



## **Expansion of VivaGel® US Trial and Completion of Enrollment in Herpes Trial**

**Melbourne, Australia, 8 January 2008.** Starpharma Holdings Limited (ASX: SPL, OTCQX: SPHRY) today announced two updates in relation to its VivaGel® (SPL7013 Gel) clinical development program:

- **Study SPL7013-006: Protocol Amendment**

An amendment is being made to the Phase I expanded safety study of VivaGel®, a vaginal microbicide that is being developed for prevention of HIV and genital herpes. The trial, which is being conducted in sexually active HIV-negative women in the USA, will add a third study group and enroll a total of 60 participants instead of 40.

The two existing trial groups are receiving either VivaGel® or its matching placebo gel. The third group of up to 20 women will receive a comparator placebo product widely used in other microbicide trials and known as the HEC (hydroxyethyl cellulose) “universal placebo.” The third study group is being added and enrollment increased to provide more comprehensive data about the safety of these products that will strengthen the study conclusions.

The study is funded by the National Institute of Child Health and Human Development (NICHD) and the National Institute of Allergy and Infectious Disease (NIAID), components of the U.S. National Institutes of Health, and is being conducted by the Microbicide Trials Network (MTN) in collaboration with the Adolescent Medicine Trials Network for HIV/AIDS Interventions (ATN).

Starpharma and its study partners mutually agreed to amend the study following an interim review of data. Enrollment into the study has been paused to allow the study protocol to be amended and to allow additional training at the two trial sites in Tampa, Florida, and San Juan, Puerto Rico. Enrollment into the study is expected to re-commence within 1-3 months.

- **Study SPL7013-004: Enrollment and Follow-up Completed**

Enrollment and follow-up has been successfully completed and data analysis is currently underway in study SPL7013-004, another NIAID funded expanded safety study of VivaGel®. This was conducted in sexually abstinent women in San Francisco, California, USA, and Kisumu, Kenya. Results from this study are expected to be announced in quarter 1, 2008. During the trial, routine interim safety reviews identified no emergent pattern of product-related adverse events or participant withdrawals from the study.

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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<sup>®</sup> (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.

The Company has recently made the following commercialisation announcements:

- February 2007 - Starpharma signed an agreement with EMD/Merck Biosciences for laboratory applications of Priofect<sup>™</sup>, an RNAi transfection reagent. Starpharma has retained all therapeutic applications of this siRNA delivery technology and is actively seeking partners to develop products based on it.
- July 2007 - Starpharma announced that it had signed an agreement with a leading condom company in relation to the use of VivaGel<sup>®</sup> as a condom coating. The agreement includes a program of evaluation and development and also commercialisation rights covering condoms with VivaGel<sup>®</sup> coatings within a specified geographical region.
- October 2007 - Starpharma announced the signing of an agreement with SSL International plc (LSE:SSL), the world's largest manufacturer of condoms, and owner of Durex<sup>®</sup>, the world's leading condom brand. The agreement, under which a commercial licence will be negotiated, sets out a co-development program for condoms with a VivaGel<sup>®</sup> coating.
- December 2007 - Starpharma announced the signing of a collaborative research agreement with Stiefel Laboratories, Inc., the world's largest independent pharmaceutical company specializing in dermatology, to apply Starpharma's dendrimer nanotechnology to certain drugs used dermally. The collaboration will apply Starpharma's dendrimer technology to deliver drugs through the skin with the aim of improving the effectiveness and tolerability of certain dermal treatments.

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 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 Stock Exchange. The Bank of New York Mellon is the depository bank. Starpharma's ADRs are listed on International OTCQX ([www.otcqx.com](http://www.otcqx.com)), a premium market tier in the U.S. for international exchange-listed companies, operated by Pink Sheets, LLC.

### 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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