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**New data provides additional support confirming CERVARIX™ demonstrated protection against HPV type 45, linked with the most aggressive form of cervical cancer**

**Mississauga, ON (July 5, 2010)** - The end-of-study results of the largest efficacy trial of a cervical cancer vaccine presented at a major international congress provides additional support confirming that CERVARIX™ demonstrated protection against human papillomavirus (HPV) types 18 and 45<sup>1</sup>, which are linked to the most aggressive form of cervical cancer, along with virus type 16 and 31.<sup>2,3</sup>

Similar to previous study findings, the end-of-study results show that CERVARIX™ demonstrated protection against the most common cervical cancer causing HPV types (16, 18, 31, and 45) after 48 months of follow-up.\*<sup>1,4</sup> Protection against types 16, 18 and 45 is especially important as these are associated with adenocarcinoma, the most aggressive type of cervical cancer which is more common in younger women and also more difficult to detect through screening.<sup>2,3</sup> Therefore a vaccine that offers protection against these three virus types could help to significantly reduce the incidence of this aggressive cervical cancer.<sup>5</sup>

Commenting on the significance of the study results, Dr. Barbara Romanowski, study investigator from the University of Alberta, said, "Even though Cervarix is designed to protect against two HPV strains (HPV 16 and 18), the results from this study demonstrate that the vaccine provided protection against the four most common strains of the cervical cancer-causing virus. This is tremendous news for women as it indicates the vaccine could offer them additional protection against cervical cancer beyond what had at first been anticipated and significant protection against the most aggressive form of the disease."

Other data presented at the 26<sup>th</sup> International Papillomavirus Congress (IPC) included results from the 24-month data from the first, large-scale comparative trial (HPV 010) of immunogenicity and safety between the two licensed cervical cancer vaccines.

Dr. Tjark Reblin, Vice-President, Medical and Chief Medical Officer, GlaxoSmithKline Inc. said, "The data presented at IPC mark a significant milestone for Canadian women. The end of the largest efficacy study of a cervical cancer vaccine confirms the unique cross-protective benefits of the vaccine. What is most significant about this data is that it demonstrates that GSK and Cervarix are delivering on the promise to help protect women against cervical cancer – a disease that kills one woman every day in Canada."

## **About CERVARIX™**

CERVARIX™ is a vaccine indicated in females from 10 to 25 years of age for the prevention of cervical cancer (squamous cell cancer and adenocarcinoma) by protecting against the following precancerous or dysplastic lesions caused by oncogenic Human Papillomavirus (HPV), types 16 and 18: cervical intraepithelial neoplasia (CIN) grade 2 and grade 3, cervical adenocarcinoma *in situ* (AIS), and cervical intraepithelial neoplasia (CIN) grade 1. In an additional analysis, statistically significant vaccine efficacy in the prevention of CIN2/3 or AIS associated with HPV-31 and HPV-45 was demonstrated in the ATP and TVC cohorts, respectively.<sup>6</sup>

CERVARIX™ is generally well tolerated. The most commonly reported adverse events within 7 days of vaccination with Cervarix™/control [500 µg Al(OH)<sub>3</sub>]: local [pain (91.8%/87.2%), redness (48.0%/24.4%) and swelling (44.1%/21.3%)] and general [fatigue (55.0%/53.6%), headache (53.4%/61.4%)].

For more information about CERVARIX™, please visit [www.cervarix.ca](http://www.cervarix.ca).

CERVARIX™ is now approved in over 110 countries around the world.

CERVARIX™ is a trademark, used under license by GlaxoSmithKline Inc.

## **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 \$144 million in 2009 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](http://www.gsk.ca).

## **About HPV-008 PATRICIA (PApilloma TRIal Cervical cancer In young Adults)**

- The Phase III multi-centre, double-blind, randomised study involved a total of 18,644 women, aged between 15 and 25 years, from 14 countries across Europe, Asia-Pacific and Latin and North America<sup>6</sup>
- Study participants were randomised to receive either CERVARIX™ or a control hepatitis A vaccine and analyses were performed in the following cohorts:
  - According-to-protocol cohort for efficacy (ATP-E; vaccine=8093; control=8069)
  - Total vaccinated cohort (TVC; vaccine=9319, control=9325)
  - Total vaccinated cohort-naïve (TVC-naïve; vaccine=5822; control=5819)
- ATP-E included all women who met eligibility criteria, complied with the trial protocol and received all three doses of study vaccine<sup>6</sup>
- TVC included all women who received at least one vaccine dose. This group comprised a diverse population of women including those with evidence of current or previous HPV infection and with high grade smear test results. This was intended to represent general population of sexually active young women<sup>6</sup>
- TVC-naïve included all women who received at least one vaccine dose and who had no evidence of previous or current HPV infection with oncogenic HPV types, and was intended to represent young girls prior to the onset of sexual activity<sup>6</sup>

