Starpharma Reports Positive VivaGel® Clinical Study Results

Melbourne, Australia, 12 May 2008: Starpharma Holdings Limited (ASX:SPL, OTCQX:SPHRY) today announced positive results of a clinical trial that achieved all its objectives demonstrating that 3% SPL7013 Gel (VivaGel®) was safe and well-tolerated in sexually abstinent women when administered vaginally, twice daily for 14 days.

Based on these results and existing supporting data, the product is deemed suitable for continued development as a topical microbicide for the prevention of HIV and genital herpes (HSV) and the exploration of other potential indications. These findings support current and future clinical studies to assess the safety and efficacy of VivaGel® for genital herpes and HIV in sexually active women.

The study enrolled 54 women in the U.S. and Kenya and was double blinded so that the participants, the investigators and study staff did not know who was receiving VivaGel® or placebo gel.

Blood tests (systemic laboratory parameters) showed no evidence of any treatment-related effects in study participants. This finding was not surprising, given that consistent with previous clinical and non-clinical studies, there was no evidence of absorption of the active ingredient of VivaGel®, SPL7013, into the blood after vaginal application in this study. Study participants also showed no evidence of any treatment-related effects on vaginal microflora.

No participant discontinued or was required to discontinue product use due to any adverse events during the trial.

An additional positive outcome was there was no statistical difference between the VivaGel® and placebo arms in the number of participants who experienced any sign or symptom including genitourinary (genital and urinary) signs or symptoms deemed to be associated with product use. During the study, there were no serious adverse events reported, nor grade 3 or 4 adverse events. Moderate (grade 2) genitourinary findings occurred in only three women receiving VivaGel® at the U.S. site. All other genitourinary findings were reported as being mild (grade 1).

The incidence of genital signs and symptoms reported with VivaGel® in this study is in line with that reported for other topical vaginal products and markedly lower than that reported with nonoxynol-9 in similar studies.

Starpharma's CEO, Dr Jackie Fairley said, "We are pleased to report that VivaGel® has met its safety and tolerability endpoints in this expanded safety study. We look forward to moving ahead with further trials of the product - both in the HIV and HSV-2 programs and also potentially in additional applications of VivaGel® including other STIs and contraception."

The clinical study was funded by the Division of Microbiology and Infectious Diseases (DMID), National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH) and conducted by DMID in collaboration with the Sexually Transmitted Infections Clinical Trials Group (STI-CTG). This was the first study to be conducted under the U.S. Investigational New Drug application (IND) for VivaGel® for prevention of genital herpes.

A summary of the results of the study is included in the Appendix to this announcement.

VivaGel® is being developed as a topical vaginal microbicide for the prevention of HIV and genital herpes, and also shows promise as a contraceptive agent. In addition, the company recently reported VivaGel® has activity against clinically relevant human papillomavirus (HPV). Starpharma is also co-developing a VivaGel® coated condom with SSL International plc and one other unnamed market leading condom company.

About Starpharma

Starpharma Holdings Limited (ASX:SPL, OTCQX:SPHRY) is a world leader in the development of dendrimer nanotechnology for pharmaceutical, life-science and other applications. SPL is principally composed of two operating companies, Starpharma Pty Ltd in Melbourne, Australia and Dendritic Nanotechnologies, Inc in Michigan, USA. Products based on SPL's dendrimer technology are already on the market in the form of diagnostic elements and laboratory reagents.

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 the wider pharmaceutical field Starpharma has specific programs in the areas of Drug Delivery and Drug Optimisation technologies (using dendrimers to control where and when drugs go when introduced to the body) and Targeted Diagnostics (using dendrimers as a scaffold to which both location-signalling and targeting groups are added to allow location of specific cell type, such as cancer cells). More broadly the company is exploring dendrimer opportunities in materials science with applications as diverse as adhesives, lubricants and water remediation.

