



News Release

Media Contact:

Sheila Murphy

Manager, Public Affairs

Merck

514-428-2748

Montreal

NATIONAL Public Relations

Roch Landriault 514-843-2345

Stephanie Lyttle 514-843 2365

Calgary

NATIONAL Public Relations

Lauren Piercy

403-531-0331 ext. #499

Toronto

NATIONAL Public Relations

Lynn Bessoudo

416-848-1426

Winnipeg

Barbara Biggar

204-781-0747

GARDASIL® APPROVED BY HEALTH CANADA FOR MALES TO PREVENT GENITAL WARTS

KIRKLAND, Quebec – February 23, 2010 – Today, Merck announced that Health Canada has approved GARDASIL® [Human Papillomavirus Quadrivalent (Types 6, 11, 16, and 18) Recombinant Vaccine] 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.

“I see a large number of men with genital warts which are both difficult and painful to treat,” said Dr. Charles Lynde, a practising Dermatologist and Assistant Clinical Professor, University of Toronto. “We have many treatments for genital warts which are often not all that effective. With Health Canada's approval of the use of Merck's vaccine in males, now rather than treating them after the fact, the prevention of warts for both sexes is possible in this country.”

“Often genital warts are imperceptible for many months, making it difficult for partners to see them,” said Dr. Marni Wiseman, a Dermatologist and Assistant Professor at the University of Manitoba. “Once out in the open, genital warts can have a major impact on a couple's sexual relationship.”

“Sophisticated research has shown viral DNA in the skin cells of young women at the location of genital warts after the warts have been destroyed and no longer visible,” said Dr. Kirk Barber, a practising Dermatologist and Associate Clinical Professor of Dermatology at the University of Calgary. “I suspect that this is the reason that recurrence rates are so high in both young women and men.”

“Social stigma is associated with all sexually transmitted diseases and genital warts is no exception,” said Dr. Marc Steben, a Canadian expert in sexually transmitted infections.

(more)

“You feel invincible when you’re young and getting genital warts has affected me. I kept to myself and I didn’t date a lot after that. I am not at all comfortable talking about genital warts with friends, family, partners,” admitted a young man who has been living with genital warts for 10 years.

HPV is the most common sexually transmitted infection in Canada and genital warts are common among males. Most (90 per cent) genital warts are caused by HPV types 6 and 11;¹ more than 40,000 new cases of ano-genital warts are estimated yearly for Canadian men and women.²

High level of shared HPV infections

In a Canadian study recently published in *Sexually Transmitted Diseases* more than half (56 per cent) of young people in a new sexual relationship were infected by HPV. Those infected were, on average, infected with 2.8 types of HPV.³

Men play an important role in the transmission of HPV to their sexual partners. Research has shown a high level of sharing of HPV infections between couples who recently became infected.⁴

The data consistently support the sexually transmitted nature of HPV and the role of men in infecting women, who subsequently can develop HPV-related ano-genital cancers and genital warts. Based on these various lines of evidence it is expected that decreasing the risk of HPV infection in men through vaccination should decrease the risk of infection in their sexual partners, thereby providing additional public health benefit.⁵

Significant decline in genital warts

In the Phase III clinical study conducted over three years with more than 4,000 males ages 16 to 26, the quadrivalent HPV vaccine was 89.4 per cent efficacious in reducing the incidence of genital warts related to HPV types 6 and 11 among males who were naïve to HPV types 6, 11, 16, and 18.⁶

A separate Australian retrospective study to assess the impact of the national vaccination program with the quadrivalent HPV vaccine on females showed early benefits from vaccination. The study found a significant decline in genital warts cases in the targeted female population as well as a drop in genital warts among heterosexual but not homosexual men.⁷

GARDASIL[®] is also indicated in girls and women nine through 26 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 these HPV types:

- Cervical cancer (*cancer of the lower end of the uterus or womb*)
- Vulvar (*the outside of the female genital area*) and vaginal cancers
- Genital warts (*condyloma acuminata*)
- Cervical adenocarcinoma *in situ* (AIS)—non invasive cancer
- Cervical intraepithelial neoplasia (CIN) grade 2 and grade 3 (*changes in cells of the cervix that have a risk of turning into cancer*)—commonly called pre-cancers

(more)

- Vulvar intraepithelial neoplasia (VIN) grade 2 and grade 3 (*abnormal lesions on the outside of the female genitalia that have a risk of turning into cancer*)—commonly called pre-cancers
- Vaginal intraepithelial neoplasia (VaIN) grade 2 and grade 3 (*abnormal lesions on the vagina that have a risk of turning into cancer*)—commonly called pre-cancers
- Cervical intraepithelial neoplasia (CIN) grade 1 (*changes in cells of the cervix that often clear up on their own*)—commonly called low-grade lesions

About Merck

Today's Merck is working to help the world be well. 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 programs that donate and deliver our products to the people who need them. Merck. Be Well. For more information, visit www.merck.com.

Forward Looking Statement

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, due to, among other things, the impact of pharmaceutical industry regulation and pending legislation that could affect the pharmaceutical industry; 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 U.S. 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 2008 Annual Report on Form 10-K, Schering-Plough's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2009, the proxy statement filed by Merck on June 25, 2009 and each company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site (www.sec.gov).

¹ Healthy Ontario © MediResource Inc., 2009. *HPV Infection Overview* [Online December 1, 2009] Available at: http://www.healthyontario.com/ConditionDetails.aspx?disease_id=345 [Accessed on November 23, 2009]

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

³ Bruchell A.N., Tellier P-P., et al 2009. Influence of Partner's Infection status on Prevalent Human Papillomavirus Among Persons With a New Sex Partner, *Sexually Transmitted Diseases*, 36(12)

⁴ GARDASIL product monograph

⁵ GARDASIL product monograph

⁶ GARDASIL product monograph

⁷ Fairley CK, Hocking J, et al, 2009. Rapid Decline in Presentations for Genital Warts after the Implementation of a National Quadrivalent Human Papillomavirus Vaccination Program for Young Women, *Sexually Transmitted Infections* [Online] (October 16, 2009) <http://sti.bmj.com/content/85/7/499.full> [Accessed December 1, 2009].