



ASX ANNOUNCEMENT

Starpharma Commences Bacterial Vaginosis Prevention Study of VivaGel[®]

Melbourne Australia; 15 August 2011: Starpharma Holdings Limited (ASX:SPL, OTCQX:SPHRY) today announced the commencement of its Phase 2 study of VivaGel[®] for the prevention of bacterial vaginosis (BV), following receipt of ethics approval.

The prevention of BV is the second area of investigation of the VivaGel[®] product for this condition. In May 2011, Starpharma announced the positive results of its first study of VivaGel[®] for the treatment of BV, which showed that the product successfully treated patients suffering the illness, with very high levels of patient acceptability. Further discussions with the US Food and Drug Administration (FDA) and other regulators on the development of VivaGel[®] for the treatment of BV will occur over the next few months, with Phase 3 studies for BV treatment expected to commence in late 2011 or early 2012.

This new phase of the program will investigate the ability of VivaGel[®] to prevent recurrence of BV, which clinicians identify as a major unmet need. The trial will be conducted in women with a prior history of recurrent BV, and the product will be used every second day.

The study will be conducted under an investigational new drug application (IND) at sites in US and will enroll approximately 200 women. Clinical trial sites have been fully assessed, and the first patient is expected to be enrolled later this month, following final initiation of sites. The primary objective of the study is to determine the efficacy of two strengths of VivaGel[®] (1% and 3%) compared with a placebo gel in preventing recurrence of BV. Whilst the duration of use of the product in this study is 16 weeks, it is intended that women would use the product as a long-term prevention tool if proven effective.

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.

Dr Jackie Fairley, Chief Executive Officer of Starpharma, said:

"There are currently very few proven options for women who wish to prevent recurrence of BV. Clinical experts in this field have repeatedly expressed the need for products to prevent the recurrence of this condition and so the commencement of this program is an important step in the development of VivaGel[®] and the management of the condition."

"In addition to the obvious unmet market need for the recurrence indication, we were very encouraged by the results obtained in our Phase 2 BV treatment trial of VivaGel[®] reported in May, and the implications of these results for recurrence. These included high rates of cure and rapid resolution of symptoms together with excellent patient acceptability", she said.

BV is caused by a disruption to the delicate balance of the vaginal bacteria, so that the bacteria that help maintain a normal healthy vagina are reduced and harmful bacteria overgrow. The symptoms of BV include vaginal irritation, discharge and odour that are unpleasant and disrupt and interfere with a woman's relationships and general quality of life. Relapse, or recurrence, of BV is extremely common following treatment with existing antibiotics, and long-term use of these existing products is not recommended.

BV is associated with serious health consequences such as pelvic inflammatory disease and pre-term births. Several studies have also 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. In addition, a recent study showed men were three times more likely to contract HIV from their female partners if the women also had BV in the three months before the men became infected.

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.

A copy of the Clinical Trial Summary is attached as Appendix A.

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 prevent the transmission of STIs, including HIV, genital herpes and bacterial vaginosis. Starpharma has a licence agreement with Durex® condom manufacturer Reckitt Benckiser to develop a VivaGel®-coated condom, and a licence agreement with Okamoto Industries Inc in relation to the VivaGel®-coated condom for the Japanese market. Okamoto is the market leader for condoms sold in Japan, the world's second largest 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 Depository 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). 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.otcm Markets.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 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 A – CLINICAL TRIAL SUMMARY

- Official Title:** A double-blind, multicenter, randomized, placebo-controlled, dose-ranging study to determine the efficacy and safety of SPL7013 Gel (VivaGel[®]) administered vaginally to prevent the recurrence of bacterial vaginosis
- Identifying Codes:** Starpharma Protocol Number: SPL7013-014
- Primary Objective:**
- To assess the efficacy of 1% and 3% SPL7013 Gel, used every second day for 16 weeks, in reducing the rate of recurrence of bacterial vaginosis (BV) in subjects with a history of recurrent BV
- Primary Endpoint:** The recurrence of BV by or at the End of Treatment visit (Week 16)
- Secondary Objectives:**
- To determine the safety and tolerability of 1% and 3% SPL7013 Gel used every second day for 16 weeks
 - To assess the acceptability of treatment with 1% and 3% SPL7013 Gel
 - To characterize the distribution of times to recurrence of BV in subjects with a history of recurrent BV when treated with SPL7013 Gel every second day for 16 weeks (vs. placebo)
- Study Design:** Randomized, double-blind, multicenter, placebo-controlled, dose-ranging study of women with active BV and a history of recurrent BV. Recurrent BV is defined as a history of at least 3 episodes of BV in the past 12 months, including the current episode. The current diagnosis of BV is defined by the presence of at least 3 of the 4 Amsel criteria and subject-reported symptoms consistent with BV.
- After receiving metronidazole for 7 days, eligible subjects will be randomized to receive 1% SPL7013 Gel, 3% SPL7013 Gel, or placebo gel every second day for 16 weeks followed by an 8-week follow-up period.
- Sites:** The study will be conducted at sites in the US
- Key Inclusion Criteria:**
- female, aged 18–45 years
 - history of recurrent BV, defined as at least 3 documented episodes in the previous 12 months (including the current episode) as indicated by subject’s medical history and/or record of a prescription of medication to treat an episode of BV
 - current diagnosis of BV (ie, subject-reported symptoms consistent with BV (any vaginal discharge considered by the subject to be abnormal, and/or unpleasant vaginal odor) and at least 3 of 4 Amsel criteria)
 - non-pregnant
 - otherwise healthy, as determined by medical history
 - normal Pap smear at or documented within 24 months of screening