

VivaGel™ is a Potent Contraceptive in Animal Model

Melbourne, Australia 14 June 2006. Starpharma Holdings (ASX:SPL, USOTC:SPHRY) today announced the results of a study which has shown that SPL7013, the active ingredient in its lead product VivaGelTM, exhibits a potent contraceptive effect in a rabbit model.

In the independent study undertaken at Johns Hopkins University (Baltimore, USA) two different formulations containing 3% SPL7013 (the dose level used in VivaGel™) resulted in a 75% and 95% reduction respectively in the number of embryos in rabbits compared to an inactive control gel. These contraceptive effects are statistically comparable to published results of marketed contraceptive products based on the detergent nonoxynol-9 (N9). (*Refer to full results below*).

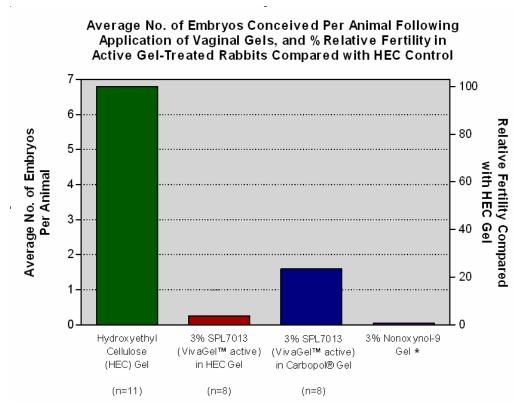
VivaGel[™] is already in clinical development as a topical microbicide for the prevention of HIV and genital herpes infection in women. If the contraceptive activity that has been observed in these initial animal studies were confirmed in humans it would allow for the development of VivaGel[™] with contraception as an additional claim.

Starpharma's CEO Dr John Raff said: "This is a very exciting finding for the company and is of significance to the development of both the condom coating and standalone versions of VivaGel™. Studies in a number of countries including the US show that contraceptive activity is a very highly valued microbicide characteristic amongst women. From such studies we anticipate that if this finding of contraceptive activity were confirmed in humans, it would increase the uptake of VivaGel™ considerably."

Importantly, and in contrast to other topical contraceptives such as detergents, VivaGelTM's contraceptive effect is not achieved though an impact on sperm motility or viability. VivaGelTM does not have a significant effect on either, and its contraceptive effect is postulated to be via interference with attachment and/or fertilization. This proposed mechanism is consistent with the positive safety profile previously demonstrated in animal studies in VivaGelTM.

This work was conducted under NIH Grant No. U19 Al60598 from the National Institute of Allergy and Infectious Diseases, part of the National Institutes of Health.

Appendix: Results of the animal trial and additional detail



* Based on published historical data, Castle et al, see below

Groups of 8-11 rabbits were pre-treated with either active or control gels prior to artificial insemination with semen and the number of embryos formed was measured after 14 days.

The contraceptive effect of formulations containing 3% SPL7013 was compared with that of an inactive control gel (hydroxy ethyl cellulose, HEC). Rabbits typically have more than one embryo per pregnancy. The control group showed 75 embryos whereas the rabbits pre-treated with VivaGelTM showed only 13 embryos and the group pre-treated with SPL7013 in hydroxyl ethyl cellulose applied showed only 2 embryos.

SPL7013 in both the VivaGel[™] formulation and when formulated at 3% SPL7013 in the HEC gel, produced a statistically significant reduction in the number of pregnant animals when compared with the inactive control gel (Fisher's exact two-sided test, P<0.024 in both cases).

Fertility, as assessed by the average number of conceptions in 8 animals, was reduced by more than 75% by SPL7013 in its VivaGel[™] formulation and 95% by SPL7013 in HEC when compared with the inactive control gel alone.

Prior similar tests of contraceptive gels based on the detergent nonoxynol-9 yielded similar reductions in conceptions ranging between 83% to 100% (See Castle et al, Contraception 1998;58:51-60, and Zeitlin et al, Sexually Transmitted Diseases, 2001;28:417-23).

In previous studies VivaGel[™] has been shown to be non-teratogenic (does not cause defects in developing fetuses) and in laboratory studies in which VivaGel[™] has been shown to be non-mutagenic (does not cause genetic mutations in cells).

Further information

Starpharma Holdings Limited (ASX:SPL, USOTC:SPHRY) leads the world in the application of nanotechnology to pharmaceuticals. The Company's lead product in development is VivaGel™ (SPL7013 Gel), a vaginal microbicide designed to prevent the transmission of STIs, including HIV and genital herpes.

VivaGel™ is the first example of a product to come from Starpharma's dendrimer-based discovery pipeline, which also includes specific programs in the fields of ADME Engineering™ (using dendrimers to control where and when drugs go when introduced to the body), Polyvalency (using the fact that dendrimers can activate multiple receptors simultaneously) and Targeted Diagnostics (using dendrimers as a scaffold to which both location-signaling and targeting groups are added to allow location of specific cell type, such as cancer cells).

Dendrimers: A type of precisely-defined, branched nanoparticle. Dendrimers have applications in the medical, electronics, chemicals and materials industries.

Microbicides: A microbicide inactivates, kills or destroys microbes such as viruses and bacteria. Microbicides may be formulated as gels, creams, sponges, suppositories or films with the purpose of reducing significantly the incidence of STIs. 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.

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