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Health Canada approves CERVARIX™, new GSK cervical cancer vaccine

Shown to provide the longest protection against cervical cancer

Mississauga, ON (February 9, 2010) - Health Canada has approved CERVARIX™ [Human papillomavirus vaccine (Types 16 and 18) Recombinant, AS04 adjuvanted]. CERVARIX™ is a vaccine intended to protect females against cervical cancer (cancer of the lower part of the uterus or womb) and abnormal and precancerous cervical lesions (changes in cells of the cervix that have a risk of turning into cancer). It is indicated for girls and women between the ages of 10 and 25.¹

“In Canada, more than one woman dies every day from cervical cancer, a disease that is largely preventable,” says Dr. Barbara Romanowski, Clinical Professor of Medicine, Division of Infectious Diseases at the University of Alberta. “Together with regular Pap tests, CERVARIX™ reduces the risk of cervical cancer caused by HPV types 16 and 18, by 98 per cent.”

CERVARIX™ has the longest duration of protection reported for any licensed cervical cancer vaccine². It is the only vaccine that has demonstrated that virtually all women tested still have protective antibodies against both HPV 16 and 18 up to 6.4 years.³

CERVARIX™ contains a unique adjuvant system, AS04, which has been added to the vaccine to improve the immune response by providing stronger and longer protection as compared with a traditional adjuvant.⁴ Duration of protection is particularly important as almost all women are at risk of HPV infection and cervical cancer throughout their lives.

Kathy Smith, a 41 year old mother and cervical cancer survivor, encourages women across the country to get vaccinated. “Cervical cancer can be fatal,” she said. “I was fortunate enough to have won my battle, but not everyone does. We should do everything we can to protect ourselves and our loved ones against this disease. The first thing we can and should do is get vaccinated – it just makes sense.”

CERVARIX™ has shown protection beyond HPV 16 and HPV 18. GSK’s Phase III clinical trial, which included over 18,000 women, evaluated the efficacy of HPV types 16 and 18 as well as other cancer causing HPV types. In this trial several subsets of women were analyzed. In one analysis CERVARIX™ demonstrated protection against HPV type 45 in addition to types 16 and 18. In another, CERVARIX™ demonstrated protection against HPV type 31 in addition to types 16 and 18.⁵ HPV types 45 and 31 are the third and fourth leading causes of cervical cancer.⁶

“When it comes to preventing cervical cancer, women have to be very diligent,” said Dr. Dion Neame, Medical Advisor Vaccines, GlaxoSmithKline Inc. “Cervical cancer vaccination and regular Pap screening is the best way to achieve the ultimate goal – to provide women with the best possible protection against cervical cancer.”

CERVARIX™ is effective against CIN1 (cervical lesions) caused by HPV-16 and 18.⁷ These lesions contribute to approximately 325,000 abnormal Paps every year in Canada which may require surgical intervention.

CERVARIX™ is now approved in over 100 countries around the world. To date ten million doses have been distributed globally.

CERVARIX™ is generally well tolerated. The most common local adverse reactions and general adverse events in ≥20% of subjects were pain, redness, and swelling at the injection site, fatigue, headache, myalgia, gastrointestinal symptoms, and arthralgia.

About cervical cancer

Women are at risk of HPV infection and cervical cancer throughout their lives and it is estimated that more than two million women who could be getting vaccinated are not taking advantage.⁸

- Approximately one woman loses her life every 20 hours in spite of regular Pap screening programs. Vaccination alongside regular Pap screening is critically important because it could reduce the risk of developing cervical cancer caused by HPV-16 and 18 by 98 per cent, compared to no intervention.⁹
- 99 per cent of women age 10 to 25 could benefit from a cervical cancer vaccine.¹⁰
- Annually 1,450 (one every 6 hours) Canadian women will be diagnosed with cervical cancer.¹¹
- As many as 80 per cent of women will be infected with HPV in their lifetime.¹²
- Up to 60 per cent of women will be infected with cancer causing types in their lifetime.^{13,14}
- Among Canadian women aged 20-44, cervical cancer incidence ranks second only to breast cancer.¹⁵
- Cervical cancer is a major health, psychological and social burden on women everywhere.
- Approximately four million Pap tests are done every year in Canada. About 8 per cent (over 325,000) have abnormal results.¹⁶

