Starpharma Announces Alliance with IDT Ltd to Conduct Human Trials

MELBOURNE 16 SEPTEMBER 2003: Starpharma Pooled Development Limited (ASX:SPL) today announced the signing of a clinical trial agreement with Victorian-based company, Institute of Drug Technology Australia Limited (IDT). IDT will conduct Phase I human clinical trials on Starpharma's vaginal microbicide SPL7013 gel (VivaGel) at CMAX, their Adelaide based clinical trial unit.

Starpharma received clearance by the United States Food and Drug Administration (FDA) on the 31st of July 2003 to commence clinical trials on VivaGel, following its successful Investigational New Drug Application.

The active component in VivaGel is SPL7013, a dendrimer based nanodrug which inhibits the HIV infection process by preventing the attachment of the virus to healthy cells. Studies in monkeys have shown complete inhibition of SHIV (a virus related closely to HIV) infection using a gel containing 5% of the active component. SPL7013 has also been shown in animal studies to prevent the infection of genital herpes and Chlamydia. Dr Raff, the CEO of Starpharma, said: "An effective vaginal microbicide would empower women to privately protect themselves from potential HIV infection".

Dr Raff said: "Starpharma investigated a range of options world-wide before deciding on IDT's CMAX facilities in Adelaide. CMAX has previously been audited by the FDA and we believe it is a world class facility. We are pleased to be able to conduct our first clinical trialling activities in Australia."

Starpharma has an established relationship with IDT, who has worked with Starpharma and become the world's first pharmaceutical chemistry facility to undertake dendrimer based synthesis to GMP standards.

In addition to the clinical trials expertise of CMAX the principal investigator, Dr John O'Loughlin, has many years' experience in clinical research. His experience in the use of colposcopy will be important in demonstrating the safety of SPL7013 gel (VivaGel).

The Phase I studies will commence immediately after ethics approval and the enrolment of healthy women volunteers.

Dr Graeme Blackman, Managing Director and Chairman of the Board of IDT, said: "Starpharma's SPL7013 has created a significant precedent, being the first dendrimer based drug to receive clearance to commence clinical trials by the FDA. We are delighted that Starpharma has commissioned CMAX to undertake the initial Phase I trials on its new drug candidate."

Starpharma Pooled Development Limited (ASX:SPL) is a registered pooled development fund with investments in wholly owned subsidiary biopharmaceutical companies focused on the development and application of dendrimer nanotechnologies as drugs against major diseases. SPL also has a 49.9% equity in a US based company – Dendritic Nanotechnologies Inc. (DNT) – established with the US pioneer of dendrimer nanotechnology Dr Donald Tomalia.

Institute of Drug Technology Australia Limited (ASX:IDT) provides a comprehensive range of consultancy, research and development, and manufacturing services to the pharmaceutical and biotechnology sectors both in Australia and internationally. The company employs over 120 scientists in Melbourne and is licensed by the Australian Therapeutic Goods Administration (TGA) and the United States Food and Drug Administration (FDA) for production of active pharmaceutical ingredients. IDT

offers early stage clinical trial services from its base at the Royal Adelaide Hospital through its CMAX division.

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