GARDASIL® [Human Papillomavirus Quadrivalent (Types 6, 11, 16, and 18) Vaccine, Recombinant], Merck’s HPV Vaccine, Available to Developing Countries through UNICEF Tender

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WHITEHOUSE STATION, N.J.--(BUSINESS WIRE)--Merck (NYSE: MRK), known as MSD outside the United States and Canada, announced today that the company has been awarded a significant portion of the UNICEF human papillomavirus (HPV) vaccine tender, and will provide sustained supply of GARDASIL® [Human Papillomavirus Quadrivalent (Types 6, 11, 16, and 18) Vaccine, Recombinant] to GAVI-eligible countries. This agreement follows the GAVI Alliance’s earlier announcement that HPV vaccines would be included in its portfolio for the first time. GAVI is expected to support the introduction of HPV vaccination in 28 countries by the end of 2017.

Through this initial tender award, Merck expects to supply approximately 2.4 million doses of GARDASIL to GAVI-eligible countries between 2013 to 2017 to help meet vaccine demand for countries already approved or recommended for approval by GAVI for HPV vaccine demonstration projects and national introductions. Additional awards by UNICEF are anticipated as vaccine demand increases.

“It is essential that every young girl around the world have access to HPV vaccines. Today’s decision by UNICEF is an important step forward,” said Julie L. Gerberding, M.D., president, Merck Vaccines. “This partnership highlights Merck’s commitment to working closely with GAVI to ensure broad and sustained access to GARDASIL in the world’s poorest countries, where the burden of cervical cancer is greatest.”

“A vast gap currently exists between girls in rich and poor countries. With today's announcement of GAVI's programmes we can begin to bridge that gap to help protect girls against cervical cancer no matter where they are born,” said Dr. Seth Berkley, CEO of the GAVI Alliance. “By 2020 we hope to reach more than 30 million girls in more than 40 countries. This is a transformational moment for the health of women and girls across the world. We thank the manufacturers for working with us to help make this happen.”

Following a 2009 report, the World Health Organization recommended that routine HPV vaccination be included in national immunization programs to help prevent cervical cancer and other HPV-related diseases. It is estimated that approximately 500,000 women develop cervical cancer annually around the world, with about 85 percent of cases occurring in developing countries. Cervical cancer is the third most common type of cancer among women worldwide. High-risk HPV types 16 and 18 cause about 75 percent of cervical cancers, 70 percent of vaginal cancers, 40 to 50 percent of vulvar cancers and 80 percent of anal cancers.

GARDASIL [Human Papillomavirus Quadrivalent (Types 6, 11, 16, and 18) Vaccine, Recombinant] is indicated in the United States for use in girls and young women 9 through 26 years of age for the prevention of cervical, vulvar, vaginal and anal cancers caused by HPV types 16 and 18; genital warts caused by HPV types 6 and 11; and precancerous or dysplastic lesions caused by HPV types 6, 11, 16 and 18. GARDASIL is also approved for use in boys and men 9 through 26 years of age for the prevention of anal cancer caused by HPV types 16 and 18; genital warts caused by HPV types 6 and 11; and precancerous or dysplastic lesions caused by HPV types 6, 11, 16 and 18.

Important information about GARDASIL

GARDASIL does not eliminate the necessity for women to continue to undergo recommended cervical cancer screening. Recipients of GARDASIL should not discontinue anal cancer screening if it has been recommended by a health care provider.

GARDASIL has not been demonstrated to provide protection against diseases from vaccine and non-vaccine HPV types to which a person has previously been exposed through sexual activity.

GARDASIL is not intended to be used for treatment of active external genital lesions; cervical, vulvar, vaginal and anal cancers; cervical intraepithelial neoplasia, vulvar intraepithelial neoplasia, vaginal intraepithelial neoplasia, or anal intraepithelial neoplasia.

