

# Successful Completion of VivaGel<sup>®</sup> Study in Sexually Active Women

**Melbourne, Australia; 12 March 2010** - Starpharma Holdings Limited (ASX:SPL, OTCQX:SPHRY) today announced positive results of a clinical trial showing 3% SPL7013 Gel (VivaGel<sup>®</sup>) was comparable in terms of safety and tolerability with its matched placebo when administered vaginally, twice daily for 14 days in sexually active women.

The study enrolled 61 healthy women who vaginally applied VivaGel<sup>®</sup>, a matched placebo gel without the SPL7013 active ingredient, or an alternative experimental placebo based on hydroxyethyl cellulose (HEC).

All three groups were found to be comparable in terms of the percentage of women with one or more abnormal genital findings observed by the investigators during a pelvic examination which were related to the study gels.

In addition, there was no statistically significant difference in the proportion of women who had one or more sign and/or symptom of genital irritation considered to be possibly, probably or definitely-related to administration of gels between the VivaGel<sup>®</sup>, matched placebo gel, and HEC gel treatment groups. The incidence of genital signs and symptoms reported with VivaGel in this study is in line with that reported in previous safety studies of VivaGel<sup>®</sup>, and of other topical vaginal products.

Starpharma CEO, Dr Jackie Fairley, said, "We are pleased to report positive findings from this study, our first in sexually active women. These data provide further evidence of the safety and tolerability of the VivaGel<sup>®</sup> active ingredient, SPL7013, and will support its development as both a stand-alone gel (bacterial vaginosis, genital herpes and HIV), and as a condom coating."

Adverse events during the study were mainly mild, self-limiting, and resolved spontaneously. As with other studies of VivaGel<sup>®</sup>, there were no severe (grade 3) or serious (grade 4) adverse events reported. Adherence by participants to the required VivaGel<sup>®</sup> and matched placebo regimens was 95-100%, indicating the products were well tolerated by the participants. Blood tests (systemic laboratory parameters) showed no evidence of any treatment-related effects in study participants.

Some further analysis of secondary assessments for the study is ongoing. As previously announced, Starpharma plans to commence further clinical studies of VivaGel<sup>®</sup>, including a phase 2 efficacy study in bacterial vaginosis, during 2010.

The clinical study was funded by the Division of AIDS (DAIDS), National Institute of Allergy and Infectious Diseases (NIAID), and the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), National Institutes of Health (NIH)\*.

#### About Starpharma

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

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<sup>®</sup> (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<sup>®</sup> coated condom. SSL manufactures and sells Durex<sup>®</sup> condoms, the market-leading condom brand worldwide.

**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.

## For further information:

Media Buchan Consulting		Starpharma www.starpharma.com	
Rebecca Wilson	Ellie Papathanasiou	Dr Jackie Fairley	Ben Rogers
Tel: +61 3 9866 4722 Mob: +61 417 382 391 <u>rwilson@bcg.com.au</u>	Tel: +61 3 8866 1204 epapathanasiou@bcg.com.au	Chief Executive Officer +61 3 8532 2704	Company Secretary +61 3 8532 2702 ben.rogers@starpharma.com

\*The following statement is included in accordance with U.S. Federal Government requirements:

The content of this announcement does not necessarily reflect the views or policies of the Department of Health and Human Services, nor does mention of trade names, commercial products, or organizations imply endorsement by the U.S. Government.

# **APPENDIX – CLINICAL TRIAL SUMMARY**

Study Title:	Safety and Acceptability of 3% w/w SPL7013 Gel (VivaGel $^{\ensuremath{\mathbb{B}}}$ ) Applied Vaginally in Sexually Active Young Women		
Protocol Number:	SPL7013-006		
Primary Objective:	To assess the safety of 3% w/w SPL7013 Gel when administered for 14 consecutive days on the vulvar and cervicovaginal mucosa of healthy sexually active HIV-negative women aged 18-24 years.		
Primary Endpoints:	Abnormal genital signs and symptoms, grade 3 or higher laboratory values for haematology, liver function, creatinine level and coagulation, and adverse events considered possibly, probably or definitely related to product use.		
Study Design:	Multi-centre, randomised, placebo-controlled, multiple-dose study conducted in USA and Puerto Rico.		
	Each subject administered doses (3.5g) of 3% SPL7013 Gel, matched placebo gel, or HEC placebo gel vaginally, twice daily for 14 days. Adverse events were assessed via medical history interview and physical exams, and via regular telephone contact between investigators and participants.		
Key Inclusion Criteria:	<ul> <li>female, aged 18-24 years</li> <li>healthy, as determined by medical history, physical examination</li> <li>sexually active</li> <li>regular menstrual cycle</li> <li>normal Pap smear</li> <li>using an adequate form of contraception</li> <li>HIV seronegative</li> <li>negative urine pregnancy test at screening, baseline and each other visit</li> </ul>		
Key Exclusion Criteria:	<ul> <li>history or presence of significant medical condition</li> <li>history of adverse reaction to latex or other product components</li> <li>history of male partner having an allergic reaction to latex</li> <li>abnormal finding on physical or pelvic exam that precludes participation</li> <li>current reproductive tract infection</li> <li>positive for STI at screening, or diagnosed or treated for STI during 6 months prior to enrolment</li> <li>currently breast feeding or planning on breast feeding while participating in this study</li> </ul>		
Number of Trial Subjects:	3% SPL7013 Gel: Matched placebo: HEC placebo: Total:	22 21 18 <b>61</b>	

## Primary Endpoint Results:

The percentage of women who were found to have one or more adverse events considered to be possibly, probably or definitely related to product use during pelvic examination conducted by the investigators was 18.2% in VivaGel, 28.6% in matched placebo, and 22.2% in HEC placebo gel groups.

Overall, there was no statistically significant difference in the proportion of women who had one or more abnormal genital signs (reported on observation by the investigator) or symptoms (as reported by the participant) considered to be possibly, probably or definitely related to administration of gels between the VivaGel (63.6%), matched placebo gel (52.4%), and HEC gel (38.9%) treatment groups (p=0.30). The incidence of signs and symptoms expressed per 100 person-years of participation in the study was 0.197 with VivaGel, 0.133 in matched placebo gel, and 0.083 with HEC placebo gel (p=0.06).

Signs and symptoms are defined as: pelvic pain; vaginal and vulvar pain; tenderness; vulvar itching, oedema, erythema, lesions, abrasions or rash; vaginal itching, oedema, erythema, dryness or lesions; cervical oedema, erythema, discharge or lesions; dysuria; vulvovaginitis; cervicitis or dyspareunia.

There were no grade 3 or higher laboratory values for haematology, liver function, creatinine level and coagulation. The percentage of women who had at least one adverse event (genital and non-genital signs and symptoms) considered possibly, probably or definitely related to product use was 77.3% in VivaGel, 66.7% in matched placebo gel, and 50.0% in HEC placebo gel groups. Non-genital adverse events were low in number and included conditions such as diarrhoea and headache.

Collaborative Partners / Funders:	Division of AIDS (DAIDS), National Institute of Allergy and Infectious Diseases (NIAI National Institutes of Health (NIH), USA		
	<i>Eunice Kennedy Shriver</i> National Institute of Child Health and Human Development (NICHD), NIH, USA		
	Microbicide Trials Network (MTN) and Adolescent Trials Network (ATN)		