



## Update on Starpharma Clinical Trials for VivaGel™

On June 20, the Australian bio-tech Starpharma announced that it had received approval from the US FDA to begin testing its candidate Microbicide, VivaGel™, to see if it can prevent genital herpes (HSV-2), a common sexually transmitted infection.

Last year, Starpharma announced that it had started testing VivaGel™ with the hope that it would ultimately turn out to be safe and effective against HIV. Starpharma is now planning a second set of trials to test the product's potential for protection against genital herpes. Their June 20 press release stated that the first HSV-related trial would take place "at two sites and enroll 60 women aged 18 to 24". ([Read the full press release](#)). In response to the press release, the Global Campaign for Microbicides posed two questions to Starpharma for clarification. These are their answers:

### **Is the genital herpes (HSV-2) trial going to be separate from the HIV microbicide trials?**

The trials we are doing now are to make sure that VivaGel™ is safe for women to use in their vaginas on an on-going basis. Measuring a product's safety is, obviously, the first step. We have to know what effect it has on vaginal tissue before we can start trials specifically looking at whether it works to reduce risk of either HIV or HSV-2. The data from all these safety trials will be submitted to FDA and go into the package of evidence we will present to them about VivaGel™'s results in both our HIV and our HSV-2 trials.

Starpharma expects to do separate studies to test VivaGel™'s efficacy against HIV and HSV. The disease researchers hope to prevent in a clinical trial is called the study's "primary endpoint". But studies can also have "secondary endpoints" – something that is not the main focus of the study but might be observable along with the primary endpoint. HIV could be a secondary endpoint in the HSV trial and vice versa – because both may be transmitted through unprotected sex.

We will be looking for both viruses as primary and secondary endpoints. That is, we will be regularly testing all the volunteers in the HIV trial for HSV as well as HIV -- and vice versa. This will enable us to gather additional information about the potential effectiveness of the gel against these two viruses.

### **As always, all trial participants will be provided with free condoms and encouraged to use the condoms and not to trust the gel to protect them from either HIV or HSV-2.**

Performing just one trial for both endpoints would clearly be more efficient. It would allow us to obtain results more quickly, thus potentially making the product publicly available more quickly if it turns out that it does work. If the FDA thinks we can get meaningful results by doing just one trial with two primary endpoints, we may try that. But the possibility of this really depends on the epidemiology of the two diseases in the populations we are studying, how we design the trial design and the statistics. So at the present time, we are planning two trials.

### **Where will the VivaGel™ HSV-2 (genital herpes) trials going to take place?**

Right now we are planning to conduct the initial HSV-2 trials at two sites – one in Kisumu, Kenya and the other in San Francisco, California in the U.S.