First dual-protection intravaginal ring design shows promise in long-term HIV and pregnancy prevention

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CONRAD is testing two IVRs -- one is a tenofovir only and the other combines tenofovir and levonorgestrel. Credit: CONRAD

A new intravaginal ring (IVR) has been developed for the sustained 90-day co-delivery of tenofovir and levonorgestrel, an anti-human immunodeficiency virus (HIV) drug and a contraceptive. Tenofovir is the only topical prophylactic shown to be effective at reducing the sexual transmission of HIV when formulated in a gel. This research is being presented at the 2013 American Association of Pharmaceutical Scientists (AAPS) Annual Meeting and Exposition, the world's largest pharmaceutical sciences meeting, in San Antonio, Nov. 10

While there are 35.3 million people living with HIV around the world, approximately 87 million unintended pregnancies occur each year, according to the World Health Organization. Meredith Clark, Ph.D., and David Friend, Ph.D., from CONRAD, a reproductive health research organization, in collaboration with the University of Utah, created this IVR using a dual-protection or multipurpose prevention technology (MPT) to concurrently protect women from the sexual transmission of HIV and unintended pregnancy.

They designed the ring using reservoir-type polyurethane segments that were individually optimized to deliver each drug at the desired dosage—a high flux of tenofovir and low flux of levonorgestrel. The researchers performed in-vitro release testing, and 3-month pharmacokinetic (PK) studies in rabbits and sheep were done in comparison against the tenofovir gel.

The PK studies found that local levels of tenofovir in the target tissue delivered from the IVR are similar or higher than the levels following gel application. In addition, release of the contraceptive agent was consistent with previous levels tested to be efficacious in women.

CONRAD will test the first one-size-fits-most diaphragm with tenofovir gel. Credit: Kessel Marketing

"We saw the urgent need to make this dual-protection intravaginal ring because a majority of the world's unintended pregnancies occur within resource-poor regions where the HIV/AIDS pandemic is most prevalent, such as sub-Saharan Africa," said Clark. "MPTs are a relatively new reproductive health technology that we expect will have a good deal of support from potential users, donors, and public health organizations, particularly in the developing world. We anticipate a lot of excitement for this product, as it is the first dual-protection ring to be evaluated clinically."

A team of investigators led by Patrick Kiser, now at Northwestern University, in partnership with CONRAD, presented research at the 2012 AAPS Annual Meeting on an intravaginal ring to deliver solely tenofovir. (Click here to view this release from last year's Annual

Meeting.)

CONRAD's Product Development group and collaborators are continuing stability studies now and anticipate beginning with phase 1 clinical trials in women in early 2014, testing the combination anti-HIV/contraceptive IVR versus the anti-HIV-only IVR.

Provided by American Association of Pharmaceutical Scientists