U.S. Clinical Trial of VivaGel™ for Genital Herpes Commences

- **U.S. clinical trial site opens for recruitment for VivaGel™ study**
- **First clinical trial funded by NIH to test a microbicide to prevent genital herpes**

Melbourne, Australia: 24 October 2006: Starpharma Holdings Limited (ASX:SPL, USOTC:SPHRY) today announced that the U.S. site for the clinical trial of SPL7013 gel (VivaGel™) for prevention of genital herpes has opened for recruitment of volunteers. This opening follows successful completion of all site preparation activities, and local ethics committee and regulatory reviews.

This trial is being funded by the National Institute of Allergy and Infectious Diseases (NIAID), part of the U.S. National Institutes of Health (NIH). The trial is the first specifically for a microbicide for prevention of genital herpes to be funded by the NIH.

On 19 July 2006, Starpharma announced that the Investigational New Drug (IND) application for the clinical development of VivaGel™ for prevention of genital herpes had successfully completed the mandatory review period within the U.S. Food and Drug Administration (FDA). Starpharma understands that this is the first clinical trial of a microbicide under an IND with prevention of genital herpes as the indication.

The U.S. clinical trial site, which opened for recruitment today, is at the University of California, San Francisco. The second site, in Kisumu, Kenya, is expected to be opened for recruitment within a month.

This clinical trial will examine the safety of VivaGel™ when applied vaginally twice daily for 14 days in healthy women. Thirty women aged 18-24 years will be enrolled in each site (total of 60 volunteers) (see Attachment for more detail). The trial will provide key data to potentially enable VivaGel™ to progress into efficacy studies.

"We are very excited with the commencement of the first clinical trial of VivaGel™ under the prevention of herpes indication. This trial represents a key milestone in the development of VivaGel™, and has been supported by NIAID and our clinical collaborators in the U.S. and Kenya. Given the high prevalence of genital herpes in Europe and the U.S., and concern about it, we also consider prevention of this disease to be a commercially very important indication for VivaGel™," said Dr Jackie Fairley, CEO of Starpharma.

VivaGel™ is being developed in parallel for the prevention of HIV, also with the support of NIAID, and another clinical trial of the product under a separate IND is ongoing in Melbourne, Australia.

Genital herpes is recognised as a key health concern in the U.S. where it is one of the most prevalent sexually transmitted diseases. It is estimated that genital herpes currently affects between 15% and 25% of adults in industrialised countries, with the incidence projected to rise drastically in the next decade. In the U.S. alone, approximately 50 million Americans already have genital herpes.

About Starpharma:

Starpharma Holdings Limited (ASX:SPL, USOTC:SPHRY) leads the world in the application of dendrimer-based nanotechnology to pharmaceuticals. The Company's lead development product is

VivaGel™ (SPL7013 Gel), a vaginal microbicide designed to prevent the transmission of STIs, including HIV and genital herpes.

VivaGel™ is the first example of a product to come from Starpharma's dendrimer-based discovery pipeline, which also includes specific programs in the fields of ADME Engineering™ (using dendrimers to control where and when drugs go when introduced to the body), Polyvalency (using the fact that dendrimers can activate multiple receptors simultaneously) 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).

Starpharma also has a wholly owned U.S. based operating subsidiary – Dendritic Nanotechnologies, Inc. (DNT). DNT is committed to the innovation, development and commercialization of its proprietary Priostar™ dendrimer technology to create new commercial products with business partners. DNT was incorporated in 2003, is a U.S. company with 16 employees, and is located in Mount Pleasant, Michigan. DNT's chief scientific officer, Donald A. Tomalia, Ph.D., is the inventor of dendrimers. DNT has a broad and comprehensive IP portfolio that comprises approximately 180 patents/applications issued and pending across 32 patent families - a unique level of IP concentration among nanotechnology companies - and has existing licensing agreements with established revenue streams for dendrimer technology. See www.dnanotech.com.

Dendrimers: A type of precisely-defined, branched nanoparticle. Dendrimers have applications in the medical, electronics, chemicals and materials industries.

