ASX Announcement

19 December 2002

Starpharma delays the timing of its application to the FDA for human trials on vaginal microbicide

Starpharma has previously announced its intention to submit an Investigational New Drug (IND) application to the US Food and Drug Administration (FDA) for permission to commence Phase I human trials on the vaginal microbicide drug candidate SPL7013 in December 2002. Starpharma has undertaken all the safety and efficacy trials and prepared the documentation for the IND submission. In preparation for Phase II/III clinical trials and to fast-track development, additional studies have been undertaken with the support of the US National Institutes of Health (NIH). These studies include both product effectiveness and further product safety investigations in preparation for large scale human population trials.

Due to confounding results with one of these latter studies, Starpharma will withhold the IND submission until this study can be repeated. At the same time we are continuing to obtain further product effectiveness data from major NIH supported macaque studies. Subject to satisfactory results in a repeat experiment we expect to submit our IND in the first quarter of 2003.

Details of recent studies:

1. Product Effectiveness (Efficacy Studies)

SPL7013 has previously been shown to be effective in preventing infection in HIV *in-vitro* studies and in animal model studies for Genital Herpes and Chlamydia. These positive results alone would be sufficient to justify proceeding with the IND application.

Additional major studies are currently underway using macaques, the closest animal model to humans. These studies are being conducted and fully funded by the NIH. We have been advised that preliminary results from the macaque study modelling human HIV infectivity indicate that the study "is going well and the results look promising for SPL7013". Full results from this study should be available in January 2003.

A major study is also planned in macaques to determine the usefulness of SPL7013 as a preventative against Chlamydia infection. Results of this study should be available during the first quarter of 2003. This study is also supported by the NIH.

Positive animal studies in the above areas will provide further confidence to proceed through to Phase II/III population studies in humans. Starpharma will be seeking external funding support for these studies.

2. Product Safety Studies

Over the past two years Starpharma has obtained successful product safety data from numerous trials in a range of animal species, including macaques. Although there was sufficient positive safety data to support the IND submission, we have continued to undertake further safety studies in order to fast-track the product towards later stage clinical trials. In a recent study in rabbits we obtained inconclusive results which are inconsistent with all previous data. This study will be repeated and a full investigation made of the results of the inconclusive study.

Dr John Raff, the CEO of Starpharma said: "It is a difficult decision to delay the IND submission. This is the first time that a defined dendrimer-based nanostructure will proceed through the US regulatory system, and we want to be totally confident of all results presented to the FDA."

The need for an effective vaginal microbicide for the prevention of sexually transmitted disease is overwhelming and there are no effective products currently available. Starpharma continues to enjoy the full support of the NIH with the development of SPL7013, which has shown considerable promise in effectiveness and safety studies.

Starpharma Limited, a wholly owned subsidiary of Starpharma Pooled Development Limited (SPL), is a biopharmaceutical company focused on the development and application of dendrimer nanotechnologies as drugs against major diseases. Starpharma Limited has an extensive intellectual property portfolio relating to dendrimer nanotechnology. SPL also has a joint venture company - Dendritic Nanotechnologies Limited (DNT) – established with the US pioneer of dendrimer nanotechnology Dr Donald Tomalia.

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