Starpharma's VivaGel™ for Prevention of HIV Receives FDA Clearance to Advance to Third Stage of Dosing in Phase 1 Clinical Trial

Melbourne (Australia), 3 August 2004: Starpharma Holdings Limited (ASX:SPL) announced today that VivaGel™, its investigational new drug for the prevention of HIV, is advancing to the next stage of dosing in the current Phase 1 study. The US Food and Drug Administration (FDA) has reviewed Starpharma's interim study results and has given clearance to proceed using the highest dosage concentration planned for this study.

This next stage, commencing today, will involve administration of VivaGel™ containing 3.0% of the active dendrimer ingredient, SPL7013, and placebo gel to a group of healthy women. This is the continuation of the US IND Study No. SPL7013-001, investigating escalating formulation strengths of VivaGel™. The study is the first assessment of the drug's safety in humans. Results from the current trial will help determine appropriate gel strengths for future clinical trials that will assess the effectiveness of VivaGel™ in preventing HIV infection.

VivaGel™ is the first drug product in the world based upon nanoscale structures called dendrimers, to enter human trials.

Data relating to blood and urine chemistry, the impact of the gel on vaginal microflora, and the impact of the gel on the lining of the vagina and cervix was collected from all women in the first two groups treated with VivaGel™ (0.5% or 1% SPL7013) and placebo gel. After reviewing the blinded data, and considering that there have been no serious adverse events reported in either of the first two dosing groups, the clinical trial Drug Safety Monitoring Board (DSMB) concluded that the VivaGel™ SPL7013 strength could be escalated to a higher level. Following the review of a protocol amendment to include the 3.0% SPL7013 gel dose group in the current study and an interim clinical safety report, the US FDA agreed with the DSMB's decision to escalate dosing.

The clinical trial is being conducted at CMAX, a Division of IDT Australia Ltd, in Adelaide.

Starpharma Holdings Limited (ASX:SPL) is focused on the development and application of dendrimer nanotechnologies as drugs against major diseases. Starpharma's lead dendrimer product, VivaGel™ has received clearance from the US FDA for human clinical trials. VivaGel™ is a topical microbicide gel product that has been developed for women as a preventative against the sexual transmission of HIV. It is also active in animal studies for the prevention of other sexually transmitted diseases including Genital Herpes and Chlamydia. SPL also has an equity interest in a US based company – Dendritic Nanotechnologies Inc. (DNT) – established with the US pioneer of dendrimer nanotechnology, Dr Donald Tomalia.

CONTACTS:

Dr John Raff
Chief Executive Officer
+61 3 8532 2701
www.starpharma.com

Mr Ben Rogers
Company Secretary
+61 3 8532 2702