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## **HEALTH CANADA APPROVES GARDASIL® FOR WOMEN UP TO AGE 45**

**KIRKLAND, Quebec – April 26, 2011** – Today, Merck announced that Health Canada has extended the indication of GARDASIL® [Human Papillomavirus Quadrivalent (Types 6, 11, 16, and 18) Recombinant Vaccine] in women up to the age of 45. Merck's HPV vaccine is now approved for girls and women nine through 45 years of age for the prevention of cervical cancer, vulvar and vaginal cancers, precancerous lesions and genital warts caused by the Human Papillomavirus (HPV) types 6, 11, 16, 18. Previously, GARDASIL® was approved in girls and women nine through 26.

“The decision to be vaccinated against HPV-related diseases as an adult should be taken by each individual woman in consultation with her healthcare professional,” said Dr. Vivien Brown, a family physician on staff at Mount Sinai Hospital, the University Health Network and North York General Hospital. “The HPV quadrivalent vaccine is not only for young people, both girls and boys, who have not yet been exposed to HPV, it’s also effective in older women.”

“Whatever the reason, there’s a tendency for women to remain at risk of acquiring new HPV infections as they get older. Whether they are changing their social status or not, women should talk to their doctors about the HPV protection provided by the quadrivalent vaccine,” said Dr. Alex Ferenczy, Professor of Pathology and Obstetrics & Gynecology at McGill University. “Evidence based medicine now suggests that physicians may propose the HPV quadrivalent vaccine to female patients up to age 45, on an individual basis.”

GARDASIL® was also approved in February 2010 for boys and men nine through 26 years of age for the prevention of infection caused by HPV types 6, 11, 16, and 18 and genital warts caused by HPV types 6 and 11.

### **Efficacy in women up to age 45**

GARDASIL® was evaluated in a placebo-controlled, double-blind, randomized efficacy study (FUTURE III) conducted in 3,817 women aged 24 to 45 years. The primary analysis was conducted in the per protocol efficacy (PPE) population which consisted of individuals who received all three vaccinations within one year of enrolment, did not have any major deviations from the study protocol, and who were naïve to HPV types 6, 11, 16 and 18 when they started the study and remained free of infection to these four HPV types through one month after receiving their last vaccine dose.

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The efficacy of GARDASIL<sup>®</sup> against the combined incidence of HPV 6-, 11-, 16- or 18-related persistent infection, genital warts, vulvar and vaginal lesions, CIN of any grade and AIS—the immediate precursors to cervical cancer and cervical adenocarcinoma—and cervical cancers was 88.7% (95% CI: 78.1, 94.8).

The most common systemic adverse reaction observed was headache. Other common adverse reactions that were observed among recipients of GARDASIL<sup>®</sup> at a frequency of at least 1.0 percent and greater than placebo were: fever, nausea, dizziness, injection-site pain, swelling, redness or itching of the skin and bruising.

### **At high risk up to age 45**

Women are at high risk for diseases caused by HPV types 6, 11, 16 and 18 up to the age of 45.<sup>1</sup> The lifetime risk for acquiring genital warts—highest for both men and women between the ages of 15 and 34—has been estimated to exceed 10%.<sup>2</sup>

In a Canadian study published in 2009 in the journal, *Sexually Transmitted Diseases*, more than half (56 per cent) of individuals in a new sexual relationship were infected by HPV.<sup>3</sup> Each year in Canada HPV infections lead to approximately 350,000 abnormal Pap smear results<sup>4</sup>, 41,450 new cases of genital warts<sup>5</sup>, 1,350 cervical cancer diagnoses and 400 cervical cancer deaths.<sup>6</sup> After breast cancer, cervical cancer is the most common cancer in Canadian women between the ages of 20 and 44.<sup>7</sup>

### **About Merck**

Today's Merck is a global healthcare leader working to help the world be well. Merck is known as MSD outside the United States and Canada. Through our medicines, vaccines, biologic therapies, and consumer and animal products, we work with customers and operate in more than 140 countries to deliver innovative health solutions. We also demonstrate our commitment to increasing access to healthcare through far-reaching policies, programs and partnerships. For more information about our operations in Canada, visit [www.merck.ca](http://www.merck.ca).

### **Forward Looking Statement**

This news release includes "forward-looking statements" within the meaning of the safe harbor provisions of the United States Private Securities Litigation Reform Act of 1995. Such statements may include, but are not limited to, statements about the benefits of the merger between Merck and Schering-Plough, including future financial and operating results, the combined company's plans, objectives, expectations and intentions and other statements that are not historical facts. Such statements are based upon the current beliefs and expectations of Merck's management and are subject to significant risks and uncertainties. Actual results may differ from those set forth in the forward-looking statements. The following factors, among others, could cause actual results to differ from those set forth in the forward-looking statements: the possibility that the expected synergies from the merger of Merck and Schering-Plough will not be realized, or will not be realized within the expected time period; the impact of pharmaceutical

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industry regulation and health care legislation; the risk that the businesses will not be integrated successfully; disruption from the merger making it more difficult to maintain business and operational relationships; Merck's ability to accurately predict future market conditions; dependence on the effectiveness of Merck's patents and other protections for innovative products; the risk of new and changing regulation and health policies in the United States and internationally and the exposure to litigation and/or regulatory actions. Merck undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in Merck's 2009 Annual Report on Form 10-K and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site ([www.sec.gov](http://www.sec.gov)).

**NOTE TO EDITORS:**

**B-ROLL AVAILABLE TODAY (APRIL 26, 2011) IN ENGLISH AND FRENCH BETWEEN 10:00 AND 11:00 AM EDT AND BETWEEN 12:00 AND 12:30 PM EDT IN ENGLISH ONLY.**

**Coordinates:**

Anik F2C 3B  
Downlink Freq: 3820 V  
Audios 6.2 and 6.8  
Telesat: 219555

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<sup>1</sup> GARDASIL<sup>®</sup> Product Monograph approved on April 14, 2011, page 18.

<sup>2</sup> GARDASIL<sup>®</sup> Product Monograph approved on April 14, 2011, page 18.

<sup>3</sup> Burchell A.N., Tellier P-P., et al. Influence of Partner's Infection status on Prevalent Human Papillomavirus Among Persons With a New Sex Partner. *Sexually Transmitted Diseases 2009*; 36(12): Epub 2009 Aug 21.

<sup>4</sup> GARDASIL<sup>®</sup> Product Monograph approved on April 14, 2011, page 56.

<sup>5</sup> GARDASIL<sup>®</sup> Product Monograph approved on April 14, 2011, page 19.

<sup>6</sup> GARDASIL<sup>®</sup> Product Monograph approved on April 14, 2011, page 18.

<sup>7</sup> GARDASIL<sup>®</sup> Product Monograph approved on April 14, 2011, page 18.