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WHO Grants Prequalification to *Cervarix*®: GSK's Vaccine to Help Combat Cervical Cancer in Developing Nations

The World Health Organization (WHO) has awarded prequalification to *Cervarix*®, GlaxoSmithKline's cervical cancer vaccine. The WHO decision is necessary for UN agencies and the GAVI Alliance to purchase the vaccine in partnership with developing countries and will help speed access to *Cervarix*® globally.

More than 80 percent of the 280,000 cervical cancer deaths a year occur in resource-poor nations.ⁱ Cervical cancer affects poor women in the least developed countries more often and more aggressively due to a lack of available screening services and the high prevalence of other serious health conditions such as HIV/AIDS.^{ii,iii}

"*Cervarix*® can save millions of women's lives throughout the world, but only if it reaches those who need it most," said **Jean Stéphenne, President of GSK Biologicals**. "That is why GSK rapidly applied for WHO prequalification of *Cervarix*®. That is why we're eager to work with our long-term partner GAVI as well as other private NGOs or governments of developing countries to identify financing mechanisms for the vaccine. And that is why we're exploring a variety of distribution partnerships to ensure *Cervarix*® will protect women and girls around the globe."

Today's WHO prequalification for *Cervarix*® is the result of a rigorous regulatory process that began nearly two years ago. GSK filed *Cervarix*® for WHO prequalification in September 2007, less than one week after the vaccine was approved by the European Medicines Agency. Registration with a major regulatory agency is a required step for any WHO prequalification filing.

GSK's track record of more than 10 WHO prequalified vaccines exemplifies the company's long-standing prioritisation of global markets and commitment to making its vaccines available to populations in developing countries. The company recently received an extended WHO prequalification for another crucial vaccine, *Rotarix*™, opening the door to making rotavirus vaccines available to children worldwide. No fewer than five other GSK vaccines are currently under consideration for WHO prequalification.

To overcome the challenges of introducing a cervical cancer vaccine in developing countries, GSK is participating in a number of HPV vaccination demonstration projects, including those led by PATH in Uganda and India, and has donated more than 100,000 doses of *Cervarix*® to these programme. These collaborations will help build and leverage developing countries' experience with the implementation of HPV vaccination programmes.

"Through our joint demonstration project, we have found that we can achieve high HPV vaccination coverage through proper sensitisation, the strengthening of healthcare systems and the mobilisation of local communities," said **Christopher J. Elias, President and CEO of PATH**. "With today's WHO decision, the public and private sectors take another significant step forward in accelerating access to HPV vaccines in GAVI countries. We look forward to continuing to partner with GSK on this public health priority."

About Cervarix®

Cervarix® provides protection against human papillomavirus (HPV), the virus that causes cervical cancer. The vaccine is highly effective at protecting against the two most common cervical cancer-causing HPV types 16 and 18 (responsible for 70% of cervical cancer worldwide).^{iv,v}

In addition, results from the final analysis of a Phase III study (HPV-008), recently presented for the first time and published in *The Lancet* July 7, showed that the vaccine also provided type-specific protection against pre-cancerous lesions associated with the three most common cancer-causing HPV types other than HPV 16 and 18 (HPV types 31, 33 and 45).^{vi} Cervarix® contains an innovative, proprietary adjuvant called AS04, which induces a higher and more sustained immune response compared to a conventional adjuvant.^{vii}

Cervarix® has been approved in 97 countries around the world. In addition, it has been exclusively selected for cervical cancer national immunisation programmes by health authorities in the UK and the Netherlands and regional programmes across Italy, Poland and Spain. Since the vaccine has been licensed, it has been successful in more than half of competitive tender processes globally.

About GlaxoSmithKline Biologicals

GSK Biologicals is headquartered in Rixensart, Belgium, where the majority of GlaxoSmithKline's activities in the field of vaccine research, development and production are conducted. In 2008, GSK Bio distributed more than 1.1 billion doses of vaccines to 176 countries. Close to 80% of these doses were distributed in developing countries.

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 further information please visit www.gsk.com

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ⁱ World Health Organization. Human papillomavirus infection and cervical cancer. Available from: http://www.who.int/vaccine_research/diseases/hpv/en. Accessed 15 June 2009.

ⁱⁱ World Health Organization, Department of Reproductive Health and Research. Sexual and reproductive health of women living with HIV/AIDS: Guidelines on care, treatment, and support for women living with HIV/AIDS and their children in resource constrained settings. Co-published by the UNFPA. 2006.

ⁱⁱⁱ World Health Organization. Cervical cancer, human papillomavirus (HPV), and HPV vaccines: Key points for policy-makers and health professionals. Published in partnership with PATH, UNFPA and with support of the Flemish Government, 2007.

^{iv} Bosch X, Burchell A, Schiffmann M et al. Epidemiology and Natural History of Human Papillomavirus Infections and Type-Specific Implications in Cervical Neoplasia. *Vaccine* 26S (2008) K1–K16.

^v Paavonen J et al. Efficacy of the HPV-16/18 AS04-adjuvanted vaccine against cervical infection and pre-cancer caused by oncogenic HPV types: final event-driven analysis in young women (the PATRICIA trial). 2009. *The Lancet*.

^{vi} Paavonen J et al. Efficacy of the HPV-16/18 AS04-adjuvanted vaccine against cervical infection and pre-cancer caused by oncogenic HPV types: final event-driven analysis in young women (the PATRICIA trial). 2009. *The Lancet*.

^{vii} Aguilar JC. Vaccine adjuvants revisited. *Vaccine* 2007; 24: 3752 – 3762.

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