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CERVARIX™ SHOWS SIGNIFICANTLY HIGHER IMMUNE RESPONSE IN HEAD-TO-HEAD TRIAL OF THE TWO CERVICAL CANCER VACCINES

MISSISSAUGA, ON (May 12, 2009) – GlaxoSmithKline’s cervical cancer vaccine, Cervarix™, has demonstrated a significantly higher immune response compared to Gardasil® in the first large-scale comparative study of the two human papillomavirus (HPV) vaccines.^{1A} Announced at the 25th International Papillomavirus Conference (IPV), the comparative study (HPV-010) looked at two key measures of immune response, neutralizing antibodies and memory B cells, believed to play an important role in how well a vaccine will protect women from HPV infection and subsequent cervical cancer over the long term.^{2A-7A} Cervarix™ is currently under review with Health Canada.

Across all ages studied (women 18 – 45 years), neutralizing antibody levels for GlaxoSmithKline’s cervical cancer vaccine were more than two times higher than those for Gardasil® for HPV type 16, and more than six times higher for HPV type 18. These results were highly statistically significant ($p < 0.0001$).^{1B} In addition, the proportion of women with detectable levels of neutralizing antibodies in cervical secretions was higher in the group that received GlaxoSmithKline’s cervical cancer vaccine.^{1C} Compared to Gardasil®, GlaxoSmithKline’s cervical cancer vaccine also produced almost three (2.7) times more memory B cells for both HPV 16 and 18.^{1D}

“The presence of neutralizing antibodies at the location of the infection (the cervix) is an integral part of vaccine-induced protection against HPV,” said Dr. Barbara Romanowski, Clinical Professor of Medicine, Division of Infectious Diseases at the University of Alberta. “For the first time, we have robust clinical evidence that one of the HPV vaccines generates much higher antibody levels against HPV types 16 and 18, the two most common cancer-causing virus types. We are confident that these results, along with new data from additional key studies being presented this week, demonstrate the impact of Cervarix™ in preventing cervical cancer,” Dr. Romanowski added.

Both vaccines were shown to be generally safe and well tolerated. Rates of solicited symptoms were somewhat higher for GlaxoSmithKline’s cervical cancer vaccine with injection site reactions being most common.^{8A} Compliance with the full vaccination course was high and comparable for both vaccines which indicates that both were well tolerated.^{8B} It is expected that the full results from this comparative study will be published in a peer reviewed journal.

“Cervical cancer vaccination is a major breakthrough against a devastating disease that often strikes women in the prime of their lives. GSK is committed to long-term investigation in order to advance our understanding of the differences between the two

vaccines. In this way, we can strengthen our insights into the important role of vaccination for the long term prevention of cervical cancer”, said Dr. Tjark Reblin, Vice President, Medical and Chief Medical Officer, GlaxoSmithKline Canada.

Key results from two other important studies of the cervical cancer vaccine, GlaxoSmithKline’s cervical cancer vaccine will be presented including results from the final analysis of the Patricia phase III study (HPV-008) showing that GlaxoSmithKline’s cervical cancer vaccine provides a statistically significant level of efficacy against pre-cancerous lesions associated with each of the HPV types included in the vaccine (HPV 16 and HPV 18).^{9A} In addition, the data demonstrated GlaxoSmithKline’s cervical cancer vaccine also generates type-specific protection against pre-cancerous lesions associated with additional common cancer-causing HPV types other than HPV 16 and HPV 18.^{10A} In women without evidence of prior cancer-causing HPV infection the overall efficacy demonstrated against any lesion, regardless of HPV type, was greater than what would be expected for a vaccine targeting only HPV types 16 and 18.¹¹

Rates of serious adverse events and medically significant conditions were similar between study and control groups.^{9B}

Results from a third study (HPV-023) to be presented in Malmö show GlaxoSmithKline’s cervical cancer vaccine elicits high and sustained antibody levels against HPV 16 and HPV 18 through the 7.3 years of follow-up after first vaccination among women vaccinated at the age of 15-25. This is the longest follow up reported to date for any licensed cervical cancer vaccine.¹² Vaccines against cervical cancer need to provide long term protection, as women remain vulnerable to acquiring cancer-causing HPV infections throughout their life. Immune response and protection are closely linked.^{2B-7B}

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For more information or to arrange an interview with a study investigator, please contact:

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Notes to Editors

About HPV 008

The efficacy and safety results from the interim analysis of the HPV-008 study were previously published in the Lancet.¹³ The data presented at the 25th International Papillomavirus Conference (IPV) are from the final event driven analysis. Further follow up results will be forthcoming from the end of study analysis in due course.

About the GSK Cervical Cancer Vaccine

The primary role of vaccination is to protect women against cervical cancer. Since women are at risk throughout their sexually active lives, the ideal cervical cancer vaccine must provide long-term protection and induce a strong protective immune response against the most common HPV cancer-causing virus types. GlaxoSmithKline’s cervical

cancer vaccine provides protection against the most common cancer-causing virus types - HPV 16 and 18^{9B-}

GlaxoSmithKline's cervical cancer vaccine was specifically designed with an innovative adjuvant, AS04.-

GlaxoSmithKline's cervical cancer vaccine has been shown to be generally well tolerated. The most common symptoms after vaccination included pain, redness and swelling at the injection site.¹⁶

To date, Cervarix™ has been approved in 95 countries around the world, including the 27 member states of the European Union (EU), Australia, Brazil, South-Korea, Mexico and Taiwan. Licensing applications have been submitted in more than 20 additional countries including Canada, Japan and the United States. GSK also submitted the vaccine to the World Health Organization (WHO) for prequalification in September 2007.

About HPV and cervical cancer

Approximately 100 types of human papillomavirus have been identified to date¹⁷ and, of these, approximately 15 virus types are known to cause cervical cancer. 18 HPV types 16 and 18 are responsible for approximately 70 percent of cervical cancers globally, with types 45, 31 and 33 among the next most common cancer-causing HPV strains.^{14B,19}

Persistent infection with cancer-causing HPV types can lead to abnormal Pap smears, cervical pre-cancer and cervical cancer. Worldwide, more than 500,000 women will be newly diagnosed with cervical cancer^{20A} and 280,000 women will die from it each year.^{20B}

According to the Canadian Cancer Society's Canadian Cancer Statistics 2008 report, 1,300 new cases of cervical cancer are diagnosed each year, and 380 women die each year of the disease.²¹ Cervical cancer ranks the 11th most frequent cancer in women, and the second most frequent cancer among women age 15-44.²² About 21.7% of women in the general population are estimated to live with cervical HPV infection at any given time, and 71% of invasive cervical cancers in Canada are attributable to HPVs 16 or 18.²³

About GlaxoSmithKline Inc.

GlaxoSmithKline – one of the world's leading research-based pharmaceutical, vaccine and health-care companies – is committed to improving the quality of human life by enabling people to do more, feel better and live longer. In Canada, GlaxoSmithKline is among the top 15 investors in research and development, contributing more than \$156 million in 2008 alone. GSK is designated a Caring Company by Imagine Canada, and is consistently recognized as one of the 50 best companies to work for in Canada. For company information please visit, www.gsk.ca.

Cervarix™ is a trademark of the GlaxoSmithKline group of companies.

Gardasil® is a registered trademark of Merck & Co., Inc.

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