

MERCK'S STUDY OF ITS INVESTIGATIONAL HPV VACCINE ON PREVIOUSLY INFECTED WOMEN REVEALS POSITIVE RESULTS

PARIS, France – April 26, 2006 – The investigational quadrivalent human papillomavirus (HPV types 6, 11, 16, 18) vaccine developed by Merck shows positive results for sexually active women who have already been infected with one or more of four HPV types—6, 11, 16 and 18. For women infected with one of these four HPV types, Merck's vaccine has shown to prevent 88 per cent of all grades of cervical intraepithelial neoplasia (CIN 1, 2, 3) and 91 per cent of all external genital lesions caused by the vaccine HPV types to which these women were still naive. The vaccine was also 100 per cent effective against high-grade cervical pre-cancer and high-grade vulvar or vaginal pre-cancer. These new findings were presented today at the European Research Organization on Genital Infection and Neoplasia (EUROGIN) Conference in Paris.

"Today's results show that sexually active women, who are already infected with at least one of the four HPV types covered by Merck's vaccine, still receive considerable protection from serious diseases like cervical, vaginal and vulvar cancer, as well as genital warts," said Dr. Marc Steben, Canadian Study Investigator and Lead Author, HPV Chapter, Canadian Guidelines on Sexually Transmitted Infections 2006 Edition. "These new findings are extremely encouraging because they typify what I see in my medical practice, where a significant percentage of young women have already been exposed to HPV."

"When I was nine years old, my mother, who was 29 at the time, died of cervical cancer, leaving behind a family of five children," recalls Manon Durocher. "A few years ago when Dr. Steben asked me to speak to my daughter, Marie-Eve, about participating in a study for a vaccine against cervical cancer, I immediately agreed. I am proud that Marie-Eve decided to help in the fight against cervical cancer. And with the study results being so positive, I hope to hear that she was part of the vaccine group."

Almost five thousand subjects were already HPV positive

Previously reported results for the investigational quadrivalent HPV vaccine dealt with the special case of naive subjects: women who had not been infected by any of the four vaccine HPV types (6, 11, 16 or 18) at enrolment. In these earlier findings, Merck's vaccine prevented 100 per cent of genital warts, cervical pre-cancers and non-invasive cancers.¹

The new findings presented at EUROGIN involve a real-life subset of 4,727 women, or 27.2 % of the trial population of 17,400 (number of subjects with no missing data), who were either DNA or antibody positive to at least one of the four vaccine HPV types. The women received either the vaccine or placebo at day 1, month 2, and month 6. The analysis started 30 days after the first vaccination with an average two years of follow-up.

This new analysis demonstrated that the quadrivalent HPV vaccine protected these infected women from diseases caused by the HPV types to which they were still naive. For example, a woman infected with HPV type 6 prior to vaccination obtained protection from disease caused by HPV 11, 16 or 18. There appears to be no interference among the four HPV types covered by the vaccine, as 100 per cent HPV type-specific efficacy was observed.

More precisely, the results show that Merck's quadrivalent HPV vaccine was:

- 88 per cent effective in preventing all grades of cervical intraepithelial neoplasia (CIN 1, 2, 3)
- 91 per cent effective at preventing external genital lesions, including genital warts, vulvar intraepithelial neoplasia (VIN1) or vaginal intraepithelial neoplasia (VaIN1)
- 100 per cent effective at preventing high-grade cervical pre-cancers (CIN 2/3) and non-invasive cervical cancers (adenocarcinoma in situ or AIS)
- 100 per cent effective at preventing high-grade vulvar pre-cancer or high-grade vaginal pre-cancer (VIN 2/3 or VaIN 2/3)

“An interesting observation from the findings is that Merck's vaccine was 100 per cent effective at preventing the more serious, high-grade pre-cancers of the cervix, vulva and vagina,” said Dr. Marc Steben. “These strong results against serious illness will definitely interest sexually active women.”

The vaccine is not approved in Canada.

About Merck Frosst

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Source:

1. Efficacy of a Prophylactic Quadrivalent Human Papillomavirus (HPV) (Types 6, 11, 16, 18) L1 Virus-Like Particle (VLP) Vaccine for Prevention of Cervical Dysplasia and External Genital Lesions (EGL). Presented by C. Sattler at the 45th Annual Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) in Washington, DC.

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FOR MORE INFORMATION PLEASE CONTACT:

Elise Giasson
Merck Frosst Canada Ltd.
(514) 428-3711

Nadia Paquet
NATIONAL PharmaCom
(514) 843-2351