



VivaGel[®] Demonstrates Anti-HIV and Herpes Activity Following Human Administration

Melbourne, Australia; 3 August 2009: Starpharma Holdings Limited (ASX:SPL, OTCQX:SPHRY) today announced the results of its clinical trial demonstrating that VivaGel[®] retains antiviral activity against human immunodeficiency virus (HIV) and herpes simplex virus (HSV, the virus that causes genital herpes), following vaginal administration in women.

The clinical study was conducted to assess the antiviral activity of VivaGel[®] (SPL7013 Gel) in cervicovaginal fluid samples (CVS) taken from healthy women immediately, then at 1, 3, 12 and 24 hours after separate vaginal doses of the product. These samples were tested for their ability to prevent HIV and genital herpes (HSV-2) infection of susceptible cells in the laboratory.

The study showed that CVS obtained immediately after vaginal administration of VivaGel[®] provided effectively complete inhibition of HIV and HSV infection *in vitro*.

At 1 and 3 hours following administration of product, the initial high level of inhibition of HIV and HSV was retained in all women tested.

Even at 12 and 24 hours following administration, more than 90% of the initial antiviral activity was retained for both HIV and HSV in more than half of the women enrolled in the study.

This is the first clinical study to demonstrate potent antiviral activity of any microbicide beyond one hour after administration of the product in humans. These data indicate the potential for VivaGel[®] to be used other than immediately prior to sexual intercourse (*i.e.*, as a coitally-dissociated microbicide). However, future testing in clinical efficacy studies is required to confirm this.

“These results are extremely encouraging,” said Dr Jackie Fairley, CEO of Starpharma. “They show not only an excellent level of activity, but also a sustainability of effect that exceeded our expectations. The retention of potent activity several hours after administration can only enhance the commercial prospects of VivaGel[®],” Dr Fairley added.

There were no serious adverse events during the study, and as previously announced the data indicate VivaGel[®] was well-tolerated.

The study was conducted in Melbourne at the Centre for Clinical Studies and in collaboration with the Burnet Institute. The study was funded by the U.S. National Institutes of Health (NIH), National Institute of Allergy and Infectious Diseases (NIAID), Division of AIDS (DAIDS), under Contract No. HHSN266200500042C.*

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 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[®] (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[®] coated condom. SSL manufactures and sells Durex[®] condoms, the market-leading condom brand worldwide. Starpharma's receipts under the agreement are estimated to exceed A\$100m comprising royalties on SSL sales, further milestone payments, and development support.

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

* The following statement is included in accordance with the requirements of Contract No. HHSN266200500042C:

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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 applications including water remediation.

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). The Bank of New York Mellon is the depository 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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APPENDIX – CLINICAL TRIAL SUMMARY

- Study Title:** Assessment of local retention and duration of activity of SPL7013 following vaginal application of 3% SPL7013 Gel (VivaGel[®]) in healthy volunteers
- Protocol Number:** SPL7013-003
- Primary Objective:** To assess the local retention and antiviral activity of SPL7013 in cervico-vaginal fluid samples (CVS) as a function of time after application of 3% SPL7013 Gel in healthy volunteers.
- Primary Endpoints:** *Ex vivo* activity in the inhibition of virus replication as measured in *in vitro* replication assays for HIV and HSV using CVS; and mass and concentration of SPL7013 determined from the CVS taken at screening, 0 (2-10minutes), 1, 3, 12 and 24 hours after vaginal application of 3% SPL7013 Gel.
- Study Design:** Single-centre, open-label, randomized, cross-over study.
Each subject received 5 single doses (3.5g) of 3% SPL7013 Gel with at least 5 days washout between doses. One CVS sample was taken after each dose application at screening and at 0, 1, 3, 12 and 24 hours after dosing in a randomized sequence. Three additional CVS samples were taken pre-dose for use in validation and as standards in the activity and content assays.
- Key Inclusion Criteria:**
- female, aged 18-45 years
 - healthy, as determined by medical history, physical examination
 - using an adequate form of contraception
 - negative urine pregnancy test at screening, baseline and each other visit
 - agrees to abstain from sexual intercourse as required by the protocol
- Key Exclusion Criteria:**
- history or presence of significant medical condition
 - abnormal pelvic exam
 - history or presence of allergy
 - history of recurrent vaginal infections, irritation or localised reaction to vaginally applied agents
 - current urinary tract infection
 - positive for STI at screening, or treated for STI during 3 months prior to enrolment
 - recent history of intermenstrual bleeding or irregular menstrual cycles
 - positive for serum antibodies to HIV-1 and/or HIV-2
 - abnormal Pap smear at or documented within 12 months of screening
 - currently breast feeding or planning on breast feeding while participating in this study
 - vaginitis or vaginosis
- Number of Trial Subjects:** A total of 12 subjects were enrolled in the study. One subject withdrew for personal reasons without receiving any doses of product, while 11 subjects completed the study.

Primary Endpoint Results:

Antiviral Activity

The study showed that cervicovaginal fluid samples (CVS) obtained immediately after vaginal administration of VivaGel[®] (SPL7013 Gel) provided effectively complete inhibition of HIV and HSV infection *in vitro*.

At 1 and 3 hours following administration of product, the initial high level of inhibition of HIV and HSV was retained in all women tested.

Even at 12 and 24 hours following administration, more than 90% of the initial antiviral activity was retained for both HIV and HSV in more than half of the women enrolled in the study.

As expected, little or no antiviral activity against either virus was seen in CVS taken prior to dosing.

Mass and Concentration of SPL7013 in CVS

The study showed that, as expected, the mass and concentration of the active ingredient of VivaGel[®], SPL7013, recovered following vaginal administration of the product decreased with time. Importantly, even when low levels (much less than one tenth of the initial dose) of SPL7013 were recovered at the later time points, there was still substantial (often greater than 90%) inhibition of antiviral activity in the *in vitro* assays.

Safety and Tolerability Results:

Safety was determined through conduct of routine biochemistry, haematology, and urinalysis, physical examination and medical history, and assessment of local and systemic adverse events (AEs).

There were no serious adverse events (SAEs) reported, nor grade 3 or 4 AEs.

A total of seven genitourinary AEs (GU AEs) were reported in four of the 12 women. The majority of these GU AEs

were mild in nature (grade 1) and resolved after 1-2 days. A total of eight non-GU AEs considered either probably not or not related to the administration of study product were reported in six of the women.

The low reporting and mild nature of AEs indicate the 3% SPL7013 Gel was safe and well tolerated in this study.

Site Details: Centre for Clinical Studies, Nucleus Network Ltd, Melbourne, Australia

Collaborative Partners: Burnet Institute, Melbourne, Australia

Division of AIDS (DAIDS), National Institute of Allergy and Infectious Diseases (NIAID),
National Institutes of Health (NIH), USA*

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