

***Cervarix*[™], GSK's Candidate Vaccine for Cervical Cancer, Demonstrated Sustained Efficacy for up to 4.5 Years and Broader Protection Against Cancer-Causing HPV Types**

Follow-up study, published in The Lancet, extends earlier findings of vaccine efficacy and protection against most prevalent cancer-causing types of the human papillomavirus (HPV)

April 6, 2006, London, UK, & Rixensart, Belgium: *Cervarix*[™], GlaxoSmithKline's (GSK) candidate vaccine for cervical cancer prevention, showed 100 per cent efficacy over 4.5 years against precancerous lesions associated with human papillomavirus (HPV) types 16 and 18, the two most common cancer-causing HPV types, a new follow-up study shows. HPV 16 and 18 are responsible for more than 70 per cent of cervical cancers globally.¹

GSK's candidate vaccine for cervical cancer is formulated with the proprietary innovative adjuvant system AS04, selected to ensure this vaccine confers strong and sustained antibody levels in women. The study, published in *The Lancet*, also found that HPV 16 and 18 antibodies were detected in over 98 per cent of women for up to 4.5 years, indicating a sustained vaccine response.

In addition, the study provided evidence that GSK's candidate vaccine demonstrated substantial protection against infection with the third and fourth most prevalent cancer-causing types of HPV, namely types 45 and 31. This protection also extends over 4.5 years. GSK is conducting further large studies to determine the potential mechanism and extent of the demonstrated broader oncogenic protection.

HPV types 16, 18, 45 and 31 are collectively responsible for 80 percent of cervical cancers globally.

Moreover the study provides additional evidence that the vaccine is generally safe and well tolerated.

Dr Diane Harper, from Dartmouth Medical School, USA, noted, "The results of this long-term follow-up analysis are an exciting milestone for those of us who are working to prevent cervical cancer. These data illustrate that this AS04-adjuvanted candidate vaccine has so far demonstrated sustained protection against HPV 16 and 18 infections and associated cervical lesions with no evidence of waning protection for these two HPV types. The vaccine has also shown evidence of protection against infection with other cancer-causing types of HPV beyond 16 and 18. In practice, these key findings may mean that GSK's candidate HPV vaccine may offer long-term, sustained protection against a broader range of the most common cancer-causing types of HPV."

Dr Philippe Monteyne, Head of Global Vaccine Development of GSK Biologicals said, “We developed this candidate vaccine for cervical cancer with the ambition to provide women with the best possible vaccination against cervical cancer. We are delighted with these results, as they demonstrate that our decision to formulate this vaccine with an innovative adjuvant to deliver high efficacy for a long duration of protection appears well founded. GSK is committed to developing innovative products that have a major impact in preventing life-threatening diseases and *Cervarix*[™] is an important proof of that commitment.”

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Notes to editors:

About the study

This was an extended follow-up (EFU) analysis of women who participated in the primary efficacy study of GSK’s candidate HPV 16/18 vaccine.

The primary study was a double-blind, controlled trial of 1,113 young women, between 15-25 years of age, randomized to receive three doses of the GSK’s candidate vaccine for cervical cancer formulated with the AS04 adjuvant system or, of a placebo on a 0, 1 and 6 month schedule.²

The extended follow-up study looked at study endpoints for 776 women from the same cohort of women for a period of up to 53 months.

The trial was conducted in the US, Canada and in Brazil and evaluated the efficacy, safety and immunogenicity of a HPV-16/18 L1 virus-like particle vaccine for the prevention of HPV 16 and/or HPV 18 infections, as well as associated Pap smear abnormalities and cervical lesions. In the extended follow up study, women were evaluated for HPV DNA using cervical samples and annual cervical cytology evaluations were performed. Women were referred for colposcopy following protocol guidelines. Women were also assessed for long-term immunogenicity and safety. The study follow-up continues.

About GSK’s candidate HPV vaccine

GSK’s candidate HPV vaccine was developed to prevent infection and lesions from the two most prevalent cancer-causing types of HPV, specifically HPV 16 and 18.

In clinical trials, the vaccine demonstrated excellent protection from persistent infection against both HPV 16 and 18, associated precancerous lesions and excellent antibody response. GSK’s vaccine is formulated with the proprietary adjuvant AS04 selected to ensure that it confers high and sustained antibody levels. The overall safety profile from the completed control trials indicate that the vaccine is generally safe and well tolerated with a very good compliance to the 3 dose schedule.

The GSK’s vaccine was filed for approval in Europe in March 2006, with submission to the US Food and Drug Administration expected by the end of 2006.

It is currently undergoing extended Phase III clinical trials involving more than 30,000 women worldwide.

About HPV and cervical cancer

HPV infection is very common; every sexually active woman is at risk of contracting a type of HPV, which may cause cervical cancer. While there are many different types of HPV that may cause cancer, HPV 16 and 18 account for more than 70 per cent of all cervical cancers globally.

Cervical cancer is a major global health problem, with nearly 500,000 new cases occurring each year worldwide. It is the second most common cancer - and the third leading cause of cancer deaths - in women worldwide. Each year an estimated 270,000 women die from the disease, and it is the leading cancer killer of women in the developing world.³

About GlaxoSmithKline and GlaxoSmithKline Biologicals

In the next five years, GSK expects to launch more major new vaccines: a vaccine against rotavirus, a vaccine to prevent pneumococcal disease, an improved flu vaccine for the elderly, and a meningitis combination vaccine for infants.

GlaxoSmithKline – one of the world's leading research-based pharmaceutical and healthcare companies – is committed to improving the quality of human life by enabling people to do more, feel better and live longer. For company information please visit www.gsk.com.

GSK Biologicals (GSK Bio), one of the world's leading vaccine manufacturers, is headquartered in Rixensart, Belgium, where the majority of GlaxoSmithKline's activities in the field of vaccine research, development and production are conducted. GSK Bio employs more than 1,500 scientists, who are devoted to discovering new vaccines and developing more cost-effective and convenient combination products to prevent infections that cause serious medical problems worldwide.

In 2005, GSK Bio distributed more than 1.2 billion doses of vaccines to 165 countries in both the developed and the developing world, an average of more than 3 million doses per day.

For further information please contact:

GSK Corporate Communications
(905) 819-3363

References:

¹ Muñoz N, Bosch FX, Castellsagué X, Diaz M, de Sanjose S, Hammouda D, Shah KV, Meijer CJLM. Against which human papillomavirus types shall we vaccinate and screen? The international perspective. *Int J Cancer* 2004; 111: 278-285.

² Harper DM, Franco EL, Wheeler C, Ferris DG, et al. Efficacy of a bivalent L1 virus-like particle vaccine in prevention of infection with human papillomavirus types 16 and 18 in young women: a randomised controlled trial. *Lancet* 2004;364:1757-65.

³ Ferlay J, Bray P, Pizani P, Parkin DM. Cancer incidence, mortality and prevalence worldwide. Available at: GLOBOCAN 2002. Accessed September 20, 2005