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## **HIV Prevention Science Scores a Victory – The Gel Works! IRMA Presses for Intensified Rectal Microbicide Research**

Vienna, Austria July 20, 2010 – Today at the XVIII International AIDS Conference in Vienna, Austria, members of the International Rectal Microbicide Advocates (IRMA) and thousands of other HIV advocates and scientists cheered a long-awaited, much anticipated success in the quest for new HIV prevention technologies. Researchers announced that a vaginal gel has been shown to significantly reduce a woman’s risk of being infected with HIV and genital herpes.

These game-changing results of the safety and effectiveness study of an antiretroviral microbicide gel were reported by the Centre for the AIDS Programme of Research in South Africa (CAPRISA).

The microbicide gel that CAPRISA studied contained 1% tenofovir—an antiretroviral drug commonly used to treat people living with HIV—and was found to be 39% effective in reducing a woman’s risk of becoming infected with HIV during vaginal intercourse and 51% effective in preventing genital herpes infections among the women in the trial. These protective effects increased as the use of tenofovir increased, so that women who used the gel in more than 80% of their sex acts during the trial had a 54% reduction in HIV infections. If and when other studies of tenofovir gel confirm these results, widespread use of the gel, at this level of protection, could prevent millions of new HIV infections over the next two decades. Tenofovir is also being studied as a form of oral pre-exposure prophylaxis.

“The positive results from the CAPRISA 004 study represent a very significant milestone in HIV prevention research and they increase optimism that we can develop safe and effective antiretroviral rectal microbicides,” said University of Pittsburgh’s Dr. Ian McGowan, IRMA

Scientific Vice-Chair and co-principal investigator of the Microbicide Trials Network. “Phase I rectal safety studies with tenofovir are ongoing and these efforts need to be intensified to help us move forward to rectal microbicide effectiveness studies as quickly as possible,” he said.

As with vaginal microbicides, safe and effective rectal microbicides are urgently needed by millions of people. Anal intercourse is a common human sexual behavior, practiced by approximately 5 – 10% of the world’s general population, including heterosexual women and men, gay men, and other men who have sex with men (MSM). Because an act of unprotected anal intercourse is 10 to 20 times more likely to result in HIV transmission compared to unprotected vaginal intercourse, it is likely that unprotected anal intercourse is a significant driver in the global HIV epidemic.

“Certainly, for gay men and other MSM across the world, unprotected anal intercourse is the chief cause of HIV infection,” said IRMA Chair Jim Pickett. “But the world has largely ignored gay men, and anal intercourse. Gay men and other MSM are under-represented in most national AIDS strategies, in epidemiology, surveillance, and in research, if they show up at all. They have been woefully underserved by prevention, care, treatment and support services. “Similarly,” he continued, “there is a paucity of data regarding anal intercourse – homosexual and heterosexual – due to politics, stigma, criminalization, and outright denial.”

Globally, gay men and other MSM are 19 times more likely to be HIV infected compared to the general population. These disproportionate rates extend to Africa, where the epidemic is often characterized as “heterosexual.” In Uganda for instance, HIV rates among gay men and other MSM are just above 40% compared to 5% for men of reproductive age. In South Africa, where the global AIDS pandemic is most severe, the HIV rates between gay men/MSM and men of reproductive age are almost the same – both hovering around 15%.

Comparing gay men and other MSM to both males and females of reproductive age, gay men and MSM are 1.3 times more likely to be HIV-infected in Eastern Europe, 3.8 times more likely in Africa, 18.7 times more likely in Asia, and 33.3 times more likely in the Americas. Data released by the U.S. Centers for Disease Control and Prevention in early 2010 revealed that gay men/MSM in the United States are 44 times more likely to be HIV-positive than other men, and 40 times more likely to be HIV-positive than women.

“The bottom line is, for the men and women who engage in anal intercourse, condoms work quite well to prevent HIV,” said Pickett, “but many people do not use them, or are simply unable to use them due to a number of issues including power dynamics in sexual relationships, stigma, and a serious lack of availability. According to the Global HIV Prevention Working Group, only 9% of individuals at risk for HIV infection had access to condoms in 2008. Condom-compatible lubricants are also in dangerously short supply.”

While the rectal microbicide field has gained significant momentum, more focus and resources are needed. In 2010, U.S. \$7.2 million is being spent globally on rectal microbicide research. IRMA has calculated that annual investments must increase by 40% from 2011 – 2014, to U.S. \$10 million/year and must increase further to U.S. \$44 million (a six-fold increase) in the years 2015 – 2020 to ensure a minimum of candidate products are moving through the research pipeline into late stage testing for effectiveness.

“We are optimistic that the CAPRISA results will not only accelerate the development of safe and effective vaginal microbicides, but that this proof of concept will also be translated into more financial and creative energy into rectal microbicide development,” said Pickett. “With five new infections for every two individuals beginning treatment, it’s absolutely imperative we find new ways to prevent HIV for individuals at risk, gay and straight, women and men.”

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IRMA is a global network of advocates, scientists, policy makers and funders from six continents working together to advance a robust rectal microbicide research and development agenda. IRMA is based in the United States at the AIDS Foundation of Chicago with chapters in Latin America and Nigeria. Currently in development, microbicides are products (cream, gel, or maybe a douche or an enema) that could be used to reduce a person’s risk of HIV infection vaginally or rectally. For further information on IRMA visit [www.rectalmicrobicides.org](http://www.rectalmicrobicides.org) and read IRMA’s new report, *From Promise to Product: Advancing Rectal Microbicide Research and Advocacy*. The report provides an overview of the maturing rectal microbicide field, updates the resource tracking exercise IRMA last conducted in 2006, and lays out global advocacy goals and objectives. Importantly, it also calls for the creation of a Global Rectal Microbicide Development plan, which would provide the foundation necessary to move the field from pre-clinical studies through Phase III efficacy trials – from promise to product.