Updates from the International Papillomavirus Society Meeting

A study published in The Lancet indicates Gardasil® prevents HPV infections and related diseases in women through age 45.

The study was reported for 3,819 women with no history of any HPV infections, genital warts or cervical diseases. Subjects were randomized into groups that received either vaccine or placebo and followed for 2 years. Among the vaccine group of older naive women, Gardasil was 90.5% effective in preventing genital infections and diseases related to HPV types 6, 11, 16, and 18. When evaluating only HPV 16 and 18, the vaccine blocked 83.1% of infections and associated diseases. The efficacy dropped to 31% when women with any HPV infection were also included in the study population.

Merck has an application before the FDA that seeks approval to market the vaccine with women up to age 45. The vaccine is currently licensed for the prevention of vulvar, vaginal, and cervical precancers and cancers in females ages 9-26.

Data presented in May at the 25th International Papillomavirus Conference (IPV) Clinical and Educational Workshop in Malmo, Sweden presented new information about the vaccines:

- Research with women in Brazil who took part in GSK’s initial clinical trials with Cervarix shows the vaccine generates a sustained immune response of 7.3 years to the high-risk HPV types found in most cervical cancers. The investigators report that in this preliminary analysis, antibody levels to HPV 16 remained 13 times higher than what’s found in response to natural infection. With HPV 18, an 11-fold increase in antibody levels versus natural infection was observed. When complete, the full analysis with this study will assess the immune response to Cervarix over 9.5 years.

- In the GSK global study of 18,644 women, the protection against cancer causing types by Cervarix is expanded. In addition to 100% protection against CIN 2+ caused by HPV 16 and HPV 18, Cervarix is 100% effective against CIN 2+ disease caused by two more cancer causing types: HPV 31 and HPV 45 in women without prior HPV exposure. Taken in the big picture, Cervarix is 68% effective at preventing CIN 2+ disease from the ten most frequent cancer types.

- Three years after vaccinating 7466 women with Cervarix, the cumulative reduction in CIN 2+ caused by any HPV type and/or 12 month persistent HR HPV infection was 57/1000 in women within one year of their sexual debut. If women had been sexually active for 1-6 years prior to vaccination, 32/1000 cases of CIN 2+/infection were prevented; and if the vaccine was given to virgins who subsequently became sexually active after vaccination, only 17/1000 cases
of CIN 2+/infection were prevented. This is powerful evidence that vaccinating within the first six years of the onset of sexual activity immediately results in the public health benefit of preventing cancer precursors.

References

