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International Study Finds High Levels of Adherence to Use of Rectal Microbicide Gel

Participants as adherent to using gel with sex as taking a daily pill for HIV prevention

CHICAGO, October 20, 2016 – Participants enrolled in a rectal microbicide study were just as likely to follow through using an anti-HIV gel with anal sex as they were to using daily oral pre-exposure prophylaxis (PrEP), according to adherence results presented today at the HIV Research for Prevention conference (HIVR4P). The study, led by the U.S. National Institutes of Health (NIH)-funded Microbicide Trials Network (MTN), was the first extended safety study of a rectal microbicide for prevention of HIV infection from anal sex, which initially reported that the gel was safe in February 2016.

The Phase II study, MTN-017, began in September 2013 and enrolled 195 men who have sex with men (MSM) and transgender women at sites in Peru, Thailand, South Africa and the United States, including Puerto Rico. MTN-017 participants –12 percent of whom were transgender women – cycled through three study regimens which each lasted eight weeks: reduced glycerin tenofovir gel used daily, reduced glycerin tenofovir gel used before and after anal sex, and daily use of the antiretroviral tablet Truvada® (emtricitabine/tenofovir disoproxil fumarate) as PrEP, developed by Gilead Sciences, Inc.

Researchers found that most participants were highly adherent during the course of MTN-017, using study products 80 percent of the time or more. Participants were similarly adherent to using gel before and after sex (93 percent) as they were to taking daily oral Truvada (94 percent). They were less adherent when using the gel on a daily basis (83 percent).

"Overall adherence to the three regimens in MTN-017 was high," said Alex Carballo-Diéguez, Ph.D., HIVR4P abstract co-author and professor of medical psychology, Columbia University. "What we found most remarkable was that even though efficacy of the gel has not been established, its adherence was similar to oral Truvada, which we know is effective. This tells us that rectal microbicide gels, provided they are proven effective, could be a potential alternative for people who don't want to use daily oral PrEP."

Adherence in MTN-017 was measured by a combination of responses to daily questions sent by text message, number of returned gel applicators, and blood tests to confirm the presence or absence of drug. Throughout the study, researchers employed real-time pharmacokinetics (PK), in which they regularly tested participants' blood to assess the presence of drug – a determinant of whether they were using their assigned study products – and shared the results with participants as part of their adherence counseling sessions. These sessions also included convergence interviews, collaborative conversations to engage participants and clarify discrepancies among adherence measures.

In a related HIVR4P poster session (P24.11), Iván C. Balán, Ph.D., assistant professor of clinical psychology, Columbia University, found that convergence interviews conducted in MTN-017, which were aimed at improving the accuracy of adherence data, were feasible and acceptable to both adherence counselors and study participants. They also provided important context to understanding discrepancies in product use assessments and PK

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results. Engaging study participants as allies in the process was critical to avoid making them feel confronted and thus becoming defensive, noted Dr. Balán.

In addition to Dr. Carballo-Diéguez, abstract co-authors include Dr. Balán, Rebecca Giguere, M.P.H., Curtis Dolezal, Ph.D., Cheng-Shiun Leu, Ph.D., William Brown III, Ph.D., Titcha Ho, Ph.D., Camagu Tuswa-Haynes, M.S., all with the New York State Psychiatric Institute and Columbia University; Javier Lama, M.D., IMPACTA PERU Clinical Trials Unit; Jeanna Piper, M.D., Division of AIDS, National Institute of Allergy and Infectious Diseases (NIAID) at the NIH; Barbra Richardson, Ph.D., University of Washington and Fred Hutchinson Cancer Research Center; Ian McGowan, M.D., Ph.D., University of Pittsburgh; and Ross Cranston, M.D., Microbicide Trials Network. Dr. Cranston is protocol chair of MTN-017 and Dr. Lama is protocol co-chair.

MTN-017 was funded by NIAID and the National Institute of Mental Health, both components of the NIH. Tenofovir gel was developed by Gilead Sciences, Inc., of Foster City, Calif., which assigned the rights for tenofovir gel to CONRAD, of Arlington, Va., and the International Partnership for Microbicides of Silver Spring, Md., in December 2006. Clinical input and study supplies of reduced glycerin tenofovir gel were provided by CONRAD, with funding from USAID.

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Dr. Carballo-Diéguez's abstract (QA20.01) is part of the HIV R4P oral presentation session *Trust But Verify: Understanding Adherence* taking place from 10:30-noon CDT, Wed., October 20. It is one of 22 MTN abstracts being presented at the HIVR4P 2016 conference. Webcasts of all HIVR4P 2016 sessions, along with the conference program and more information on the meeting is available at hivr4p.org.

More information and materials about MTN-017 and rectal microbicides are available at http://www.mtnstopshiv.org/news/studies/mtn017.

About the Microbicide Trials Network

The Microbicide Trials Network (MTN) is an HIV/AIDS clinical trials network established in 2006 by the National Institute of Allergy and Infectious Diseases with co-funding from the Eunice Kennedy Shriver National Institute of Child Health and Human Development and the National Institute of Mental Health, all components of the U.S. National Institutes of Health. Based at Magee-Womens Research Institute and the University of Pittsburgh, the MTN brings together international investigators and community and industry partners whose work is focused on the development and rigorous evaluation of promising microbicides – products applied inside the vagina or rectum that are intended to prevent the sexual transmission of HIV – from the earliest phases of clinical study to large-scale trials that support potential licensure of these products for widespread use. More information about the MTN is available at www.mtnstopshiv.org.

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