

Media contacts:

Sheila Murphy

Merck
514-428-2748

Montreal

Stephanie Lyttle
NATIONAL Public Relations
514-843-2365

Toronto

Kristen King
NATIONAL Public Relations
416-848-1427

NEW DATA REINFORCES GARDASIL'S SAFETY PROFILE

KIRKLAND, Quebec – May 9, 2011 – A real-world study evaluating the safety of GARDASIL® [Human Papillomavirus Quadrivalent (Types 6, 11, 16, and 18) Recombinant Vaccine] among 189,629 females in California found no serious adverse events related to vaccination, no safety signals for any health event resulting in an emergency room visit or hospitalization and no safety signals associated with pre-specified autoimmune conditions or pregnancy outcomes. The data were presented at the European Research Organization on Genital Infection and Neoplasia (EUROGIN) conference in Lisbon, Portugal, May 8-12, 2011.

Among the attendants and presenters at the EUROGIN scientific sessions is Dr. Michel Roy, professor in the Department of Obstetrics and Gynaecology at Laval University in Quebec City. “The data from this large US study supports what the international clinical trials found: the quadrivalent HPV vaccine has a good safety profile. Available in Canada since 2006, the vaccine has been studied and used for about a decade now. The new safety data are reassuring especially regarding autoimmune and neurologic conditions.”

“This is a very helpful study that should lay to rest any lingering concerns regarding safety of the quadrivalent HPV vaccine. It is particularly relevant because it is a “real – world” test in a very large population, with good follow up” said Dr. Jennifer Blake, Professor and Associate Chair, Department of Obstetrics and Gynaecology, Faculty of Medicine, University of Toronto, presently onsite in Lisbon. “Many people have been asking for exactly this sort of evidence before getting vaccinated, or advising others to get vaccinated against HPV. This study answers that question.”

About the study

The observational database study of 189,629 females provided safety data on all females who received at least one dose of GARDASIL® at two large managed care organizations in California between August 2006 and March 2008. The study evaluated three main areas: general safety, including post-vaccination emergency room (ER) visits and hospitalizations; new onset of 16 pre-specified autoimmune conditions among all females; and pregnancy outcomes among females with inadvertent vaccination with the quadrivalent HPV vaccine during pregnancy.

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General safety outcomes were evaluated by comparing the incidence of ER or hospital electronic diagnosis codes shortly after vaccination to the incidence in a post-vaccination self-comparison period, using conditional logistic regression. Medical records of potential new onset cases of autoimmune conditions after receiving GARDASIL[®] as well as pregnancy outcomes (2,678 women received GARDASIL[®] during pregnancy) were reviewed by expert committees blinded to vaccination status. The incidence of new onset autoimmune conditions was compared to the incidence in an unvaccinated female population at the same managed care organizations. An independent external Safety Review Committee evaluated results for potential safety signals.

No serious adverse events related to vaccination were reported in the study. No safety signals were detected for any health event resulting in an ER visit or hospitalization within 60 days of each vaccination of GARDASIL[®]. And no safety signals associated with pre-specified autoimmune conditions or pregnancy outcomes were identified.

The adverse events seen in this study were related to fainting (syncope) on the day of vaccination (OR 6.0, 95% CI 3.9-9.2) and possible inflammation (cellulitis) within 14 days of vaccination (OR 1.6, 95% CI 1.2-2.3). Some of the cellulitis cases may have been misdiagnosed injection-site reactions.

GARDASIL[®] is now approved for girls and women nine through 45 years of age for the prevention of cervical cancer, vulvar and vaginal cancers, precancerous lesions and genital warts caused by the Human Papillomavirus (HPV) types 6, 11, 16, 18.

It was also approved in February 2010 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.

About Merck

Today's Merck is a global healthcare leader working to help the world be well. Merck is known as MSD outside the United States and Canada. Through our prescription medicines, vaccines, biologic therapies, and consumer care and animal health 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 policies, programs and partnerships. For more information, visit www.merck.ca.

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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 2009 Annual Report on Form 10-K and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site (www.sec.gov).