



17 November 2004

STARPHARMA Phase 1 Preliminary Report: Positive Results for VivaGel™

Melbourne (Australia) 17 November 2004: Starpharma Holdings Limited (ASX:SPL) today announced that VivaGel™, its vaginal microbicidal gel for the prevention of HIV was found to be well tolerated during a clinical trial held in Australia.

Starpharma's VivaGel™ is a topical microbicide that has the potential to prevent or reduce the transmission of HIV and other STDs when applied to the vagina prior to sexual intercourse. Microbicides are chemical agents that in the form of gels can be used before intercourse to inactivate STD pathogens. Microbicides are currently being viewed by health officials as one of the best potential opportunities for stemming the spread of HIV/AIDS.

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

The Phase I study to test the safety and tolerability of VivaGel™ compared two groups of women who received either VivaGel™ or a placebo daily for one week. Although the study remains blinded (ie no one knows which women received the VivaGel and which received placebo), assessment by a gynaecologist has shown no subject in the trial experienced a significant adverse event. The clinical trial was conducted at CMAX, a Division of IDT Australia Ltd, in Adelaide.

“Even though the study remains blinded, that is before we know which women received VivaGel™ or placebo, from the perspective of my gynaecological examinations I can report that no subject suffered any significant adverse event. I am confident that none of the subjects in this study suffered any untoward consequences from exposure to SPL7013 Microbicide Gel (VivaGel™).,” said Dr John O’Loughlin of the Royal Adelaide Hospital, the principal investigator on the study.

Dr John Raff, CEO of Starpharma, said: “This preliminary finding is terrific news for Starpharma. There is no doubt that it is the most significant step to-date in our clinical development program for VivaGel™. On this basis, we anticipate that we will be able to proceed to the next steps in our clinical program with the objective of efficacy studies for the prevention of HIV and other sexually transmitted diseases.”

This study tested three groups of 12 women in succession, eight of whom received VivaGel™ containing 0.5%, 1% or 3% of the active dendrimer ingredient respectively, and four of whom received only placebo. Both active gel and placebo were administered vaginally.

The possibility of irritation to the vagina and cervix was assessed by colposcopy, a standard gynaecological technique for detecting abnormalities in these tissues. Other measurements in the trial included the level of active compound entering the blood stream and whether the gel affected the normal vaginal microflora.

Full trial results will be available following complete analysis of data and publication of the full study report.

Last month, it was announced that Starpharma would lead a consortium to develop a second generation microbicide for the prevention of infection by HIV and other sexually transmitted diseases. This consortium is being funded by a US\$5.4 million (A\$7.5 million) grant from the National Institute of Allergy and Infectious Diseases (NIAID), part of the US National Institutes of Health (NIH). The consortium consists of Starpharma and ReProtect, Inc., together with research groups from the Johns Hopkins University, the University of Texas Medical Branch, the University of Kentucky, the University of Washington and the Burnet Institute in Melbourne.

About Starpharma:

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.

Microbicides

A microbicide inactivates, kills or destroys microbes. Microbicides may be formulated as gels, creams, sponges, suppositories or films with the purpose of reducing significantly the incidence of STDs. There are currently no vaginal microbicides on the market.

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 by inhibiting sperm.

Dendrimers

Dendrimers are a type of nanoparticle. They are man-made chemicals that form tiny balls made up of a dense network of branches. Dendrimers have applications in the medical, electronics, chemicals and materials industries.

For further information, please contact

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