# VivaGel®: New Clinical Trial Commences

**Melbourne Australia; 13 August 2008**: Starpharma Holdings Limited (ASX:SPL, OTCQX:SPHRY) today announced the start of its next clinical trial of VivaGel®. The study will measure the level of antiviral activity retained by VivaGel® after vaginal administration. Assessment will be by laboratory assay of vaginal samples collected up to 24 hours after VivaGel® application. The study in 12 women will determine the timescale over which VivaGel® retains activity against HIV and HSV-2 (genital herpes).

"The value of this short trial is that it provides a potential surrogate for antiviral efficacy of VivaGel® in humans ahead of Phase 3 studies," said Dr Jackie Fairley, Chief Executive Officer of Starpharma. "It will also give an indication of just how long before sex you could apply VivaGel® to prevent infection," added Dr Fairley.

The study is being conducted at the Centre for Clinical Studies in Melbourne and is funded by the U.S. National Institutes of Health (NIH).*

Additional details of the study are included in Appendix 1 to this announcement.

VivaGel® is being developed as a vaginal microbicide for the prevention of HIV and HSV-2. Other applications of VivaGel® are also under assessment, including prevention of human papillomavirus (HPV), contraception and treatment of bacterial vaginosis (BV).

* NIH Contract No. HHSN266200500042C

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**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.

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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 – CLINICAL TRIAL SUMMARY

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| **Official Title:** | Assessment of local retention and duration of activity of SPL7013 following vaginal application of 3% SPL7013 Gel (VivaGel®) in healthy volunteers |
| **Identifying Codes:** | Starpharma Protocol Number: SPL7013-003 |
| **Primary Objective:** | To assess the local retention and antiviral activity of SPL7013 in cervico-vaginal (CV) samples as a function of time after application of 3% SPL7013 Gel in healthy volunteers. |
| **Primary Endpoints:** | i) $IC_{90}$s measured in *ex vivo* replication assays for HIV and HSV using CV samples, and ii) amount and concentration of SPL7013 in CV contents in samples taken at screening, 0, 1, 3, 12 and 24 hours after vaginal application of 3% SPL7013 Gel. |
| **Study Design:** | Single-centre, open-label, randomized, cross-over study.<br>Each subject will receive 5 single doses of 3% SPL7013 Gel with at least 5 days washout between doses. One CV sample will be taken after each dose application at screening and at 0, 1, 3, 12 and 24 hours after dosing in a randomized sequence. Three additional CV samples will be taken pre-dose for use in validation and as standards in the activity and content assays. |
| **Site Details:** | Centre for Clinical Studies, Nucleus Network Ltd, Melbourne, Australia |
| **Key Inclusion Criteria:** | • female, aged 18–45 years<br>• healthy, as determined by medical history, physical examination<br>• negative urine pregnancy test at screening, baseline and each other visit<br>• agrees to abstain from sexual intercourse as required |
| **Key Exclusion Criteria:** | • history or presence of significant medical condition<br>• abnormal pelvic exam<br>• history or presence of allergy<br>• history of recurrent vaginal infections, irritation or localized reaction to vaginally applied agents<br>• current urinary tract infection<br>• positive for STI at screening, or treated for STI during 3 months prior to enrollment<br>• recent history of intermenstrual bleeding<br>• positive for serum antibodies to HIV-1 and/or HIV-2<br>• abnormal Pap smear at or documented within 12 months of screening<br>• currently breast feeding or planning on breast feeding while participating in this study<br>• vaginitis or vaginosis |
| **Partners:** | Division of AIDS (DAIDS), National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH)* |

* NIH Contract No. HHSN266200500042C