbiology: Statistically significant normalisation of vaginal microbiology from baseline (Nugent score 7-10 at baseline to 0-3) was achieved in 30%, 22% and 29% of patients receiving 3%, 1% and 0.5% SPL7013 Gel, respectively, compared with 0% of patients in the placebo group at EOT. At TOC, 22% of patients receiving 1% SPL7013 Gel, compared with just 4% of those in the placebo group, had normalisation of Nugent score.

At EOT, patients' Nugent scores were improved from 7-10 to 0-6, or from 4-6 to 0-3 in 72%, 69% and 59% of participants in the 3%, 1% and 0.5% SPL7013 Gel groups, respectively, compared with only 7% of participants in the placebo group.

One of the primary assessments of BV is the presence of an abnormal level of so-called "Clue Cells". In this study, treatment with 1% SPL7013 Gel normalised Clue Cells in 89% of patients compared with just 26% of patients using placebo.

Statistically significant Therapeutic Cure of BV (Clinical Cure and Nugent score 0-3) was achieved at EOT in patients receiving 1% SPL7013 Gel (28%, Per Protocol population) compared with placebo gel (4%) (P=0.03).

Statistically significant Therapeutic Resolution of BV (Clinical Cure and Nugent score 0-6) was achieved at EOT in 54%, 50% and 38% of patients receiving 3%, 1% and 0.5% SPL7013 Gel, respectively, compared with 11% in the placebo group.

Safety and Tolerability: SPL7013 Gels were safe and well tolerated in this study when administered once daily at night for seven consecutive days. Genitourinary adverse events (AEs) possibly, probably or definitely related to treatment occurred in 24%, 19% and 25% of patients using 3%, 1% and 0.5% SPL7013 Gels, respectively, compared with 22% using placebo gel. Rates of non-genitourinary AEs were similar between SPL7013 Gel and placebo groups, and there were no AEs indicative of systemic exposure or toxicity to SPL7013.

Two participants using HEC placebo gel experienced a severe (Grade 3) AE, compared with no participants using SPL7013 Gels. No serious adverse events (SAEs) were experienced by any participants who received treatment. Only two participants using 1% SPL7013 Gel and two participants using placebo gel discontinued from the study due to an AE, indicating the treatments were very well tolerated.

Patient Reported Symptom Resolution and Acceptability: Symptoms of BV, unpleasant vaginal discharge and odour, were assessed by the patients. At baseline, prior to use of gel, 92%, 93%, and 77% of patients in the 3%, 1% and 0.5% SPL7013 Gel groups, respectively, reported abnormal vaginal discharge compared with 86% in the placebo group. At EOT, this proportion was reduced to 40%, 37% and 45% in the 3%, 1% and 0.5% SPL7013 Gel groups, respectively, while abnormal discharge was still reported by a high proportion (72%) of patients using placebo gel. In the 1% SPL7013 Gel group, 63% of patients, compared with just 12% in the placebo group, reported vaginal discharge was 'much better/gone' at EOT compared with the visit prior to use of gel.

At baseline, prior to use of gel, 92%, 82%, and 73% of patients in the 3%, 1% and 0.5% SPL7013 Gel groups, respectively, reported unpleasant vaginal odour compared with 93% in the placebo group. At EOT, this proportion was reduced to 16%, 22% and 35% in the 3%, 1% and 0.5% SPL7013 Gel groups, respectively, while unpleasant odour was still reported by a high proportion (68%) of patients using placebo gel. In the 1% SPL7013 Gel group, 52% of patients, compared with just 12% in the placebo group, reported unpleasant odour was 'much better/gone' at EOT compared with the visit prior to use of gel.

In patients who had resolution of BV symptoms, time to resolution of symptoms of discharge and odour was markedly shorter for patients receiving SPL7013 Gels compared with placebo. For example, the median time to resolution of abnormal vaginal discharge was 4 days for users of 1% SPL7013 Gel compared with 9 days for placebo gel recipients. In addition, the median time to resolution of unpleasant vaginal odour was just 1 day for users of 1% SPL7013 Gel compared with 7 days for placebo gel recipients.

Not surprisingly given the above data, acceptability of the product, as rated by patients using a validated treatment satisfaction questionnaire for medication (TSQM), was very high with 83% of patients using 1% SPL7013 Gel extremely satisfied, very satisfied or satisfied with the product when taking all aspects of the treatment into account, compared with just 35% of patients using the placebo. TSQM scores for effectiveness were statistically significantly better in all SPL7013 Gel groups compared with the placebo gel group.

Summary: Treatment with SPL7013 Gels (VivaGel®) once daily at night for 7 consecutive days resulted in statistically significant cure of BV and resolution of symptoms at all dose levels. The 1% SPL7013 Gel dose strength performed best. All gels were safe and well tolerated and comparable with placebo in this study.

1. The Nugent score is a weighted score between 0 and 10 derived from a microbiological analysis using a Gram-stained vaginal smear. The composite score is based on the level of abundance of the following bacteria: i) *Lactobacillus* spp. morphotypes: 0-4 (abundant-none); ii) *Gardnerella/Bacteroides* spp. morphotypes: 0-4 (none-abundant); and iii) curved gram-variable rods: 0-2 (none-abundant).