



VIVAGEL™ RECEIVES *FAST TRACK* STATUS FROM FDA

Melbourne, Australia: Monday 9 January 2006: Starpharma (ASX:SPL, USOTC:SPHRY) today announced that the US Food & Drug Administration (FDA) has granted *Fast Track* status to VivaGel™, an Investigational New Drug (IND) for the prevention of HIV.

“There are currently no approved products for the prevention of HIV infection. The FDA recognises the potential of VivaGel™ to address this unmet medical need,” commented John Raff, CEO of Starpharma. “VivaGel’s™ New Drug Application (NDA) will receive Priority Review which has a shorter review time. *Fast Track* status also provides more opportunity for Starpharma to communicate with the FDA to ensure the success of the VivaGel™ development program. This is excellent news for VivaGel™ and for Starpharma.”

Under the FDA Modernization Act of 1997, the *Fast Track* drug development program facilitates and expedites the development of products that serve unmet medical needs of serious or life-threatening conditions. This program provides formal mechanisms for sponsors to communicate with the FDA on product development issues, including clinical trial design. Under the *Fast Track* program, portions of the NDA can be submitted to the FDA before the application is completed. This early review is expected to shorten FDA approval times significantly.

VivaGel™ is currently being developed as a vaginal microbicide gel to prevent the transmission of genital herpes and HIV. VivaGel™ was also recently awarded US\$20 million by the US-based NIAID, a division of the National Institutes of Health (NIH) to accelerate its development.

The commercial opportunity for VivaGel™ is very significant, both in industrialized nations and the developing world. In the USA, AIDS (a result of HIV infection) is now the number one cause of death among African-American women between the ages of 25 and 34 and genital herpes affects approximately 50 million Americans. With no cure currently available for HIV or genital herpes, and the limited success of existing prevention strategies, infection rates in the US and elsewhere are expected to continue to rise sharply. Microbicides such as VivaGel™ are now recognised as a key element in this fight against genital herpes and HIV.

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)* – established with the pioneer of dendrimer nanotechnology Dr Donald A. Tomalia and based in Michigan, USA; and
- *Dimerix Bioscience Pty Ltd* – a specialist drug development company established to commercialise unique technology developed at the Western Australian Institute for Medical Research in the new 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.

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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