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**HIV INCIDENCE AND ADHERENCE IN DREAM: AN OPEN-LABEL TRIAL OF DAPIVIRINE VAGINAL RING**

**Epidemiology/Public Health:** (T) Prevention Interventions

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**Background:** The monthly Dapivirine Vaginal Ring (DVR; 25 mg) was evaluated for safety and efficacy in two Phase III clinical trials, The Ring Study and ASPIRE. The trials demonstrated that the ring was safe and reduced the risk of HIV-1 infection in women, 18 to 45 years, by ≈ 30% relative to placebo. DREAM is an ongoing Phase IIIb, multi-center, open-label follow-on trial to The Ring Study to evaluate continued safety and adherence to ring use. The preliminary results are presented.

**Methods:** Women who participated in The Ring Study and who were HIV-negative at screening for DREAM were eligible for enrolment at 5 Research Centers (RCs) in South Africa and 1 in Uganda. Monthly RC visits take place up to 3 months after enrolment, whereafter participants continue on a quarterly visit schedule. HIV testing and safety evaluations are conducted at each visit, and used rings are returned for analysis of dapivirine residual levels. HIV-1 incidence was compared descriptively to the rate expected by bootstrap sampling, based on the placebo arm of The Ring Study, selecting 10,000 times for a subset of women matched for RC, age, and presence of a curable sexually transmitted infection (STI) at enrolment.

**Results:** By September 2017, 900 women were enrolled in DREAM. The median age was 29 years (range: 20-50); 3% were ≤21, 24% were >21 and ≤25; 33% were >25 and ≤30; 21% were >30 and ≤35; and 19% were >35 years. A total of 11 HIV-1 seroconversions in 623 person-years (PY) of follow-up was observed on product: an incidence rate of 1.8 per 100 PY (95% CI: 0.9-3.2). Based on RC, age, and STI distribution of the population enrolled, HIV-1 incidence was expected to be 3.9 per 100 PY (95% CI: 2.9-4.9) in the absence of DVR use. An incidence of 1.8 per 100 PY would be expected to occur with a frequency of less than 1 in 10,000 samplings. Only 4% of returned rings had a residual level >23.5 mg, indicative of non-adherence to ring use, compared to 17% in The Ring Study. Eleven serious adverse events were reported, all unrelated to ring use.

**Conclusion:** Preliminary results from DREAM indicate a similar safety profile of DVR to that observed in Phase III. Based on dapivirine ring residual levels, adherence to ring use is higher. Although interpretation is limited by the lack of a placebo arm, the observed HIV-1 incidence rate is ≈ 54% lower than the expected rate in the absence of access to DVR, supporting the hypothesis that increased efficacy would occur when participants knew the DVR's safety and efficacy from Phase III.