

**FOR IMMEDIATE RELEASE**

**GARDASIL® MAY OFFER ADDITIONAL PROTECTION AGAINST  
10 EXTRA CANCER-CAUSING HPV TYPES**

*First study to meet WHO efficacy standards for cross-protection*

**MONTREAL, Quebec – October 5, 2007** – Gardasil® [Quadrivalent Human Papillomavirus (Types 6, 11, 16, 18) Recombinant Vaccine] has been shown to be up to 100 per cent effective at preventing cervical cancer caused by HPV types 16 and 18, which account for more than 70 per cent of all cases. It is also the only HPV vaccine effective at preventing most cases of genitals warts. In a recent study, Gardasil® has shown to provide 38 per cent cross-protection efficacy against 10 additional cancer-causing HPV types that contribute to approximately 20 per cent of cervical cancer cases around the world. These new findings are being presented today at the European Research Organization on Genital Infection and Neoplasia (EUROGIN) Conference in Monte Carlo.

Cross-protection is a term used to describe the potential impact that a vaccine designed to protect against certain types of HPV can have on other HPV not included in the vaccine. The new data presented at EUROGIN measured the efficacy of the four vaccine HPV types (6, 11, 16 and 18) to provide cross-protection against 10 additional HPV types (31, 33, 35, 39, 45, 51, 52, 56, 58 and 59). These 10 additional types were chosen because, when pooled together, they are the largest contributors to cervical cancer in the world, after HPV types 16 and 18.<sup>1</sup>

“This study examining the impact of an HPV vaccine on cervical disease caused by HPV types not found in the vaccine shows true cross-protection,” said Dr. Michel Roy, a gynaecologic oncologist at the Hôtel-Dieu de Québec Hospital and Professor of Gynaecology at the University of Laval. “This promising new data shows that the vaccine provides cross-protection against 10 cancer-causing types not found in the vaccine, indicating a potential extra benefit to HPV vaccination.”

**Cross-protection results based on studies of 17,599 women in 16 countries**

For this cross-protection study, researchers analyzed combined results from two studies, FUTURE I and FUTURE II, which were phase III, prospective, double-blind, placebo controlled, randomized studies conducted among 17,599 women ages 16 to 23 in 16 countries. Among generally HPV-naive women, vaccination with Gardasil resulted in:

- Reduced incidence of HPV 31- and HPV 45-related CIN\* 2/3 or AIS\*\* by 62 per cent;
- Reduced incidence of HPV 31-, 33-, 45-, 52-, and 58-related CIN 2/3 or AIS by 44 per cent;
- Reduced incidence of HPV 31-, 33-, 35-, 39-, 45-, 51-, 52-, 56-, 58-, 59-related CIN 2/3 or AIS by 38 per cent.

\* Abnormal changes in the cells of the cervix that will lead to cancer if not treated.

\*\* Adenocarcinoma in situ, an abnormal proliferation of glands that will lead to cancer if not treated.

## **HPV vaccine and cervical cancer**

While this new data on the broader protection for cervical cancer are compelling, it has been demonstrated that Gardasil® provides wider-ranging and earlier benefits than the prevention of cervical cancer alone.

"Wider benefit because it also helps prevent cervical lesions, vulvar lesions and genital warts; earlier benefit because cervical lesions and genital warts occur much faster than cervical cancer, often within only a few months after exposure to the virus," said Dr. Michel Roy.

Clinical studies have shown Gardasil to be 96 to 100 per cent effective at preventing diseases caused by the four HPV types (6, 11, 16 and 18) that account for more than 90 per cent of genital warts, approximately 70 per cent of cervical and anogenital cancers and high-grade pre-cancers as well as 35 to 50 per cent of low-grade cervical, vaginal and vulvar lesions. All four types also cause abnormal Pap test results.<sup>2</sup>

Three in four (75 per cent) sexually active Canadians will have at least one HPV infection episode in their lifetime.<sup>3</sup> HPV infections annually lead to approximately 400,000 abnormal Pap smear results,<sup>4</sup> 85,000 consultations due to genital warts and 36,000 new cases of genital warts,<sup>5</sup> as well as 1,400 cervical cancer diagnoses and 400 cervical cancer deaths.<sup>6</sup> HPV is also linked to other cancers in both men and women, such as cancer of the penis, anus, vagina and vulva, as well as loss of female fertility.<sup>7</sup>

## **About Merck Frosst**

At Merck Frosst, patients come first. Merck Frosst Canada Ltd. is a research-driven pharmaceutical company. Merck Frosst discovers, develops 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 \$114 million in 2006. 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>.

## 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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## MEDICAL EXPERT AVAILABLE FOR INTERVIEWS

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## SOURCES:

- <sup>1</sup> Brown, D, HPV Type 6/11/16/18 Vaccine: First Analysis of Cross-Protection against Persistent Infection, Cervical Intraepithelial Neoplasia (CIN), and Adenocarcinoma In Situ (AIS) Caused by Oncogenic HPV Types in Addition to 16/18. Presented at the 47th Annual Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) in Chicago.
- <sup>2</sup> 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.
- <sup>3</sup> Health Canada, *It's Your Health HPV* Web site.  
(Accessed at [http://www.hc-sc.gc.ca/iyh-vsv/diseases-maladies/hpv-vph\\_e.html](http://www.hc-sc.gc.ca/iyh-vsv/diseases-maladies/hpv-vph_e.html)).
- <sup>4</sup> Statement by the Society of Obstetricians and Gynaecologists of Canada (SOGC) on CMAJ Commentary, "Human papillomavirus, vaccines and women's health: questions and cautions". (Accessed on August 14, 2007 at: [http://www.sogc.org/media/guidelines-hpv-commentary\\_e.asp](http://www.sogc.org/media/guidelines-hpv-commentary_e.asp))
- <sup>5</sup> Brisson, M et al. The health and economic burden of HPV infection, genital warts, cervical dysplasia and cervical cancer in Canada. Presented at the 7<sup>th</sup> Canadian Immunization Conference (CIC) on December 3, 2006 in Winnipeg.
- <sup>6</sup> Public Health Agency of Canada, Cervical Cancer Screening in Canada: 1998 Surveillance Report, Executive Summary. (Accessed at [http://www.phac-aspc.gc.ca/publicat/ccsic-dccuac/exec\\_e.html](http://www.phac-aspc.gc.ca/publicat/ccsic-dccuac/exec_e.html)).
- <sup>7</sup> Statement by the Society of Obstetricians and Gynaecologists of Canada (SOGC) on CMAJ Commentary, "Human papillomavirus, vaccines and women's health: questions and cautions". (Accessed on August 14, 2007 at: [http://www.sogc.org/media/guidelines-hpv-commentary\\_e.asp](http://www.sogc.org/media/guidelines-hpv-commentary_e.asp))