

## **European Commission Approves GARDASIL<sup>®</sup>, Merck's Cervical Cancer Vaccine**

WHITEHOUSE STATION, N.J., Sept. 22, 2006 - GARDASIL<sup>®</sup> [Quadrivalent Human Papillomavirus (Types 6, 11, 16, 18) Recombinant Vaccine], the cervical cancer vaccine from Merck & Co., Inc., has been granted a license by the European Commission. GARDASIL has been approved as the first and only vaccine in the European Union (EU) for use in children and adolescents aged 9 to 15 years and in adult females aged 16 to 26 years for the prevention of cervical cancer, high-grade cervical dysplasias/precancers [cervical intraepithelial neoplasia (CIN 2/3)], high-grade/precancerous vulvar dysplastic lesions (VIN 2/3) and external genital warts (condyloma acuminata) caused by human papillomavirus (HPV) types 6, 11, 16 and 18. This license applies to the 25 countries that are members of the EU, including the five largest which are France, Germany, Italy, Spain and the United Kingdom.

GARDASIL will be marketed by Sanofi Pasteur MSD (SPMSD), a joint venture between Sanofi Pasteur and Merck & Co., Inc, in 19 European countries including 15 in the EU. In the remaining Central and Eastern European countries, GARDASIL will be marketed by Merck Sharp & Dohme as either GARDASIL or SILGARD<sup>®</sup>.

Cervical cancer is the second most common cause of death from cancer (after breast cancer) among young women (15 to 44 years) in Europe. Approximately 33,500 women are diagnosed with, and 15,000 women die from cervical cancer each year (40 each day) in Europe.

**Worldwide Availability of GARDASIL** On June 8, the U.S. Food and Drug Administration approved GARDASIL to prevent cervical cancer and vaginal and vulvar pre-cancers caused by HPV types 16 and 18 and to prevent low-grade and pre-cancerous lesions and genital warts caused by HPV types 6, 11, 16 and 18. GARDASIL is approved in the United States for 9- to 26-year-old girls and women. GARDASIL is also approved for use in several countries throughout the world including Mexico, Australia, Canada, New Zealand, Brazil and two countries in Africa. Additional applications for GARDASIL are currently under review with regulatory agencies in more than 50 countries around the world. Additionally, Merck is actively working to accelerate the availability of GARDASIL in the developing world: in December, Merck announced a partnership with India's Council of Medical Research to study GARDASIL. Merck is also working with PATH and the Gates Foundation to develop HPV vaccination programs that will facilitate the introduction of GARDASIL to the most impoverished nations. Merck will make our new vaccines, including GARDASIL, available at dramatically lower prices to developing world countries.

**Selected important information about GARDASIL** GARDASIL is contraindicated in individuals who are hypersensitive to the active substances or to any of the excipients of the vaccine. As with any vaccine, vaccination with GARDASIL may not result in protection in all vaccine recipients. GARDASIL is not intended to be used for treatment of active genital warts; cervical cancer; CIN, VIN, or VaIN. GARDASIL has not been shown to protect against disease due to non-vaccine HPV types. The

health-care provider should inform the patient, parent or guardian that vaccination does not substitute for routine cervical cancer screening. Women who receive GARDASIL should continue to undergo cervical cancer screening per standard of care.

Vaccine-related adverse experiences that were observed in clinical trials at a frequency of at least 1.0 percent among recipients of GARDASIL and also greater than those observed among recipients of placebo, respectively, were pain (83.9 percent vs. 75.4 percent), swelling (25.4 percent vs. 15.8 percent), erythema (24.6 percent vs. 18.4 percent), fever (10.3 percent vs. 8.6 percent), nausea (4.2 percent vs. 4.1 percent), pruritis (3.1 percent vs. 2.8 percent) and dizziness (2.8 percent vs. 2.6 percent).

**Other Information about GARDASIL** In 1995, Merck entered into a license agreement and collaboration with CSL Limited relating to technology used in GARDASIL. GARDASIL also is the subject of other third-party licensing agreements.

**About Merck** Merck & Co., Inc. is a global research-driven pharmaceutical company dedicated to putting patients first. Established in 1891, Merck currently discovers, develops, manufactures and markets vaccines and medicines to address unmet medical needs. The Company devotes extensive efforts to increase access to medicines through far-reaching programs that not only donate Merck medicines but help deliver them to the people who need them. Merck also publishes unbiased health information as a not-for-profit service. For more information, visit [www.merck.com](http://www.merck.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, 2005, and in its periodic reports on Form 10-Q and Form 8-K, which the Company incorporates by reference.

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