

## **NEW STUDY ON MALES SHOWS GARDASIL® REDUCED HPV-RELATED DISEASES**

### ***First study on effectiveness of HPV vaccine in males***

**NICE, France – November 13, 2008** – GARDASIL® [Human Papillomavirus Quadrivalent (Types 6, 11, 16, and 18) Vaccine, Recombinant], “the HPV vaccine”, prevented 90 per cent of external genital lesions, including genital warts caused by HPV types 6, 11, 16 and 18 in a Phase III study in men aged 16 to 26 who were not infected with one or more of the four vaccine HPV types through one month post dose three. These data, presented at the European Research Organization on Genital Infection and Neoplasia (EUROGIN) International Multidisciplinary Conference taking place in Nice, France, are the first on the efficacy of the HPV vaccine in males.

“Almost everyone will acquire an HPV infection in their lifetime and these infections cause a significant burden of disease in Canada,” said Dr. François Coutlée, professor at the University of Montreal, study investigator and Clinical Researcher at the Molecular Virology Laboratory, CHUM - Hôpital Notre-Dame. “In fact, HPV diseases are on the rise among Canadian men so I am encouraged by these new results showing the efficacy of the HPV vaccine in males against diseases caused by HPV types 6, 11, 16 and 18.”

The HPV vaccine is not indicated for males. It was approved in Canada in 2006 for females nine 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.

### **The HPV vaccine reduced external genital lesions in males by 90 per cent**

This placebo-controlled study was designed to determine the efficacy of the HPV vaccine in males against HPV 6/11/16/18-related external genital lesions, a composite endpoint that included: 1) genital warts (condyloma), 2) penile/perineal/perianal intraepithelial neoplasia (or PIN; lesions that can be pre-cursors to cancer) and 3) penile/perineal/perianal cancer.

The study evaluated 3,400 heterosexual males 16 through 23 years of age and 600 men having sex with men 16 to 26 years of age. Participants were randomized in a 1:1 ratio to receive either the vaccine or placebo at day one, two months and six months, with 36 months of planned follow-up from day one. At the time of vaccination, participants had no evidence of genital lesions, no history of genital warts and five or fewer lifetime sexual partners.

## ***New study on males shows GARDASIL® reduced HPV-related diseases / 2***

In the study, the HPV vaccine was 90.4 per cent effective at reducing external genital lesions (three cases in the vaccine group vs. 31 cases in placebo group; 95 per cent CI: 69.2, 98.1, p-value <0.001). The three cases seen among those vaccinated with the HPV vaccine were all cases of genital warts, resulting in the vaccine being 89.4 per cent effective in preventing genital warts (95 per cent CI: 65.5, 97.9). For penile/perineal/perianal intraepithelial neoplasia or PIN, there were zero cases in the vaccine group vs. three cases of PIN 1 or PIN 2/3 in the placebo group. There were no cases of penile/perineal/perianal cancer in either the vaccine or placebo group.

No vaccine-related serious adverse events were reported in the male efficacy study. A slightly higher proportion of study participants reported injection-site adverse events in the vaccine group compared to placebo (60.1 per cent vs. 53.7 per cent).

### **The HPV vaccine also significantly decreased persistent HPV infection**

Two secondary endpoints also were evaluated in this pivotal study and results from these analyses were presented at EUROGIN. The vaccine was 85.6 per cent effective at reducing persistent infection (15 cases in the vaccine group vs. 101 cases in the placebo group; 95 per cent CI: 75.1, 92.2, p-value <0.001). In addition, the HPV vaccine was 44.7 per cent effective at reducing anytime HPV DNA detection (136 cases in the vaccine group vs. 241 cases in the placebo group; 95 per cent CI: 31.5, 55.6, p-value <0.001).

### **Human Papillomavirus: a virus that affects both men and women**

Genital human papillomavirus (HPV) is a common virus. There are more than 40 types of HPV that are passed on during sex. Most sexually active people will have HPV at some time in their lives.

Most people who get HPV (of any type) never develop any symptoms or health problems. But some types of HPV can cause genital warts. Other types can cause penile cancer or anal cancer. The types of HPV that can cause genital warts are not the same as the types that can cause penile or anal cancer.

A recent Canadian report estimated the number of new cases (both men and women) of ano-genital warts at 41,450 per year.<sup>1</sup> In the year 2003-04, there were 491 new cases of anal cancer (203 in men, 288 in women) and 142 new cases of penile cancer in Canada.<sup>2</sup>

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

<sup>2</sup> Cancer Incidence in Canada. 2003 to 2004, Second Edition. Statistics Canada, Health Statistics Division. p. 38.