ASPIRE
A Study to Prevent Infection with a Ring for Extended Use

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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