

Further US Government support for Starpharma's Vaginal Microbicide

A gel developed by an Australian company is about to be tested in two major US trials on the prevention of sexually transmitted diseases.

The new studies are being fully funded by the US National Institutes of Health (NIH) and will assess the gel's ability to prevent HIV/SIV and Chlamydia infection in macaque monkeys. The gel, developed by the Melbourne company Starpharma Limited, contains a compound known as SPL7013 and is being developed as a topical vaginal microbicide for application by women before sex to provide broad-based protection against infection by sexually transmitted diseases (STDs).

Starpharma is currently preparing an Investigational New Drug (IND) application to submit to the US Food and Drug Administration (FDA) for Phase I testing of the SPL7013 gel in humans. The new trials are not required for the IND application, however they will provide valuable additional information that will assist with the approval and potential funding of large scale Phase II and III human clinical population trials. SPL7013 will be the first dendrimer-based nanostructure approved for human testing. Because the dendrimers are a totally new class of compounds it has been necessary for Starpharma to pioneer all aspects of the regulatory development of its drugs, which are being referred to as "Nanodrugs".

Starpharma's dendrimer development program has been strongly supported by the NIH and the commissioning of two major monkey studies is further indication of that support.

US NIH-supported trials of this nature require previous demonstrations of efficacy in cell-based studies, and of safety in smaller animal models. Evidence of a stable drug product is also required for studies in monkeys. In previous trials, SPL7013 has been shown to be effective against a range of STDs, including HIV, Herpes, Hepatitis B and Chlamydia.

HIV/AIDS

Recent studies conducted by the Division of AIDS Research in the US National Institute of Allergy and Infectious Disease (NIAID) have shown that SPL7013 protects cells from infection by a range of HIV-1 and HIV-2 strains isolated from HIV patients. In addition to these studies on SPL7013, another two of Starpharma's compounds, SPL7304 and SPL7320, were also shown to be active in these assays. SPL7304 and SPL7320 were prepared by Starpharma's research team in order to investigate the structure/activity relationship of this class of compounds against HIV, and to provide back-up compounds to SPL7013. A fourth compound SPL7032 was shown to be less active in the same assays.

Due to the high potency exhibited by SPL7013 against the clinical isolates of HIV, SPL7013 has been selected to advance to US NIH-supported trials for the prevention of HIV/SIV infection in monkeys.

Chlamydia

An additional NIH-supported macaque monkey study will also be conducted with SPL7013 to study the prevention of Chlamydia infection. This study will initially examine the safety of SPL7013 following multiple intravaginal applications and will then assess the ability of SPL7013 to prevent Chlamydia infection. Once again, SPL7013 gel was selected to enter this study following preliminary positive results in mice, good stability data and after having demonstrated safety in other cell-based and animal models.

Sexual disease, particularly in women, is a major problem worldwide, with more than 15 million people in the US alone expected to acquire a new STD each year. Globally, the AIDS epidemic is growing and decimating many developing communities. Approximately 40 million people, many of them women and children, are living with HIV/AIDS infection. Everyday, about 14,000 new infections occur. Since the beginning of the AIDS epidemic, almost 30 million people have died from AIDS. Until now, most HIV/AIDS drug development programs have targeted treatment of the disease. There are currently no effective topical vaginal microbicides on the market that have been shown to prevent HIV.

The recent cell-based studies and an update on the development of SPL7013 will be presented in full at the Microbicides 2002 conference in Antwerp, Belgium from 12-15 May (<http://www.itg.be/micro2002/>) and

at the meeting of the Australasian College of Sexual Health Physicians in Perth, Australia from 29 May to 1 June.

Starpharma Limited, a wholly owned subsidiary of Starpharma Pooled Development Limited (SPL), is a biopharmaceutical company focussed 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 has recently established a joint venture company - Dendritic Nanotechnologies Limited (DNT) - with the US pioneer of dendrimer nanotechnology Dr Donald Tomalia.

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