

PRESS RELEASE

Road-map agreed for confirmatory trials of promising microbicide

Call for further trials needed to make promising antiretroviral gel available to women at risk of HIV as quickly as possible

GENEVA, 3 September 2010—Two further clinical trials are planned to confirm a vaginal gel which has shown potential in reducing the risk of HIV. The results of the first trial of the gel, which were announced in July at the XVIII International AIDS Conference in Vienna, must be confirmed before the product can be made available for general use.

The tenofovir-based gel was found to be 39% effective to reduce a woman's risk of becoming infected with HIV during sex in a study completed by the Centre for the AIDS Programme of Research in South Africa (CAPRISA), a UNAIDS Collaborating Centre on HIV prevention research.

The CAPRISA study was conducted in South Africa with women aged 18 to 40 years who used the gel once during the 12 hours before sex and once during the 12 hours after sex.

Experts at a meeting convened last week by UNAIDS and WHO in Johannesburg, South Africa, proposed that further trials should determine whether different populations of women will have the same level of protection as seen in the CAPRISA trial.

One study, which will take place primarily in South Africa, will establish if the CAPRISA results can be repeated in a variety of settings with a population that includes younger women. It will also evaluate whether the gel can be used safely by sexually active 16 and 17 year olds in settings where HIV incidence is high.

The other study, which will be conducted in other African countries, will examine if a different dosing schedule is safe and effective. It will test if a single application of the gel before sex, or failing that immediately after, is equally effective and safe as the original two dose regimen. The single dose schedule would be less expensive and easier for women to use.

In addition, an ongoing trial being conducted by the Microbicides Trial Network, studying the same gel but used daily, will generate additional data on safety and product use.

Research in the communities where the CAPRISA trial was carried out will also examine how to best promote, distribute, and monitor gel use through existing family planning facilities. This would allow former trial participants and others in their communities to have early access to the new gel, but within the context of programmatic research.

While participants agreed on research priorities, concerns were expressed over the limited funding committed thus far to carry forward the next phase of research, which is estimated to cost US\$ 100 million. Only US\$ 58 million is available.

Nearly 20 years of research have gone into microbicides. If confirmed, the tenofovir gel would empower women by adding significantly to the options they have to protect themselves from HIV without requiring the cooperation of their male partner. About half the people living with HIV in the world are women. In sub-Saharan Africa more women are infected than men. HIV is a major cause of maternal mortality.

“This promising tenofovir gel is a woman-initiated and controlled HIV prevention tool that could now be within reach,” said Dr. Catherine Hankins, Chief Scientific Adviser to UNAIDS. “Funders, advocates, and scientists can work together to close the funding gap rapidly, gather the evidence, and ensure that no time is lost in getting a safe and effective microbicide to women.”

Convened at the invitation of the South African government, the meeting brought together members of government agencies from South Africa and other countries, microbicide research teams and product developers, women’s health and HIV prevention advocates, people living with HIV, clinical and social science researchers, statisticians, civil society representatives, public health experts, ethicists, and representatives from national drug regulatory authorities.

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