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**Statement on the Closing of Cellulose Sulfate Gel Trials Due to Concerns of Potential Increased Risk of HIV Infection**

*Dr. Zeda Rosenberg, CEO, International Partnership for Microbicides*

Today CONRAD, a not-for-profit reproductive health research organization, announced it has halted the Phase III efficacy trial of its cellulose sulfate based product, a microbicide gel that was being tested for HIV prevention in women. CONRAD made this decision “because preliminary data indicated that cellulose sulfate could lead to an increased risk of HIV infection in women who use the product.” The CONRAD cellulose sulfate trial was being conducted in South Africa, Benin, Uganda and India.

In addition, Family Health International (FHI) halted a second Phase III efficacy trial of the same cellulose sulfate product in Nigeria. Although the FHI trial has not detected an increased HIV risk associated with cellulose sulfate, FHI made the decision “as a precautionary measure given the preliminary results in the CONRAD trial.” The cellulose sulfate product was one of four candidate microbicides in efficacy trials for prevention of HIV and other infections.

This development greatly saddens everyone working to develop HIV-prevention strategies, and reminds us of the continued need to conduct well-designed clinical trials like these to help ensure that new prevention tools are safe and effective. It is also an important reminder that the women who volunteer to participate in these trials are among the true heroes in the global fight against HIV/AIDS.

The swift decision to close the trials and openly communicate these preliminary results reflects the commitment of the microbicide field to protect volunteers and advance the search for a safe, effective product that could protect millions of women. All of us working to develop new HIV-prevention tools will carefully examine the lessons of this trial and incorporate them into our efforts to minimize risks, design and conduct the most efficient trials and provide the highest possible standard of care to participants.

The closure of this trial is a stark reminder that drug development in general is a difficult and unpredictable process, and we must constantly bear in mind that the majority of drugs that enter the clinical trial process fail. This is especially true for first-in-class drugs like microbicides. But when success finally occurs, millions benefit.

While the closing of these trials is a profound disappointment for the microbicide field, we cannot let it paralyze us. Globally, 17.7 million women are living with HIV, and thousands more are infected every day. Prevention is the only way out of this epidemic, and a safe and effective

microbicide can be a vital tool. This is why we and others have been working so hard to expand the microbicide pipeline.

Advanced clinical trials of three other potential microbicides remain underway. In addition, IPM is actively developing a next-generation class of microbicides based on antiretroviral compounds similar to those already being used successfully in HIV treatment. We remain firmly committed to developing tools that women can use to protect themselves from HIV.

For more information on the closing of the CONRAD and FHI cellulose sulfate trials, see [www.who.org](http://www.who.org).

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