



IND for Clinical Development of VivaGel™ for Genital Herpes Prevention Clears US FDA

- **Clearance gained to proceed with clinical trial under IND for SPL7013 Gel (VivaGel™) for prevention of genital herpes**
- **First microbicide development program specifically for prevention of genital herpes to be funded by NIH**

Melbourne, Australia: 19 July 2006: Starpharma Holdings Limited (ASX:SPL, USOTC:SPHRY) today announced that the Investigational New Drug application (IND) for the clinical development of SPL7013 gel (VivaGel™) for prevention of genital herpes has successfully completed the mandatory review period within the US Food and Drug Administration (FDA).

This is the first microbicide clinical development program specifically for prevention of genital herpes to be funded by the US National Institutes of Health (NIH). Starpharma also understands that this is the first IND submitted to the FDA for a microbicide with prevention of genital herpes as the indication.

Starpharma announced lodgement of the IND on 26 June, 2006. Completion of the IND review period clears the way for the first clinical trial under this new clinical indication for VivaGel™ - prevention of genital herpes. The clinical trial is expected to commence in the third quarter of 2006 following local ethics committee approvals. The trial will be conducted at two sites – San Francisco (USA) and Kenya with safety as the primary endpoint. Thirty women, aged 18-24 years, will be enrolled at each site (total of 60 volunteers).

The IND was submitted by the National Institute of Allergy and Infectious Diseases (NIAID), part of the NIH, under the agreement executed between Starpharma and NIAID, which was announced by the company in April 2006. VivaGel™ is being developed in parallel for the prevention of HIV, also with the support of NIAID.

“Starpharma is very excited to be working with the NIH on this microbicide development program, and with being the first to receive their funding support for a microbicide for prevention of genital herpes,” said Dr Jackie Fairley, CEO of Starpharma.

Genital herpes is recognised as a key health concern, especially in the US where it is one of the most prevalent sexually transmitted diseases. It is estimated that genital herpes currently infects between 15% and 25% of adults in industrialised countries, with the incidence projected to rise in the next decade. In the US alone, approximately 45 million American adolescents and adults are already infected with genital herpes.

About Starpharma:

Starpharma Holdings Limited (ASX:SPL, USOTC:SPHRY) leads the world in the application of 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 equity interests in two companies:

- *Dendritic NanoTechnologies, Inc. (DNT)* – a US company established with the pioneer of dendrimer nanotechnology Dr Donald A. Tomalia and in which the Dow Chemical Company holds 30% equity; and
- *Dimerix Bioscience Pty Ltd* – a drug development company specialising in the field of receptor coupling, specifically G-Protein coupled receptors (“GPCRs”).

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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