

# VivaGel™ Market Update

**Melbourne, Australia: 13 November 2006:** Starpharma Holdings Limited (ASX:SPL, USOTC:SPHRY) today announced a market update of the development program and associated timelines for VivaGel™, its microbicide under development for the prevention of sexually transmitted infections (STIs) in women.

The development of VivaGel<sup>TM</sup> for the prevention of both HIV and HSV-2 (genital herpes) indications involves a broad range of concurrent clinical, non-clinical and scale-up activities and continues to make strong progress, with a number of significant milestones achieved in the past 12 months. With no topical microbicides yet approved for the prevention of STIs, the development path for this product category is less well established than for many traditional pharmaceutical products, and this results in a degree of uncertainty related to factors outside the Company's control.

Some other microbicide development programs for prevention of HIV have experienced delays due to several factors including shortfalls in enrolment targets for HIV prevention trials, lower than expected background incidence levels for HIV, and higher than expected incidence of pregnancy in HIV prevention trial participants. As a result of such developments and Starpharma's own observations of trial practicalities the Company has reassessed some of the underlying assumptions in the development program and the timelines for VivaGeI<sup>TM</sup>.

The Company has previously published development path timelines projecting first regulatory approval for VivaGel™ at the end of 2008. Starpharma now estimates that regulatory approval milestones will be extended by 12 to 24 months. Starpharma will continue to seek to minimise any potential delays by optimising clinical trial design, location, site numbers, sample size and other factors within its control, drawing on industry experiences to date. Clinical trial modifications will include features predicted to minimise the loss of participants, such as careful definition of selection criteria, and will be supported by the timely completion of toxicology studies to minimise the number of exclusion criteria.

Starpharma is increasingly confident that the genital herpes indication has significant commercial potential and also is likely to provide a faster route to market without many of the challenging factors inherent in HIV trials. Based on current information it is anticipated that VivaGel™ is likely to be the first microbicide product to market for the prevention of genital herpes. As genital herpes is a prevalent disease in many parts the developed world (eg 26% of US women) the potential efficacy trial sites for herpes are more extensive with more well developed infrastructure than for HIV, facilitating potentially faster recruitment and trial completion.

The development of VivaGel™ continues to be a positive and exciting commercial opportunity for Starpharma with a number of significant milestones achieved over the past 12 months, including the following:

- More than US\$20 million non-dilutive funding for its development for HIV without downstream commercial obligations;
- US Food and Drug Administration (FDA) Fast Track status for HIV prevention;
- Announcement of non-dilutive support for the development of VivaGel<sup>™</sup> for the prevention of genital herpes;
- Identification of contraceptive activity which potentially expands VivaGel™'s applications and the product's commercial potential;
- Two clinical trials commenced recently including VivaGel™'s first US trial site, with a Kenyan trial site to commence shortly;
- Further preparations for trials in the US, Australia and Asia continue to make good progress;
- Starpharma understands that VivaGel<sup>™</sup> remains the only microbicide in clinical development for the prevention of the increasingly important worldwide disease, genital herpes;
- Scale-up of VivaGel<sup>™</sup> manufacturing on track;
- Toxicology programs continue to make good progress.

In addition, commercial activities regarding the potential condom coating opportunity and development of a combination product with broader STI application (ComboGel) continue to make solid progress.

### **Market opportunity for Microbicides**

Data supporting the market demand for microbicides continue to build with recent US studies showing 30-40% of female college students in California would buy a microbicide, with higher numbers if the product had contraceptive properties. Awareness of herpes which afflicts approximately 45 million Americans today continues to grow. US opinion leaders are calling for a national genital herpes prevention program and given the current paucity of effective prevention measures, this augurs well for topical microbicides that have this as an approved application.

# Starpharma's Pipeline

VivaGel<sup>™</sup> continues to represent an important part of Starpharma's dendrimer drug candidate portfolio, and it is by no means its only commercial opportunity. In addition to the VivaGel<sup>™</sup> line extensions (as a condom coating and Combo-gel) and Starpharma's other pharmaceutical applications of dendrimers such as ADME Engineering<sup>™</sup> and Targeted Diagnostics programs, the company recently significantly strengthened its pipeline and near-term commercial potential through the acquisition of US company, DNT Inc.

As a result of this acquisition the company now has a balanced pipeline which includes royalties from marketed products, together with additional near-term commercial opportunities such as anticipated launch of its siRNA transfection kit in 2007. Starpharma is now positioned as an international dendrimer nanotechnology company with a wide range of commercialisation opportunities in the pharmaceutical, life-science and industrial sectors. Its portfolio has been strengthened and balanced for risk and return. In addition, the company's profile in the US capital markets has been strengthened significantly through the Dow Chemical Company becoming its largest shareholder and close to 20% of its equity now held in the USA.

#### **About Starpharma:**

Starpharma Holdings Limited (ASX:SPL, USOTC: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 pharmaceutical field Starpharma has additional specific programs in the areas of Drug Delivery and ADME Engineering<sup>TM</sup> (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).

More broadly the company is actively 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 180 patents/applications issued and pending across 32 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.

**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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