Microbicides: A microbicide inactivates, kills or destroys microbes such as viruses and bacteria. Microbicides may be formulated as gels, creams, sponges, suppositories or films with the purpose of reducing significantly the incidence of STIs. They are intended for vaginal or rectal use to afford protection for varying periods, from several hours up to days. Microbicides may also be designed to have a contraceptive function.

Genital herpes: A recurrent, lifelong viral infection caused by the sexually transmitted herpes simplex virus type-2 (HSV-2). It is one of the most prevalent STIs, estimated to infect between 15% and 25% of male and female adults in developed countries. This figure is expected to rise to about 39% for males and 49% for females by 2025, unless effective preventive measures are found to reverse the trend. Herpes is estimated to affect one in six adults in America and new cases cost more than US$1.5 billion each year. The figures for Australia are similar with an estimated one in six adults suffering from genital herpes (3.4 million people).

HSV-2 infection has a marked effect on a sufferer's quality of life. The virus is highly contagious and women appear to be at greater risk of infection than men. HSV-2 infection can make people more susceptible to infection by HIV and increase the transmission rate of HIV. If transmitted from mother to baby, the disease has very serious consequences.

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 Stock Exchange. The Bank of New York is the depositary bank.

For further information:

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APPENDIX – CLINICAL TRIAL SUMMARY

Official Title: An expanded phase I, randomized, placebo controlled trial of the safety and tolerability of 3% w/w SPL7013 Gel (VivaGel™) in healthy young women when administered twice daily for 14 days.

Identifying Codes: Starpharma Protocol Number: SPL7013-004

DMID Protocol Number: 05-0121

Primary Objective: To assess the safety and tolerability of VivaGel™ when applied twice-daily for 14 consecutive days in HIV negative and STI-free young women, and compare the safety and tolerability profile with placebo.

Primary Endpopints:
(i) Incidence and severity of all adverse events (AEs);
(ii) Effect of VivaGel™ on vaginal flora;
(iii) Systemic toxicity;
(iv) Proportion of subjects that discontinue product use due to overt AEs.

Study Design: Randomized, double blinded, placebo controlled, expanded phase 1 study of 3% w/w SPL7013 Gel (VivaGel™) to be conducted among 60 HIV-uninfected, previously sexually active, young women, 18-24 years of age, from Kisumu, Kenya and San Francisco, USA. Participants will apply 3% w/w SPL7013 Gel (20 subjects at each site, 40 in total) or placebo gel (base gel without SPL7013) (10 subjects at each site, 20 in total) twice daily (morning and evening) for 14 consecutive days between menses, and agree to abstain from intercourse during the week prior to enrollment, through the two weeks of product application, and for a week following the last dose of study product.

Site Details:
(i) University of California, San Francisco (UCSF) Medical Center, San Francisco, USA
(ii) Kenya Medical Research Institute (KEMRI)-UCSF Program Site, Kisumu, Kenya

Key Inclusion Criteria:
- female, aged 18-24 years
- in good health, as determined by medical history, baseline physical examination, and clinical laboratory tests
- no significant abnormal vaginal microflora at screening
- negative urine pregnancy test at screening and enrollment
- agrees to abstain from all sexual activities 7 days prior to enrollment through the completion of all follow up visits and procedures

Key Exclusion Criteria:
- history of significant drug allergy
- history of latex allergy
- clinically significant history of systemic allergic disease
- history of recurrent vaginal infections, irritation or localized reaction to vaginally applied agents
- recent (within 3 months) history of intermenstrual bleeding
- active, uncontrolled medical condition
- clinically significant illness within 30 days prior to screening
- clinically detectable genital abnormality
- positive for serum antibodies to HIV-1 and/or HIV-2
- positive for serum antibodies to herpes simplex virus, type 2 (HSV-2)
- positive for Chlamydia, gonorrhea, trichomonas, syphilis or a urinary tract infection at screening or enrollment
- abnormal Pap smear at screening
- currently breast feeding or planning on breast feeding while participating in this study

Partners: Division of Microbiology and Infectious Diseases (DMID), National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH)

Sexually Transmitted Infection Clinical Trials Group (STI CTG)