



VOLUNTEER ENROLMENTS COMMENCE FOR VIVAGEL™ PHASE I STUDY

Melbourne, 13 November 2003: Starpharma Pooled Development Limited (ASX: SPL) is pleased to announce that volunteer enrolment has now commenced for the VivaGel™ Phase I human safety study following receipt of final ethical approval from the Royal Adelaide Hospital Ethics Committee.

Starpharma announced on 31 July 2003 that the United States Food and Drug Administration (FDA) allowed the proposed clinical studies of VivaGel™ (SPL7013 gel) to proceed. As the study will be conducted at CMAX, a Division of the Institute of Drug Technology Australia Ltd (IDT) located within the Royal Adelaide Hospital (Adelaide, Australia), Starpharma required approval from the responsible ethics committee before the study could commence.

VivaGel™ is a vaginal gel designed to provide women with a means to protect themselves from the sexual transmission of HIV. The first clinical trials of VivaGel™ will be Phase I safety studies of the product with healthy female volunteers aged 18-45 years. The patients in this study will not be exposed to the HIV virus.

This Australian based trial is creating major international interest for the Company because:

- VivaGel™ offers significant potential to add to the international fight against HIV;
- This trial of VivaGel™ is creating a precedent as it is the first dendrimer nano-drug to advance to clinical trials under the FDA regulatory system.

This precedent has been recognized internationally in several leading journals. The US nanotechnology journal *Smalltimes* has a full page feature titled "Clinical trials put dendrimers on course for treating HIV" (September/October edition, page 62). There is also a series of articles highlighting nanobiotechnology in the current edition of *Nature Biotechnology* (Volume 21 Number 10, October 2003). In the article "Little science, big bucks", the huge international investment in nanotechnology is outlined with over US\$3 billion invested by government organizations in 2003, in addition to large scale investment by multi-national companies. The article "Commercializing nanotechnology" cites Starpharma's VivaGel™ product as an advanced significant application of dendrimer nanotechnology in the area of human health. The article states: "*In July, a first dendrimer drug, developed by Starpharma (Melbourne, Australia) for use against HIV, received regulatory clearance for Phase I clinical trials from the US Food and Drug Administration (FDA: Rockville, MD, USA).*"

Dr Raff, Starpharma CEO said: "Dendrimers are a major building block of nanotechnology and we are excited to be at the forefront of practical human health applications for this new field of opportunity."

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.

CONTACTS:

Dr John Raff
Chief Executive Officer
+61 3 8532 2701

Mr Ben Rogers
Company Secretary
+61 3 8532 2702

www.starpharma.com