

## **STUDY SHOWS HPV-16 VACCINE DEMONSTRATED MORE THAN 8 YEARS OF PROTECTION AGAINST DISEASE**

*Other study shows GARDASIL® significantly reduced abnormal Pap tests  
and follow-up procedures*

**Kirkland, Quebec - May 8, 2009** – The monovalent human papillomavirus (HPV) type 16 L1 virus-like particle (VLP) vaccine demonstrated efficacy against HPV-16 infection for an average of 8.5 years in a Phase II extension follow-up study, according to data presented at the 25th Annual International Papillomavirus Conference in Malmö, Sweden. The monovalent vaccine is a component of GARDASIL® [Quadrivalent Human Papillomavirus (Types 6, 11, 16, 18) Recombinant Vaccine].

“Canadian physicians are frequently asked about the long-term efficacy of the HPV vaccine. I am therefore encouraged by these results for the HPV-16 vaccine showing more than eight years of protection against the major cervical cancer causing HPV type,” said Marc Steben, Canadian physician and HPV vaccine investigator.

In another study in women who were naïve to 14 common HPV types, GARDASIL® reduced the number of abnormal Pap test results by 17 to 45 per cent, depending on the abnormality, and reduced colposcopies by 20 per cent, cervical biopsies by 22 per cent as well as surgery and other invasive treatments by 42 per cent.

“Every year in Canada, there are approximately 400,000 abnormal Pap tests, which lead to thousands of other resource-intensive procedures such as colposcopies and cervical biopsies,” said James A. Mansi, Regional Director, Medical Affairs, Vaccines, Merck Frosst Canada. “Abnormal Pap tests and treatment of precancerous cervical lesions have been calculated to cost Canadians close to \$300 million a year.”

“When I tell patients that their Pap tests are abnormal, not only do they have to deal with this immediate stressful reality but also with further tests and treatments that can be equally or more stressful,” said Marc Steben. “Abnormal Pap tests and the necessary follow-up procedures have a real human cost that should not be underestimated.”

GARDASIL® is currently indicated for use in girls and young women 9 through 26 years of age for the prevention of cervical cancer, vulvar cancer, vaginal cancer, their precancerous lesions and genital warts caused by HPV types 6, 11, 16 and 18.

## **Efficacy of the Prophylactic Human Papillomavirus (HPV) type 16 L1 Virus-like Particle (VLP) Vaccine**

The HPV 16 VLP vaccine, a component of GARDASIL®, remained effective against HPV-16 infection and associated precancerous lesions an average of 8.5 and up to 9.5 years after administration, as demonstrated in a follow-up study of 290 women from a randomized, placebo-controlled clinical trial.

These women had participated in a Phase IIb randomized-controlled trial of the prophylactic HPV-16 L1 VLP vaccine between November 1998 and January 2004. They were enrolled in an extended follow-up study between March 2006 and May 2008 to evaluate the vaccine's long-term efficacy.

During the extended follow-up period, no one in the vaccine group developed HPV-16 infection (vaccine efficacy = 100 per cent; 95 per cent confidence interval [CI]: 25 to 100 per cent) or HPV-16 associated cervical intraepithelial neoplasia (CIN) (vaccine efficacy = 100 per cent; 95 per cent confidence interval [CI]: <0 to 100 per cent). In the placebo group, six women developed HPV-16 infection and three women developed HPV-16 associated CIN during the follow-up period.

During the combined trial and extended follow-up period, vaccine efficacy against HPV-16 infection was 96 per cent (95 per cent CI: 73 to 100 per cent) and 100 per cent against CIN in the vaccine group (95 per cent CI: 47 to 100 per cent). In the placebo group, 21 women developed HPV-16 infection and eight women developed HPV-16 associated CIN.

## **Impact of GARDASIL® on Abnormal Pap Tests and Procedures**

In two randomized, placebo-controlled, efficacy trials, a total of 17,622 women received either three doses of GARDASIL® or placebo over six months. Pap testing occurred at the start of the study and then at intervals of six to 12 months. An analysis of the reduction of healthcare utilization endpoints (Pap tests and procedures) was conducted in a population of women who were naïve to 14 common HPV types and had a normal Pap test on day 1. The analysis evaluated squamous intraepithelial lesions (SIL) which are similar to cervical intraepithelial neoplasia (CIN) except that CIN is evaluated through a microscope and SIL is evaluated through further microbiological study of the cells.

After an average follow-up of 3.6 years, when compared to women receiving placebo (n=4679), women who received GARDASIL® (n=4616) had significant reductions in the following abnormal Pap test results: atypical squamous cells of undetermined significance associated with a high risk type of HPV (17 to 22 per cent reduction), low-grade squamous intraepithelial lesion (17 per cent reduction), atypical squamous cells/cannot exclude high-grade squamous intraepithelial lesion (36 per cent reduction), and high-grade squamous intraepithelial lesion (45 per cent reduction).

## **The Significant Burden of HPV**

Three in four (75 per cent) sexually active Canadians will have at least one HPV infection in their lifetime.<sup>1</sup> While most infections will clear on their own, the burden of genital HPV-related diseases is significant. In addition to 400,000 abnormal Pap tests, HPV infections in Canada annually lead to approximately 85,000 consultations due to genital warts and 41,450<sup>2</sup> new cases of genital warts, as well as 1,400 cervical cancer diagnoses and 400 cervical cancer deaths.<sup>3</sup>

To consult the April 10 position paper on human papillomavirus by the World Health Organization, go to: <http://www.who.int/immunization/documents/positionpapers/en/index.html>

## **About Merck Frosst**

At Merck Frosst, patients come first. Merck Frosst Canada Ltd. is a research-driven pharmaceutical company discovering, developing and marketing a broad range of innovative medicines and vaccines to improve human health. Merck Frosst is one of the top 25 R&D investors in Canada, with an investment of close to \$110 million in 2007. More information about Merck Frosst is available at <http://www.merckfrosst.com>

## **Forward-Looking Statement**

This press release contains "forward-looking statements" as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements are based on management's current expectations and involve risks and uncertainties, which may cause results to differ materially from those set forth in the statements. The forward-looking statements may include statements regarding product development, product potential or financial performance. No forward-looking statement can be guaranteed, and actual results may differ materially from those projected. Merck undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise. Forward-looking statements in this press release should be evaluated together with the many uncertainties that affect Merck's business, particularly those mentioned in the cautionary statements in Item 1 of Merck's Form 10-K for the year ended Dec. 31, 2006, and in its periodic reports on Form 10-Q and Form 8-K, which the Company incorporates by reference.

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<sup>1</sup> Health Canada, *It's Your Health HPV* Web site.

(Accessed at [http://www.hc-sc.gc.ca/iyh-vsv/diseases-maladies/hpv-vph\\_e.html](http://www.hc-sc.gc.ca/iyh-vsv/diseases-maladies/hpv-vph_e.html)).

<sup>2</sup> Twenty Year Trends (1985-2004) in the Incidence and Prevalence of Anogenital Warts in Manitoba. 2008 Report to Cancer Care Manitoba. p. 37.

<sup>3</sup> Health Canada Web site. (Accessed at: <http://www.hc-sc.gc.ca/hl-vs/pubs/women-femmes/cancer-eng.php>)