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## **PATRICIA : TRIAL LAUNCHED OF NEW VACCINE AIMED AT PREVENTING CERVICAL CANCER**

GSK today announced that investigators at more than 90 sites worldwide are commencing a global phase III clinical trial of a new vaccine that could offer protection against developing cervical cancer. In preliminary studies, the investigational cervical cancer vaccine was well tolerated and appeared to demonstrate clinical benefit.

The study has been given the name “PATRICIA”, which is short for “PAPilloma TRIal to prevent Cervical Cancer In young Adults”.

Cervical cancer is the second most common cause of death from cancer in women worldwide and the number one cause in the developing world. The World Health Organization recently estimated that 510,000 women are diagnosed with cervical cancer and 288,000 women die from the disease every year.

Cervical cancer is caused by infection with a virus called human papillomavirus (HPV). HPV infection is very common. Approximately 75% of women become infected with HPV at some time in their lives, usually soon after the onset of sexual activity. Although there are more than 100 different types of HPV, approximately 70% of all cervical cancers are associated with infection with only two types, HPV 16 and HPV 18. These are the most important of the so-called ‘high-risk’, or oncogenic (cancer-causing) types of HPV.

GSK Biologicals has recently completed a pilot phase II study with the investigational cervical cancer vaccine, which is intended to offer protection against HPV 16 and HPV 18. The results were promising and the vaccine has progressed to phase III trials. Investigators at more than 90 sites in 14 countries around the world are currently seeking to enrol approximately 13,000 young women aged 15–25 years as volunteers to participate in this 4-year phase III study, which is aimed at evaluating the safety and efficacy of the new cervical cancer vaccine.

## **Notes for editors**

### **CERVICAL CANCER AND HPV INFECTION**

Cervical cancer is a major global health problem, with approximately 510,000 new cases being reported every year. It is the second leading cause of death from cancer in women worldwide and the leading cause in the developing world. The median age of women with cervical cancer is 38 years (the age range is 21–67 years), and, on average, women who die from cervical cancer die approximately 25 years prematurely. This is greater than the number of years 'lost' by women who die from any other type of cancer, with the exception of Hodgkin's Disease, which is less common than cervical cancer.

Recent research has confirmed that infection with human papillomavirus (HPV) leads to the development of cervical cancer. Virtually all (99.7%) tissue samples taken from cervical cancers contain DNA from HPV, confirming the presence of HPV infection.

HPV infection is very common. Approximately 75% of women become infected with HPV at some point in their lives, usually soon after the onset of sexual activity. HPV infections are usually transient, lasting only a matter of months, and in many women they cause no symptoms. However, some infections last longer and it is these persistent infections that can lead to the development of cervical cancer.

Although there are more than 100 different types of HPV, approximately 70% of all cervical cancers are associated with infection with only two types, HPV 16 and HPV 18. These are the most important of the so-called 'high-risk', or oncogenic (cancer-causing) types of HPV.

In countries in which cervical screening programmes are in place, the successful development and widespread use of a prophylactic vaccine against HPV 16 and HPV 18 infections could reduce by 70% women's lifetime risk of developing cervical cancer. In countries in which such screening programmes are not commonly available for socio-economic reasons, the implementation of an immunisation programme with the new vaccine might dramatically reduce the incidence of cervical cancer and the number of related deaths.

If this cervical cancer-specific prophylactic vaccine is approved for use, it will represent a landmark achievement in the global fight against cervical cancer.

### **ABOUT THE VACCINE**

Since the causative link between cervical cancer and infection with HPV was confirmed, GSK Biologicals, in collaboration with MedImmune Inc, has been developing a preventive vaccine against infection with HPV 16 and HPV 18 that might therefore protect against subsequent development of cervical cancer. This new investigational vaccine contains virus-like particles for HPV types 16 and

18, plus a substance called AS04, a novel proprietary adjuvant being developed by GSK Biologicals in collaboration with Corixa, that increases the immune system's response to a vaccine. In 2004, the results from a phase II, randomised, double-blind clinical trial indicated that the vaccine may have clinical benefit.

#### **ABOUT THE NEW PHASE III TRIAL**

The new phase III clinical trial will be a double-blind, randomised, parallel-group design with an active vaccine control. This will ensure that neither volunteers nor investigators will know until the end of the 4-year trial who received the new vaccine and who received the control, to avoid bias affecting the results.

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## GLAXOSMITHKLINE BIOLOGICALS

GlaxoSmithKline Biologicals (GSK Biologicals), one of the world's leading vaccine manufacturers, is located in Rixensart, Belgium, which is the centre of all GlaxoSmithKline's activities in the field of vaccine research, development and production. GSK Biologicals employs more than 1000 research 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 2003, GSK Biologicals distributed more than 850 million doses of vaccines to 152 countries in both the developed and the developing world – an average of 27 doses per second. Of those vaccine doses, approximately 85 million were doses of combination paediatric vaccines, which protect the world's children against a minimum of three – and as many as six – diseases in one vaccine. For more information, visit GlaxoSmithKline's vaccine websites at [www.gsk-bio.com](http://www.gsk-bio.com) and [www.worldwidevaccines.com](http://www.worldwidevaccines.com) (for medical professionals).

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.

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