



## News Release

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### **Merck and QIAGEN Collaborate to Accelerate Access to Cervical Cancer Vaccination and Screening in Developing Countries**

#### **Major New Collaboration Announced at Clinton Global Initiative Annual Meeting**

**NEW YORK, N.Y., Sept. 23, 2009** -- Merck & Co., Inc. and QIAGEN N.V. today announced their intent to collaborate on a new program to increase access to HPV vaccination and HPV DNA testing in some of the most resource-poor areas of the world. This initiative is the first time a vaccine manufacturer and a molecular diagnostics company are collaborating to address the burden of cervical cancer with a comprehensive approach. Representing a combined value of approximately \$600 million based on current U.S. prices, the commitments of Merck and QIAGEN were highlighted today among a select group of corporate initiatives announced at the annual meeting of the Clinton Global Initiative.

"My dream of helping to reduce the burden of cervical cancer for women is increasingly within reach. I commend Merck and QIAGEN for their contribution to advancing women's health," said Graça Machel, founder and president of the Foundation for Community Development (FDC), Mozambique, and a passionate advocate for women's health. "This program is a fine example of how vaccination and screening can be used together in a comprehensive fashion. I hope that this will pave the way for new partnerships, involving the public and private sectors, donor organizations and global health leaders to address cervical cancer in developing countries."

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This collaboration will integrate two breakthrough and complementary advances in healthcare, Merck's cervical cancer vaccine, GARDASIL® [Human Papillomavirus Quadrivalent (Types 6, 11, 16 and 18) Vaccine Recombinant], and QIAGEN's HPV tests, the *digene* HC2 HPV DNA Test (called the *digene* HPV Test) and a new HPV DNA test that is currently in development for use specifically in the developing world.

Merck intends to provide, for free, up to five (5) million doses of GARDASIL and QIAGEN intends to add to its existing one million test donation program by providing HPV DNA tests to screen an additional 500,000 women. Merck and QIAGEN plan to seek other public and private partners to design and implement national public sector cervical cancer programs, provide treatment as needed, and support improvements in laboratory and vaccine delivery infrastructure, training of healthcare workers, education and advocacy. The two companies also plan to work with cervical cancer experts to support the development and implementation of sustainable best practice models for cervical cancer reduction in low-income, high disease burden countries.

"Nearly every minute of every day a woman is diagnosed with cervical cancer, and many of these women live in developing countries where the burden of the disease is disproportionately high and healthcare infrastructure is limited," said Margaret G. McGlynn, president, Merck Vaccines and Infectious Diseases. "We see this collaboration between the two companies as innovative and fundamental to reaching our shared goal of reducing the global burden of cervical cancer."

"With broadened access to both vaccines and testing through this initiative, we hope to ensure that girls and women - regardless of where they live - will benefit from these advances in healthcare," said Peer Schatz, CEO of QIAGEN. "Our complementary tools can demonstrate the unique impact that collaborations between pharmaceutical and diagnostic companies can have on global public health."

Merck and QIAGEN plan to reach out to select GAVI-eligible countries to explore the feasibility of implementing cervical cancer reduction programs. These programs are expected to be national in scope - all girls within a defined age range in the selected countries would be offered vaccination, and the program would work towards implementation of screening - and treatment as needed - for all women of a defined age group. The participating countries will be announced once program details and implementation strategies have been finalized. While both companies are willing to work with countries on an individual basis, Merck and QIAGEN

strongly believe that working together to develop country-wide programs that include cervical cancer vaccination and screening would bring unique benefits to global public health.

GARDASIL has received WHO prequalification and is approved for use in 112 countries, 23 of which are GAVI-eligible. In the U.S., the vaccine is indicated for use in girls and young women 9 through 26 years of age for the prevention of cervical, vulvar and vaginal 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. HPV types 16 and 18 cause approximately 70 percent of cervical cancer cases.

HPV testing identifies women with high-risk HPV infections that can cause cervical cancer, enabling diagnosis and treatment to be put in place before cervical cancer develops. The *digene* HPV Test is approved in the U.S. and Europe where it is used as a screening test. In the U.S., it is approved to be used together with a Pap test in women 30 years and older. In Europe it is approved as an initial general population screening test either alone or together with a Pap test. It is also used as a follow-up to inconclusive Pap test results and as a post-cervical cancer treatment follow-up. To ensure that HPV testing can reach women in all regions of the world, QIAGEN is developing a new HPV DNA test for public-health programs in low-resource countries. The cervical cancer collaboration with Merck will include the *digene* HPV Test as well as the new HPV DNA test in development, when commercially available.