SPL has a comprehensive IP portfolio that comprises more than 224 patents/applications issued and pending across 56 patent families - a unique level of IP concentration among nanotechnology companies.

Dendrimers: 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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CLINICAL TRIAL RESULTS APPENDIX – STUDY NO. SPL7013-004

This appendix contains a summary of the results of the clinical trial assessing the safety of 3% SPL7013 Gel (VivaGel®). The clinical trial achieved its objectives and demonstrated that VivaGel® is safe and well-tolerated in sexually abstinent women when administered vaginally, twice daily for 14 days.

Study Title	An expanded phase I randomised placebo controlled trial of safety and tolerability of 3% w/w SPL7013 Gel (VivaGel®) in healthy young women when administered twice daily for 14 days
Study Number(s)	SPL7013-004; DMID 05-0121
Study Design	Multi-centre, randomised, placebo-controlled, repeat dose study
Study Sites	UCSF, San Francisco, USA and KEMRI, Kisumu, Kenya
Blinding Status	Double-blind
Treatment Method	3.5g of 3% SPL7013 Gel or placebo gel, twice daily for 14 days
Route of Admin	Vaginal
Number of Trial Subjects	3% SPL7013 Gel: 35 Placebo: 19 **Total: 54**
Subject Dropout	No study participants were withdrawn or dropped out due to an adverse event (AE)
Subject Selection Criteria	Previously sexually active women who agreed to be abstinent for the duration of their participation in the study; 18-24 years of age; regular menstrual cycle; HIV and HSV-2 seronegative; free from any active sexually transmitted infection (STI); not pregnant; no history of illness or allergy which would make them unsuitable for inclusion in the study
Primary Objective	To determine the safety and tolerability of 3% SPL7013 Gel (VivaGel®) applied vaginally twice daily for 14 days in sexually abstinent, HIV negative and STI-free young women
Primary Endpoint(s) Results	The primary endpoints for the determination of safety were incidence and severity of adverse events, disruption of vaginal microflora and laboratory evidence of grade 3 or higher events. Tolerability was assessed as the proportion of participants who discontinued product due to overt adverse events.

There were no grade 3 or 4 adverse events (AEs), and no deaths or serious adverse events (SAEs) reported during this study. The proportion of participants that experienced an AE during the study was not statistically different between the SPL7013 Gel and placebo arms. The most common AEs included vaginal discharge, laboratory abnormalities, metrorrhagia (intermenstrual bleeding/spotting), abdominal symptoms, candidiasis, headache, and vaginal and vulvar pain.

There was no statistical difference in the number of participants in the SPL7013 Gel and placebo arms who experienced a grade 1, or mild, genitourinary AEs deemed to be associated with product use (OR* = 1.18, 95% CI** 0.79-1.75). In general, each type of genitourinary AE was experienced by few women. Signs and symptoms of localised genital irritation potentially associated with administration of the study product were experienced by 57% and 47% of participants in the SPL7013 Gel and placebo arms, respectively. Grade 2 genitourinary AEs, of moderate severity, occurred in three women receiving SPL7013 Gel at the U.S. site.

Maintenance of normal vaginal flora, in particular H_2O_2-producing lactobacilli, was common in women throughout the dosing period and overall study, and did not differ by study arm. No laboratory abnormalities were deemed to be clinically significant; these were balanced between the SPL7013 Gel and placebo arms, and none were grade 3 or higher.

There were no study participants that discontinued product use due to any AE, indicating that SPL7013 Gel was well tolerated.

In keeping with other clinical and nonclinical studies of SPL7013 Gel, the active ingredient, SPL7013, was not absorbed into the plasma following twice daily dosing for 14 days in sexually abstinent women in this study.

(*OR: Odds Ratio, **CI: Confidence Interval)

Conclusion	The study showed that 3% w/w SPL7013 Gel (VivaGel®) is safe and well-tolerated when administered to the vagina of sexually abstinent young women, twice daily for 14 consecutive days. There was no evidence of systemic absorption of SPL7013.

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