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## AIDS Drug Shown to Prevent HIV in Multinational Trial of HIV-Negative Gay Men; Data Suggests Need for Rectal Gel Option

Chicago, November 23, 2010 – Results of the world’s first efficacy trial of an HIV-prevention approach called oral pre-exposure prophylaxis, or PrEP, were released online in the *New England Journal of Medicine* today. Data from this trial, called iPrEx, indicated an estimated 43.8% reduction of new HIV infections among men who took an antiretroviral tablet daily to prevent HIV, compared to those who took a placebo pill.

“This discovery alters the HIV prevention landscape forever. While this level of efficacy is relatively strong, PrEP is not quite ready for prime time and work remains before this strategy is rolled out. However, we are thrilled to have a new prevention option beyond male and female condoms visible on the horizon,” said Jim Pickett, Director of Advocacy at AIDS Foundation of Chicago and Chair of IRMA – International Rectal Microbicide Advocates.

The iPrEx trial evaluated the safety and efficacy of the antiretroviral (ARV) drug TDF/FTC (brand name Truvada) taken once daily for HIV prevention among HIV-negative gay men, transgender women, and other men who have sex with men (MSM).

The participants, 2,499 in all, included individuals from Peru, Ecuador, Brazil, South Africa, Thailand and the United States. Half the men were randomized into the active arm that received Truvada, and the other half were randomized into the placebo arm and received a look-alike pill with no active ingredient. The participants and the researchers did not know who was in either arm. Enrollment for the trial began in June 2007 and was completed in December 2009. The primary analysis of the results released today includes participants who were followed until May 1, 2010, or for an average of 14 months.

Each participant was tested for HIV at monthly trial visits and given intensive pre-and-post test counseling. Additionally, they were regularly screened for sexually transmitted infections and received condoms, making up a very robust prevention package.

At the end of the trial, there were 36 infections in participants who received Truvada and 64 in recipients who took the placebo. Researchers calculated that the use of Truvada reduced new HIV infections by an estimated 43.8% overall when compared to placebo. While there appeared to be few side effects reported by the men who were taking the Truvada tablet, it is clear that much more information is needed regarding long term safety of this drug.

Other PrEP trials are ongoing. Results from studies among heterosexuals in Africa and injection drug users in Thailand are expected next year.

It is important to emphasize the factors that led to successful use of Truvada to prevent HIV in iPrEx. Taking the pill regularly was one of the most important. Efficacy appeared to be higher among those participants who took the study drugs consistently. Men who did not take the pill regularly did not see a protective benefit. Regular HIV testing and ongoing monitoring by a physician was also critical. For this strategy to work, each of these pieces, including a doctor's prescription, need to be in place.

"The study team found that about half of the men in the active arm of the trial were in fact not taking their pills regularly, if at all," said Pickett. "It is not clear why this happened, but it certainly suggests that alternate means of using ARVs to prevent HIV infection may be more acceptable for these men. The primary means of transmission among gay men and other MSM is through unprotected anal intercourse. If we develop an ARV as a gel or lubricant applied rectally – a rectal microbicide – it could be more acceptable for some individuals who don't like taking pills."

Many gay men and other MSM already use lubricants for anal intercourse, so they wouldn't have to modify their behavior to achieve higher levels of protection with a rectal microbicide formulated as a lubricant. Adopting a new behavior—such as taking a pill every day—can be a considerable challenge for some.

Dr. Ian McGowan, one of the principal investigators of the Microbicide Trials Network and Scientific Vice Chair of IRMA agreed. "The data from the iPrEx study are encouraging but the less than ideal adherence rate to oral PrEP clearly show that we need additional prevention approaches such as rectal microbicides that could be used by men and women at risk of HIV infection through unprotected receptive anal intercourse," he said.

The world's third rectal microbicide trial is currently underway with sites in Pittsburgh, Pennsylvania; Boston, Massachusetts; and Birmingham, Alabama. Scientists are testing the

rectal safety and acceptability of tenofovir gel, a microbicide developed for vaginal use that has shown promise for preventing HIV through vaginal intercourse. Depending on the outcome of this new study, tenofovir gel could be further evaluated to determine if it can reduce the risk of HIV among both men and women who engage in receptive anal intercourse.

This new Phase I rectal microbicide study, known as MTN-007, aims to determine if rectal use of tenofovir gel is safe, and in particular, does not cause cells in the rectum to become more vulnerable to HIV. Investigators will also ask trial participants questions regarding the gel's desirability. The trial is planning to recruit a total of 60 men and women.

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. These targets need to be met to ensure a minimum of candidate products are moving through the research pipeline into late stage testing for effectiveness.

Just as we use a combination of drugs to treat individuals living with HIV, we need a combination approach to prevention. That approach should include male and female condoms, sterile syringes, and access to treatment as well as new interventions like PrEP, topical microbicides, and vaccines. Adequate funding must continue for all of the methods we currently have, and it must continue for the new strategies that are still being developed as well.

In a global context where millions of individuals do not have access to life saving medications, it is imperative that funding provided for PrEP accessibility not compete with funding for treatment. Treatment funding has not kept pace with the need.

IRMA congratulates the trial sponsors, scientific collaborators and partners who conducted this landmark trial, with special thanks to the 2,499 participants in the study who volunteered so much of their time and energy. Their extraordinary contribution to HIV prevention science brings us another step closer to a day without AIDS, and for that we are supremely grateful.

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Based at the [AIDS Foundation of Chicago](#), IRMA is a global network of more than 1,000 advocates, scientists, policy makers and funders from six continents working together to advance a robust rectal microbicide research and development agenda. 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](#).