GARDASIL has not been demonstrated to protect against disease due to HPV types not contained in the vaccine.
Not all vulvar, vaginal and anal cancers are caused by HPV, and GARDASIL protects only against those vulvar, vaginal and anal cancers caused by HPV Types 16 and 18.

**Select safety information for GARDASIL**

GARDASIL is contraindicated in individuals with hypersensitivity, including severe allergic reactions to yeast, or after a previous dose of GARDASIL.

Because vaccines may develop syncope, sometimes resulting in falling with injury, observation for 15 minutes after administration is recommended. Syncope, sometimes associated with tonic-clonic movements and other seizure-like activity, has been reported following vaccination with GARDASIL. When syncope is associated with tonic-clonic movements, the activity is usually transient and typically responds to restoring cerebral perfusion.

GARDASIL is not recommended for use in pregnant women.

The most common adverse reaction was headache. Common adverse reactions that were observed among recipients of GARDASIL [Human Papillomavirus Quadrivalent (Types 6, 11, 16 and 18) Vaccine, Recombinant] at a frequency of at least 1.0 percent and greater than placebo were: fever, nausea, dizziness; and injection-site pain, swelling, erythema, pruritus and bruising.

**Dosage and administration for GARDASIL**

GARDASIL is a ready-to-use, three-dose, intramuscular vaccine. GARDASIL should be administered in three separate intramuscular injections in the deltoid region of the upper arm or in the higher anterolateral area of the thigh. The following dosage schedule is recommended: first dose at elected date, second dose two months after the first dose and the third dose six months after the first dose.

**About GARDASIL**

GARDASIL is approved for use in more than 125 countries. To date, more than 111 million doses have been distributed worldwide; however, it is not known how many doses have been administered.

**Other Merck access efforts for GARDASIL in the developing world**

Merck is pursuing a systematic and thoughtful approach to improve access to GARDASIL in the developing world through four key pillars: innovation, partnerships, pricing and implementation. Key efforts include:

- In September 2012, Merck announced it will donate 460,000 doses of GARDASIL over a two-year period to the Republic of Uganda to help the Ministry of Health launch a HPV vaccination program in 12 districts in the country. The program represents the first phase of Uganda's national rollout plan for HPV vaccination.
- In April 2011, the Government of Rwanda, Merck and QIAGEN launched a comprehensive cervical cancer prevention program in Rwanda incorporating both HPV vaccination and HPV testing, the first program of its kind in Africa. In its initial year, an estimated 93 percent of eligible girls 12 to 15 years of age in Rwanda were vaccinated with three doses of GARDASIL.
- In 2010 Merck partnered with the Royal Government of Bhutan and the Australian Cervical Cancer Foundation to launch a six-year national vaccination program with GARDASIL for appropriate girls and young women between the ages of 12 and 18 in Bhutan. Merck provided GARDASIL to the program partners at no cost in the first year and for the remaining five years is providing it at an access price.
- In 2009 Merck also announced a partnership with QIAGEN N.V. focused on increasing access to HPV vaccination and HPV DNA testing in some of the most resource-poor areas of the world. This initiative was the first time a vaccine manufacturer and a molecular diagnostics company collaborated to help address the burden of cervical cancer with a comprehensive approach.
- Merck has also donated more than one million doses of GARDASIL [Human Papillomavirus Quadrivalent (Types 6, 11, 16 and 18) Vaccine, Recombinant] through the GARDASIL Access Program, which was established in 2007 to help enable organizations and institutions in eligible lowest income countries to gain operational experience designing and implementing HPV vaccination projects.

**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.com](http://www.merck.com) and connect with us on [Twitter](http://twitter.com), [Facebook](http://facebook.com) and [YouTube](http://youtube.com).

**Merck Forward-Looking Statement**

This news release includes “forward-looking statements” within the meaning of the safe harbor provisions of the United States Private Securities Litigation Reform Act of 1995. These statements are based upon the current beliefs and expectations of Merck’s management and are subject to significant risks and uncertainties. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including...
obtaining regulatory approval; Merck’s ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of Merck’s patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

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 2012 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).


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