Cervical cancer affects approximately 500,000 women worldwide and about 85 percent of these women live in the developing world. By affecting women in their most productive years, cervical cancer strikes at the heart of families and deprives developing world economies of the many important contributions women make.

#### **Important information about GARDASIL**

GARDASIL does not substitute for routine cervical cancer screening, and women who receive GARDASIL should continue to undergo screening.

GARDASIL has not been demonstrated to provide protection against diseases from vaccine and non-vaccine HPV types to which a woman has previously been exposed through sexual activity. GARDASIL is not intended to be used for treatment of active genital warts; cervical, vulvar, and vaginal cancers; cervical intraepithelial neoplasia (CIN), vulvar intraepithelial neoplasia (VIN) or vaginal intraepithelial neoplasia (VaIN).

GARDASIL has not been demonstrated to protect against diseases due to HPV types not contained in the vaccine. Not all vulvar and vaginal cancers are caused by HPV, and

GARDASIL protects only against those vulvar and vaginal cancers caused by HPV types 16 and 18.

### **Select safety information**

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

Because vaccinees 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 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.

### **Other Merck and QIAGEN access efforts for the developing world**

Merck is pursuing a systematic and thoughtful approach to accelerate access to GARDASIL in the developing world through four key pillars: innovation, partnerships, pricing and implementation. In 2007 at the Clinton Global Initiative, Merck made a pledge to donate at least three (3) million doses of GARDASIL through the GARDASIL Access Program, which enables organizations and institutions in eligible lowest income countries to gain operational experience in the design and implementation of HPV vaccination projects.

The collaboration between Merck and QIAGEN represents a new commitment and approach that is in addition to the GARDASIL Access Program.

QIAGEN is working to improve access to HPV testing through the development of its new HPV test and the QIAGENcares corporate social responsibility program. In April 2009,

QIAGEN announced a donation of one million HPV tests to low-income countries over five years. This new collaboration with Merck increases QIAGEN's HPV test donation by 50 percent bringing a total commitment of 1.5 million HPV tests to be provided to developing regions. Both the previous donation program and the Merck-QIAGEN collaboration are part of the QIAGENcares effort.

#### **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).

#### **About QIAGEN**

QIAGEN N.V., (NASDAQ: QGEN; Frankfurt Prime Standard: QIA), a Netherlands holding company, is the leading global provider of sample and assay technologies. Sample technologies are used to isolate and process DNA, RNA and proteins from biological samples such as blood or tissue. Assay technologies are used to make such isolated biomolecules visible. QIAGEN has developed and markets more than 500 consumable products as well as automated solutions for such consumables. The company provides its products to molecular diagnostics laboratories, academic researchers, pharmaceutical and biotechnology companies, and applied testing customers for purposes such as forensics, animal or food testing and pharmaceutical process control. QIAGEN's assay technologies include one of the broadest panels of molecular diagnostic tests available worldwide. This panel includes the *digene* HPV Test, which is regarded as the "gold standard" in testing for high-risk types of human papillomavirus (HPV), the primary cause of cervical cancer. QIAGEN employs more than 3,000 people in over 30 locations worldwide. Further information about QIAGEN can be found at <http://www.qiagen.com/>.

#### **Forward-looking statements**

**Merck:** 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 risk factors and cautionary statements in Item 1A of Merck's Form 10-K for the year ended Dec. 31, 2008, and in any risk factors or cautionary statements contained in the Company's periodic reports on Form 10-Q or current reports on Form 8-K, which the Company incorporates by reference.

**QIAGEN:** Statements contained in this release that are not historical facts are forward-looking statements, including statements about QIAGEN products, markets, strategy and operating results. Such statements are based on QIAGEN's current expectations that involve risks and uncertainties including, but not limited to, those associated with: management of growth and international operations (including currency fluctuations and logistics), variability of operating results, commercial development of markets (including applied testing, clinical and academic research, proteomics, women's health/HPV testing and molecular diagnostics), relationships with customers, suppliers and strategic partners, competition, changes in technology, fluctuations in demand, regulatory requirements, identifying, developing and producing integrated products differentiated from competitors' products, market acceptance of products, and integration of acquired technologies and businesses. For further information, refer to QIAGEN's reports filed with or furnished to the SEC, including its latest Form 20-F. Information in this release is as of the date of the release, and QIAGEN undertakes no duty to update this information unless required by law.

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