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FOR IMMEDIATE RELEASE

Women facing intimate partner violence were less likely to use vaginal ring in ASPIRE

Study results demonstrate counseling and support can improve adherence in these women

New findings among those being presented by Microbicide Trials Network researchers at HIVR4P 2016

CHICAGO, October 18, 2016 – Of the 2,629 women enrolled in the ASPIRE study, a large HIV prevention trial of a monthly vaginal ring, only 85 participants (fewer than 5 percent) reported that they were subject to or feared intimate partner violence. However, as a group, they were overall 1.5 times less likely to use the ring and were up to 2.5 times less likely to use the ring if they had recently experienced such events, researchers reported today at the biennial HIV Research for Prevention conference (HIVR4P 2016) taking place at the Sheraton Grand Hotel in Chicago.

Importantly, adherence to ring use improved for some women after they disclosed events to study staff.

"Violence against women is a significant problem globally, and particularly so in the communities where we conducted ASPIRE. Disclosing exposure to intimate partner violence was a major step forward for many of these women, who are often too afraid to talk openly, and an acknowledgement to trial sites who created safe environments women felt comfortable to seek help from," said Thesla Palanee-Phillips, MMed Sci, PhD, MSc., director of network trials at the Wits Reproductive Health and HIV Institute in Johannesburg, South Africa, and protocol co-chair of the ASPIRE study.

ASPIRE– A Study to Prevent Infection with a Ring for Extended Use, or MTN-020, was a Phase III trial designed to determine whether a vaginal ring containing an antiretroviral (ARV) drug called dapivirine is safe and effective in protecting women against HIV when used for a month at a time. The trial was led by the National Institutes of Health-funded Microbicide Trials Network (MTN) and enrolled women ages 18-45 at 15 trial sites in Malawi, Uganda, South Africa and Zimbabwe. The dapivirine ring was developed by the International Partnership for Microbicides, which also conducted The Ring Study, a Phase III sister study.

ASPIRE's primary results, which were reported earlier this year, found the dapivirine ring was both safe and helped protect against HIV. HIV risk was reduced by 27 percent overall (there were 27 percent fewer women who acquired HIV in the group assigned to use the dapivirine ring than in the group assigned to use a placebo ring containing no active drug). HIV risk was reduced significantly more among the study's older participants; women 25 and older in the dapivirine ring group were 61 percent less likely to acquire HIV than women of the same age in the placebo group. Additional analyses have since found the level of HIV protection is at least 56 percent and may be as high as 75 percent or more when the ring is used most consistently.

Dr. Palanee-Phillips discussed the new findings on social harms, a term researchers often use to describe intimate partner violence, in an official HIVR4P press conference today. She will present them formally Thursday.

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Women most likely to report intimate partner violence or related harms during ASPIRE were between the ages of 18 and 21 when they enrolled, had a new primary partner or not disclosed study participation or ring use to their primary partner.

The analysis was based on behavioral and demographic data collected when participants first enrolled into ASPIRE and questions asked of women at different time points during the study, as well as information from participants who came forward on their own. Researchers also looked at drug levels in blood as a measure of adherence.

"Looking ahead, we need to find simple ways to empower women with support to be adherent to HIV prevention strategies in the face of potential exposure to intimate partner violence. We need to ensure that women feel comfortable reporting social harms in studies and in seeking help so that we can better understand how to protect all women against HIV infection," commented Dr. Palanee-Phillips.

Other presentations at HIV R4P include abstracts reporting additional results from ASPIRE as well as VOICE and MTN-017, the first extended safety study of a rectal microbicide for HIV prevention from anal sex. Of the 22 presentations related to MTN studies, seven are oral abstracts.

MTN Principal Investigator Sharon L. Hillier, Ph.D., will also be giving an invited plenary talk, titled "Rings and Things," in the Wednesday (Oct. 19) plenary session, Which Way is Forward: Emerging Challenges and Opportunities. Dr. Hillier is professor and vice chair for faculty affairs, and director of reproductive infectious disease research in the department of obstetrics, gynecology and reproductive sciences at the University of Pittsburgh School of Medicine and the affiliated Magee-Womens Research Institute.

The 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 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 http://www.mtnstopshiv.org.

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(OA20.03) Frequency of Partner-related Social Harms and Their Impact on Adherence to the Dapivirine Vaginal Ring during the MTN020/ASPIRE HIV Prevention Trial will be presented Thursday, 18 Oct. in Oral Abstract Session 20 (10:30 am -12 pm). Webcasts of sessions will be available at hivr4p.org

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For more information about the dapivirine ring, go to www.ipmglobal.org.

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