HPV/Cervical Cancer Vaccines Update

Data presented at the Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) in December 2005 offer more evidence that the HPV/cervical cancer vaccines under current development are effective at blocking diseases associated with the virus as well as in producing an immune response.

GlaxoSmithKline and Merck and Company are developing cervical cancer vaccines that many observers think will be available within the next year or two. Merck applied for FDA approval for its *Gardasil* vaccine late in 2005, while GSK plans to seek European regulatory approval for its *Cervarix* vaccine early this year. *Gardasil* is a quadravalent vaccine designed to protect against the HPV types most commonly found in cervical cancer (HPV 16, 18) and genital warts (HPV 6, 11), while *Cervarix* is a bivalent vaccine designed to protect against cervical cancer caused by HPV 16 and18.

At the recent ICAAC meeting, researchers from GSK presented data from large phase III trials that indicate 100% of subjects vaccinated with *Cervarix* produced detectable antibody levels after one month, and 10-14 year-old females developed antibody levels roughly twice as high as 15-24 year olds. In a press release, GSK says increased antibody levels in the younger group may translate to a longer duration of protection (as the antibody levels are much higher than those achieved using an alum based vaccine alone). If this prediction is correct, the company argues, it would provide another reason to vaccinate females at a younger age, in addition to wanting to vaccinate before the start of sexual activity. Results from phase III trials with *Gardasil* also indicate higher antibody levels in preadolescent subjects. It remains unknown just why both vaccines stimulate stronger antibody responses in younger subjects.

At the same meeting, Dr. Diane M. Harper of Dartmouth Medical School presented data from more than 5,500 women in phase III *Gardasil* trials in which none who received the full regimen of three doses (n=2,261) developed cervical, vaginal, or vulvar diseases associated with the four HPV types against which the vaccine offer protection (“low-risk” HPV 6, 11 and “high-risk” HPV 16, 18). Studies also indicate *Cervarix* holds promise in this regard, as in phase IIb trials the vaccine has been able to prevent 100% of persistent infections and cervical disease related to HPV 16 and 18.