

Media contacts:

Sheila Murphy
Merck
514-428-2748

Roch Landriault / Stephanie Lyttle
NATIONAL Public Relations
514-843-2345 / 514-843-2365

GARDASIL[®] APPROVED TO HELP PREVENT ANAL CANCER IN WOMEN AND MEN

KIRKLAND, Quebec – May 31, 2011 – Today, Merck announced that Health Canada has approved a new indication for GARDASIL[®] [Quadrivalent Human Papillomavirus (Types 6, 11, 16, 18) Recombinant Vaccine] for the prevention of anal cancer in both men and women caused by HPV types 16 and 18 and anal precancerous lesions caused by HPV types 6, 11, 16 and 18.

“Anal cancer affects both men and women. It is not a disease restricted either to homosexual men or to people who engage in anal sex,” said Dr. Jennifer Blake, Professor and Associate Chair, Department of Obstetrics and Gynaecology, Faculty of Medicine, University of Toronto. “This newest indication for the quadrivalent HPV vaccine increases the reasons for vaccinating both genders.”

Efficacy against anal cancer

The efficacy of GARDASIL[®] against anal disease – anal intraepithelial neoplasia (AIN) and anal cancer – was evaluated in a population of 598 men who have sex with men between 16 and 26 years of age. 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 were naïve to HPV types 6, 11, 16 and 18 when they started the study and remained free of infection from these four HPV types through one month after receiving their last vaccine dose.¹

The efficacy of GARDASIL[®] in reducing the combined incidence of AIN grades 1, 2 and 3 related to vaccine HPV types 6, 11, 16 and 18 was 77.5% (95% CI: 39.6%; 93.3%). The efficacy against the more advanced pre-cancers, AIN 2/3, in the post-hoc analysis was 91.7% (95% CI: 44.6%; 99.8%).²

Anal cancer on the rise

“Anal cancer is on the rise in Canada and around the world,” said Dr. Marc Steben, a family physician and expert in sexually transmitted diseases. “Given there are no screening tests for anal cancer, doctors should talk to their patients about preventing anal cancer and other HPV diseases through vaccination.”

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The incidence of anal cancer has been increasing in both men and women over the last five decades.³ Approximately 100,000 new cases of anal cancer are estimated to occur annually around the world.⁴ In Canada, there are about 358 new cases of anal cancer every year, 156 in men and 202 in women.⁵ The great majority of anal cancers are squamous cell carcinoma (SCC) and these cancers are HPV positive in 80 to 90% of cases in men and women.⁶ HPV types 16 and 18 cause approximately 90% of HPV-related anal cancers.⁷ It is estimated that 75% of sexually active Canadians will have at least one HPV infection during their lifetime.⁸

Current Indications⁹ for GARDASIL[®]

GARDASIL[®] is now indicated in girls and women nine through 45 years of age for the prevention of infection caused by the Human Papillomavirus (HPV) types 6, 11, 16 and 18 and the following diseases associated with the HPV types included in the vaccine:

- Cervical, vulvar and vaginal cancer caused by HPV types 16 and 18
- Genital warts (condyloma acuminata) caused by HPV types 6 and 11

And the following precancerous or dysplastic lesions caused by HPV types 6, 11, 16 and 18:

- Cervical adenocarcinoma *in situ* (AIS)
- Cervical intraepithelial neoplasia (CIN) grade 2 and grade 3
- Vulvar intraepithelial neoplasia (VIN) grade 2 and grade 3
- Vaginal intraepithelial neoplasia (VaIN) grade 2 and grade 3
- Cervical intraepithelial neoplasia (CIN) grade 1

GARDASIL[®] is also indicated in girls and women nine through 26 years of age for the prevention of:

- Anal cancer caused by HPV types 16 and 18
- Anal intraepithelial neoplasia (AIN) grades 1, 2 and 3 caused by HPV types 6, 11, 16 and 18

GARDASIL[®] is also indicated in boys and men nine through 26 years of age for the prevention of infection caused by HPV types 6, 11, 16 and 18 and the following diseases associated with the HPV types included in the vaccine:

- Anal cancer caused by HPV types 16 and 18
- Genital warts (condyloma acuminata) caused by HPV types 6 and 11
- Anal intraepithelial neoplasia (AIN) grades 1, 2 and 3 caused by HPV types 6, 11, 16 and 18

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 prescription medicines, vaccines, biologic therapies, and consumer care and animal health 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, visit www.merck.ca.

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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 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).

¹ GARDASIL[®] Product Monograph, May 24, 2011.

² GARDASIL[®] Product Monograph, May 24, 2011.

³ WHO/ICO Information Center on HPV and Cervical Cancer (HPV Information Centre). Human Papillomavirus and Related Cancers in Canada. Summary Report 2010.

⁴ GARDASIL[®] Product Monograph, May 24, 2011.

⁵ WHO/ICO Information Center on HPV and Cervical Cancer (HPV Information Centre). Human Papillomavirus and Related Cancers in Canada. Summary Report 2010.

⁶ GARDASIL[®] Product Monograph, May 24, 2011.

⁷ GARDASIL[®] Product Monograph, May 24, 2011.

⁸ GARDASIL[®] Product Monograph, May 24, 2011.

⁹ GARDASIL[®] Product Monograph, May 24, 2011.