Approximately 100 types of human papillomavirus have been identified to date and, of these, approximately 15 virus types are considered to cause cervical cancer.^{17,18 19}

About GlaxoSmithKline

GlaxoSmithKline Inc. – one of the world’s leading research-based pharmaceutical, vaccine and healthcare 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 a top 15 investor 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 or www.cervarix.ca.

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Notes for editors:

Clinical trial information:

Health Canada’s approval follows a review of data from clinical trials which involved almost 30,000 women and which evaluated efficacy, immunogenicity and safety data. The file included:

- Data from the largest Phase III cervical cancer vaccine efficacy trial to date called *HPV 008 PATRICIA (PApilloma TRial Cervical cancer In young Adults)*²⁰
 - This multi-centre, double-blind, randomized study that 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
 - This study assessed the efficacy of CERVARIX™ in the prevention of precancerous lesions and efficacy against 6 and 12 month persistent infection and High grade pre-cancerous lesions caused by HPV-16 or HPV-18 or other cancer-causing virus types as well as immunogenicity and safety,

- Study participants were randomized 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; vaccine=8093; control=8069)
 - Total vaccinated cohort (TVC; vaccine=9319, control=9325)
- ATP included all women who met eligibility criteria, complied with the trial protocol and received all three doses of study vaccine
- 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 a real world, general population of sexually active young women¹
- Data from a long term Phase II efficacy study of CERVARIX™²¹
 - 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 CERVARIX or three doses of placebo on a 0, 1 and 6 month schedule.
 - This study was conducted in the US, Canada and in Brazil and evaluated the efficacy, safety and immunogenicity of CERVARIX™ for the prevention of HPV-16 and or HPV-18 infections as well as associated Pap smear abnormalities and cervical lesions.
 - This extended follow-up study looked at study endpoints for 776 women from the same cohort of women for a period of up to 76 months.

Statements about Cervical Cancer Vaccination

In Canada and worldwide, cervical cancer and its precursors continue to be a significant health problem for women. The Society of Gynecologic Oncology of Canada (GOC) strongly supports the integration of cervical cancer vaccines in our cervical cancer prevention programs.

The new CERVARIX™ studies demonstrate a wider spectrum of coverage of cancer-causing HPV types, raising the potential for even greater cancer protection and reinforcing the role of vaccination in the prevention of cervical cancer and precursor lesions.

At the present time, vaccination combined with regular Pap testing offers the optimal approach to prevention of cervical cancer.

Marie Plante, MD, FRCSC
President
The Society of Gynecologic Oncology of Canada

In Canada, one woman loses her life every day from cervical cancer. In addition, more than 1,000 Canadian women are told every day that their Pap test results are abnormal. This causes a significant amount of anxiety and distress that may be preventable.

The Society of Canadian Colposcopists welcomes an additional vaccine that can protect women against this deadly cancer.

The Society of Canadian Colposcopists

The Federation of Medical Women of Canada supports the use of the HPV (Human Papillomavirus) vaccine for Canadian women, including the recently-approved CERVARIX™ vaccine. Cervical cancer and abnormal Pap smears caused by cancer-causing HPV strains are preventable and we urge women and their physicians to take advantage of the protection these vaccines offer.

The Federation of Medical Women of Canada

“Each year, approximately 580 Canadian women die of cervical cancer, with thousands more receiving the diagnosis. Women are dying needlessly from this largely preventable disease. CERVARIX™ is a welcomed addition to Canada’s arsenal in the fight against HPV and cervical cancer.”

Dr. Michel Fortier,
President of the Society of Obstetricians and Gynaecologists of Canada.

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