



FOR IMMEDIATE RELEASE

**NEW STUDY SHOWS MERCK'S INVESTIGATIONAL VACCINE AGAINST
HUMAN PAPILLOMAVIRUS – THE WORLD'S MOST COMMON SEXUALLY TRANSMITTED
INFECTION – REDUCED INFECTION AND RELATED DISEASES**

VANCOUVER, BC - May 2, 2005 – GARDASIL™, the investigational vaccine against human papillomavirus (HPV) from Merck & Co., Inc., reduced the combined incidence of persistent HPV 6, 11, 16 and 18 infection and related diseases – including new cervical pre-cancers and genital warts – by 90 per cent compared to placebo. Results from this phase II study will be presented tomorrow in Vancouver for the first time at the 22nd International Papillomavirus Conference and were recently previewed in the online version of the international medical journal *The Lancet Oncology*.

“The level of protection in this study against infection with these four HPV types, including pre-cancerous lesions, was momentous,” said the study's lead investigator, Luisa Villa, PhD, head of the Virology Group at Brazil's Ludwig Institute for Cancer Research. “Though not originally designed to do so, the study showed that efficacy of the investigational vaccine against cervical pre-cancers caused by the HPV types 16, 18, 6 and 11 was 100 per cent.”

“Unfortunately, about 50 per cent of Canadian women who are discovered with cervical pre-cancer have not received a Pap test,” said Dr. Alex Ferenczy, Professor of Pathology and Obstetrics/Gynecology at McGill University. “And cancer of the cervix is the most common cancer that affects a woman's reproductive organs.”

“Genital warts, caused by HPV 6 and 11, are a highly troubling, distressing infection which results in a significant human and health care burden. Sparing patients this infection while preventing cervical cancer would be of great benefit to the women and men affected and could spare the health care system from a difficult to treat problem,” said Dr. Deborah Money, Assistant Professor and Head of the Division of Maternal Fetal Medicine, University of British Columbia. “In addition, the prevention of the uncommon but serious problem of childhood laryngeal infection would be very valuable.”

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New study on HPV/2

About the study

The randomized, double-blind, placebo-controlled study evaluated the efficacy of GARDASIL™ in preventing infection from the types of HPV responsible for 70 per cent of all cases of cervical cancer¹ and 90 per cent of all cases of genital warts.² In the study, 552 women between the ages of 16 and 23 were randomized to receive vaccine or placebo at day 1, month 2, and month 6.

The primary endpoint of the study was to assess the efficacy of the investigational vaccine in reducing the combined incidence of persistent HPV 6, 11, 16, and 18 infections and related diseases, including cervical pre-cancers (cervical intraepithelial neoplasia, or CIN), cervical cancer, and/or external genital warts.

Over the two and a half years of follow-up after vaccination, GARDASIL™ reduced the combined incidence of persistent infection from HPV 6, 11, 16, and 18 and related genital disease including new cervical pre-cancers and genital warts by 90 per cent compared with placebo among women who were naïve to the relevant HPV types at baseline (p<0.001).

“HPV types 6 and 11 are not linked to cervical cancer, but they can cause abnormal Pap smears, which then lead to additional tests – and unnecessary worries about cancer,” said Dr. Eliav Barr, Senior Director Biologics Research, Merck Research Laboratories. “GARDASIL™ was purposefully designed to target the HPV types most commonly associated with cervical cancer, as well as the types that cause genital warts and many abnormal Pap smears, to reduce the burden from HPV infection as much as possible.”

In the study, adverse events related to the injection site were higher among those who received GARDASIL™ compared with placebo recipients. The most common injection site and systemic adverse events were pain and headache, respectively. None of the subjects who received the investigational vaccine discontinued the study due to an adverse experience.

Phase III clinical trials to evaluate GARDASIL™ are currently underway with over 25,000 participants enrolled worldwide. Phase III data are expected to be available later this year.

GARDASIL™ is not approved for use in Canada.

New study on HPV/3

HPV, cervical cancer and genital warts

Between three to nine million Canadians are infected with HPV³ and it is estimated that 75 per cent of Canadians will have at least one HPV infection in their lifetime.⁴ In most people, HPV appears to go away on its own. In some, the virus has been linked to cervical cancer, abnormal Pap smear test results and genital warts.

- Cervical cancer is the third most frequent cancer in women between the ages of 20 and 49.⁵
- Genital warts are common in about two per cent of sexually active Canadian women.⁶

About Merck Frosst

At Merck Frosst, patients come first. Merck Frosst Canada & Co. is a research-driven pharmaceutical company. Merck Frosst discovers, develops, manufactures and markets a broad range of innovative medicines to improve human health. Merck Frosst is one of the top 20 R&D investors in Canada, with an investment of \$117 million in 2004. The Company is committed to fostering partnerships to deliver the most valuable health outcomes for Canadian patients. More information about Merck Frosst is available at <http://www.merckfrosst.com>.

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B-Roll will be transmitted via satellite Monday, May 2nd 2005

between 10:00 and 10:30 AM EST and between 1:00 and 1:30 PM EST.

Coordinates: Anik F2 C Band Analog, Transponder 3B, Audio subcarrier 6.2 and 6.8, Downlink frequency 3820 vertical.

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