ASPIRE Results At- A-Glance

- 2,629 women were enrolled across 15 clinical trial sites in four African Countries
  - 1,426 (54%) from South Africa (9 sites)
  - 678 (26%) from Zimbabwe (3 sites)
  - 272 (10%) from Malawi (2 sites)
  - 253 (10%) from Uganda (1 site)
  - Mean age was 26 (39% were younger than 25); and less than half (41%) were married

- 1,313 women were assigned to the dapivirine ring group and 1,316 women were assigned to the placebo ring group. Women were provided a new ring at each monthly visit. Follow-up was for a minimum of 12 months and an average of 18 months; 1,024 women completed more than 2 years follow-up.

- Participants attended 91% of all scheduled study visits; excluding early withdrawals, participants attended 97% of all scheduled visits.

- Dapivirine was detected in 82% of plasma samples at levels that indicated eight hours of product use prior to the visit (>95 pg/mL).

- No safety concerns were identified, and there were no differences in the frequency in antiretroviral resistance between arms among those who acquired HIV.

- Two primary analyses were conducted following intention-to-treat (ITT) principles, one including all 15 ASPIRE sites, and one defined early into the study that excluded data from two sites with less than ideal retention and adherence.

  **Full 15 site analysis:** 27% reduced risk of HIV (CI: 1%, 46%) p = 0.046
  - 168 women acquired HIV
  - 71 in the dapivirine arm (3.3% annual incidence) vs. 97 in the placebo arm (4.5% annual incidence)

  **13 site analysis:** 37% reduced risk of HIV (CI: 12%, 56%) p = 0.007
  - 139 women acquired HIV
  - 54 in the dapivirine arm (2.8% annual incidence) vs. 85 in the placebo arm (4.4% annual incidence)

- In pre-defined as-randomized subgroup analyses, HIV protection differed significantly by age:
  - 61% reduced risk of HIV for women ≥ 25 years [CI: 32%, 77%] p<0.001
  - 10% reduced risk for women < 25 years (CI: -41%, 43%) p=0.64

- Additional analyses were performed to further explore these results. Participants were stratified by age and divided into three groups with approximately equal numbers of HIV infections to balance statistical power

  **Age 18-21:** -27% effective (95% CI -133-31%) p=0.45
  - 451 women, 44 HIV infections, placebo annual incidence 5.4% (95% CI 3.2-8.4)

  **Age 22-26:** 56% reduced risk of HIV (95% CI 19-76%) p = 0.009
  - 752 women, 51 HIV infections, placebo annual incidence 6.1% (95% CI 4.3-8.3)

  **Age 27-45:** 51% reduced risk of HIV (95% CI 8-74%) p =0.028
  - 1,192 women, 44 infections, placebo annual incidence 3.0% (95% CI 2.0-4.4)

  **Women >21 years:** 56% reduced risk of HIV (CI: 31%, 71%, p<0.001)

  Adherence appeared to be higher in those >21 years of age than in those ages 18-21

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