

Modelling research shows *Cervarix*TM-induced immune response may be prolonged for at least 20 years for both HPV 16 and 18

Three statistical models predict sustained HPV 16 and 18 antibody levels well above natural infection levels

Results of three statistical models presented recently at the European Research Organisation on Genital Infection and Neoplasia (EUROGIN) annual meeting in Nicesuggest that young women vaccinated with GlaxoSmithKline's HPV vaccine *Cervarix*TM could look forward to a prolonged immune response against the two most common cancer-causing human papillomavirus virus (HPV), types HPV 16 and 18 for at least 20 years.^{1,2}

The three statistical models (power-law, modified power-law and piece-wise models) provide a robust and reproducible way of predicting long-term persistence of antibodies against HPV 16 and 18. All three models show that the levels of antibodies against HPV 16 and 18 induced by *Cervarix*TM will remain significantly above those seen following natural infection for over 20 years.²

"Predicting the levels of antibodies generated and sustained against HPV 16/18 is important as long as we have no better options to directly measure duration of protection." said Dr Koen Van Herck of the Centre for the Evaluation of Vaccination, Antwerp, Belgium. "Long term immune response is particularly important when vaccinating adolescents and young women against cervical cancer as new infections with cancer-causing HPV types can occur throughout their lives."

The statistical models used in this study utilised data from an ongoing phase II study conducted up to 6.4 years. This is the longest study in HPV vaccination to date and will continue to provide data on antibody levels against both HPV 16 and 18 for up to 9.5 years.³

Data from this study show that *Cervarix*TM has demonstrated high and sustained antibody levels associated with 100 percent efficacy in preventing pre-cancerous lesions caused by HPV 16/18 for up to 6.4 years.³ The study also showed that *Cervarix*TM induces antibody levels that remain significantly higher than the body's own immune response to natural infection from cancer-causing virus types 16 and 18 for up to 6.4 years.³

*Cervarix*TM is formulated with the innovative adjuvant system AS04, specifically designed and selected to enhance the immune response against HPV, which is responsible for cervical cancer. Data show that *Cervarix*TM induces a stronger and more sustained immune response compared to the same vaccine antigens formulated with conventional aluminium hydroxide alone.⁴

Favourable tolerability profile for *Cervarix*TM

Additional new data from an integrated analysis of 11 phase II and III trials involving nearly 30,000 adolescent girls and women 10-72 years old, presented at EUROGIN, confirmed the positive tolerability profile of *Cervarix*TM.⁵

Previous data sets from the same integrated analysis have shown that no differences were observed between the *Cervarix*TM and control groups in serious adverse events and medically significant conditions after the completion of the three-dose vaccination schedule.⁶ This is the largest safety analysis of cervical cancer vaccination reported to date and included a geographically and ethnically diverse population with a very broad age range.

References:

1. Bosch FX, Burchell AN, Schiffman M et al. Epidemiology and natural history of human papillomavirus infections and type-specific implications in cervical neoplasia. *Vaccine* 2008; 26S: K1-K16
2. David M-P, Hardt K, Tibaldi F et al. Modelling of long-term persistence of anti-hpv-16 and anti-hpv-18 antibodies induced by an as04-adjuvanted cervical cancer vaccine. Abstract at European Research Organisation on Genital Infection and Neoplasia (EUROGIN), Nice, France, November 12-15 2008
3. Wheeler C, Teixeira J, Romanowski B et al. High and sustained HPV 16 and 18 antibody levels through 6.4 years in women vaccinated with *Cervarix*TM (GSK HPV-16/18 AS04 vaccine) Abstract at European Society for Paediatric Infectious Diseases (ESPID), Graz, Austria, 14-16 May 2008
4. Giannini SL, et al. Enhanced humoral and memory B cellular immunity using HPV16/18 L1 VLP vaccine formulated with the MPL/aluminum salt combination (AS04) compared to aluminium salt only. *Vaccine* 2006 24: 5937-5949
5. Rombo L, Schwarz TF, Thomas F et al. Tolerability of hpv-16/18 as04-adjuvanted cervical cancer vaccine. Abstract at European Research Organisation on Genital Infection and Neoplasia (EUROGIN), Nice, France, November 12-15 2008
6. Descamps D, Hardt K, Spiessens B et al. Safety of human papillomavirus (Hpv)-16/18 AS04 adjuvanted vaccine for cervical cancer prevention: integrated summary of 11 clinical trials. Abstract at ESPID's Annual Meeting, May 13-16, 2008, Graz, Austria.