



Starpharma receives FDA Clearance to commence Phase 2 Bacterial Vaginosis Study for VivaGel®

Melbourne Australia; 15 July 2010: Starpharma Holdings Limited (ASX:SPL, OTCQX:SPHRY) today announced it had received clearance from the US Food and Drug Administration (FDA) to commence a phase 2 study to investigate VivaGel® for the treatment of bacterial vaginosis (BV).

VivaGel® is under investigation for both the short term treatment and longer term suppression of recurrence of BV in women. This initial phase of the clinical program will investigate the treatment of BV with a once daily for seven days treatment of VivaGel® and its findings will guide further investigation of suppression of recurrence.

The study will be conducted under an investigational new drug application (IND) at sites in US and will enroll 132 women. Final preparations are already well advanced and it is expected that the study will commence within a month. The primary objective of the study is to identify the efficacy and optimal dosing for VivaGel® for BV with three strengths (0.5%, 1% and 3%) being compared with a placebo gel. Subjects will be assessed at the end of treatment and then two to three weeks after the end of treatment.

BV is the most common vaginal infection worldwide, and the most common cause of vaginal irritation, discharge and malodor. 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 may also be associated with an increased risk of sexually transmitted infections, including HIV, and pre-term birth.

The global market for topical BV treatments alone is estimated at approximately US\$350M. The current treatment for BV with conventional antibiotics (orally or topically) is acknowledged to be inadequate by clinicians with high recurrence rates and common side effects. Current treatments may lead to the development of drug resistance, increased susceptibility to thrush (candidiasis), and drug interactions and topical treatments are often incompatible with condoms. Earlier trials of VivaGel® for BV have shown no signs of these issues and VivaGel® is designed to be used with condoms.

Dr Jackie Fairley, Chief Executive Officer of Starpharma, said: "The commencement of our BV program is an important milestone in VivaGel®'s development. The treatment and suppression of recurrence of BV opens up a whole new application for the product in an attractive, established market. Feedback we've received suggests that a product without the drawbacks of a conventional antibiotics and designed for use during sex, is likely to be very well received indeed."

VivaGel® is also being developed as a topical microbicide for the prevention of HIV and genital herpes and as a condom coating in collaboration with SSL International. Other indications are also under assessment, including prevention of human papillomavirus, and other STIs.

Additional details of the study are included in the Appendix to this announcement.

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 KgA.

The Company's lead pharmaceutical development product is VivaGel[®] (SPL7013 Gel), a vaginal microbicide designed to prevent the transmission of STIs, including HIV and genital herpes. In September 2008 Starpharma signed a full licence agreement with SSL International plc (LSE:SSL) to develop a VivaGel[®] coated condom. SSL manufactures and sells Durex[®] condoms, the market-leading condom brand worldwide.

Starpharma also has agreements in place with Lilly, Elanco, Stiefel Laboratories (a GSK Company), and Unilever as well as many research collaborations with some of the world's leading organisations.

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 (www.otcqx.com), a premium market tier in the U.S. for international exchange-listed companies, operated by Pink OTC Markets, Inc.

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.

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APPENDIX – CLINICAL TRIAL 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: SPL7013-013A
- 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 will be 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 will be assessed for BV (both clinically by Amsel's criteria and microbiologically by Nugent score) at screening, baseline (screening and baseline may be combined), after last application (Day 9-12) and at the final study visit approximately 2-3 weeks after last dose (Day 21-30).
- Sites:** The study will be conducted at 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) odor 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