- The efficacy and safety results from the interim analysis as well as the final event driven analysis of the HPV 008 study were published in The Lancet<sup>7</sup>

\*Vaccine efficacy differed for each of the HPV types 16, 18, 31, and 45, and varied in different cohorts and endpoints.

### About HPV-010 study

- The phase III, randomised, observer-blind trial involved 1,106 healthy women aged 18-45 years at 40 centres across the United States
- This comparative clinical study – the first of its kind – was carried out to compare the immune response, tolerability and safety of the two available cervical cancer vaccines CERVARIX™ and GARDASIL®
- The study looked at neutralising antibodies and memory B cells, two key measures believed to predict how effectively a vaccine will protect women from cervical cancer over the long term<sup>8,9,10,11,12</sup>

GARDASIL® is a registered trademark of Merck Frosst Canada.

### For more information or to arrange an interview, please contact:

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<sup>1</sup> Romanowski B. Efficacy of the HPV-16/18 adjuvanted vaccine against non-vaccine oncogenic HPV types: End-of-study results. Abstract presented at the 26<sup>th</sup> International Papillomavirus Congress (IPC), Montreal, Canada. July 2010.

<sup>2</sup> Bulk S et al. Incidence and survival rate of women with cervical cancer in the Greater Amsterdam area. *British Journal of Cancer* 2003; 89: 834-839.

<sup>3</sup> Castellsagué X et al. Worldwide Human Papillomavirus Etiology of Cervical Adenocarcinoma and Its Cofactors: Implications for Screening and Prevention. *Journal of the National Cancer Institute* 2006; 98 (5): 303-315.

<sup>4</sup> Paavonen J, Naud P et al. End-of-study results of PATRCIA: A phase III efficacy study of HPV-16/18 AS04-adjuvanted vaccine in young women. Abstract presented at the 26<sup>th</sup> International Papillomavirus Congress (IPC), Montreal, Canada. July 2010.

<sup>5</sup> Pimenta J et al. Estimates of the global burden of cervical adenocarcinoma: impact of HPV vaccination. Abstract presented at the 19th FIGO World Congress of Gynaecology and Obstetrics 4-10 October 2009; Cape Town, South Africa.

<sup>6</sup> CERVARIX™ Product Monograph, GlaxoSmithKline Inc., March 2010.

<sup>7</sup> Paavonen J, Naud P, Romanowski B, Aoki F MD. Efficacy of human papillomavirus 16/18 AS04-adjuvanted vaccine against cervical infection and precancer caused by oncogenic HPV types. *The Lancet*, 2009; 374: 301-314.

<sup>8</sup> Stanley M et al. Chapter 12: Prophylactic HPV vaccines: Underlying mechanisms. *Vaccine*. 2006; 24 Suppl 3:S106-13.

<sup>9</sup> Giannini SL et al. Enhanced humoral and memory B-cellular immunity using HPV16/18 L1 VLP vaccine formulated with the MPL/aluminium salt combination (AS04) compared to aluminium salt only. *Vaccine* 2006; 24:5937-5949.

<sup>10</sup> Inglis S et al. Chapter 11: HPV vaccines: Commercial Research & Development. *Vaccine* 2006;24 Suppl 3:S99-S105.

<sup>11</sup> Villa LL. Vaccines against papillomavirus infections and disease. *Rev Chilena Infectol*. 2006; 23:157-163.

<sup>12</sup> David M-P, et al., Long-term persistence of anti-HPV-16 and -18 antibodies induced by vaccination with the AS04-adjuvanted cervical cancer vaccine: Modeling of sustained antibody responses, *Gynecol Oncol* (2009), doi:10.1016/j.ygyno.2009.01.011.