Merck’s 9-Valent HPV Vaccine, GARDASIL®9, Recommended by CDC’s Advisory Committee on Immunization Practices for Females Aged 9-26 and Males Aged 9-21

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KENILWORTH, N.J.--(BUSINESS WIRE)--Merck (NYSE: MRK), known as MSD outside the United States and Canada, announced today that the U.S. Centers for Disease Control and Prevention’s (CDC’s) Advisory Committee on Immunization Practices (ACIP) voted to include GARDASIL®9 (Human Papillomavirus 9-valent Vaccine, Recombinant) in the recommendations for use of HPV vaccines. GARDASIL 9 has been added to the routine recommendations for vaccination of 11- and 12-year-old females and males. The vaccination series can be started at age nine. Vaccination is also recommended for females aged 13 to 26 and for males aged 13 to 21 who have not been vaccinated previously or have not completed the 3-dose series. GARDASIL 9 is not approved by the U.S. Food and Drug Administration (FDA) for use in males 16 years of age and above.

GARDASIL 9 was approved by the FDA in December 2014 for use in girls and young women 9 to 26 years of age for the prevention of cervical, vulvar, vaginal, and anal cancers caused by HPV types 16, 18, 31, 33, 45, 52 and 58, pre-cancerous or dysplastic lesions caused by HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58, and genital warts caused by HPV types 6 and 11. GARDASIL 9 is also approved for use in boys 9 to 15 years of age for the prevention of anal cancer caused by HPV types 16, 18, 31, 33, 45, 52 and 58, precancerous or dysplastic lesions caused by HPV types 6, 11, 16, 18, 31, 33, 45, 52 and 58, and genital warts caused by HPV types 6 and 11. GARDASIL 9 is contraindicated in individuals with hypersensitivity, including severe allergic reactions to yeast, or after a previous dose of GARDASIL 9 or GARDASIL® [Human Papillomavirus Quadrivalent (Types 6, 11, 16, and 18) Vaccine, Recombinant].

"The CDC has made increasing HPV vaccination rates a public health priority," said Jacques Cholat, M.D., president, Merck Vaccines, "and today’s recommendation for GARDASIL 9 is an important milestone in the shared effort to help further reduce the burden of HPV-related cancers and diseases:"

The ACIP also recommends that if vaccination providers do not know or do not have available the HPV vaccine previously administered, or are in settings transitioning to GARDASIL 9, for protection against HPV 16 and 18 any HPV vaccine may be used to continue or complete the series for females; GARDASIL or GARDASIL 9 may be used to continue or complete the series for males. As stated in the Prescribing Information for GARDASIL 9, studies using a mixed regimen of HPV vaccines to assess interchangeability were not performed for GARDASIL 9.

Due to the condensed meeting, the ACIP noted that vaccination with GARDASIL 9 in prior HPV vaccine recipients will be considered as a future policy discussion and vote at the June 2015 meeting. Efficacy of GARDASIL 9 in preventing infection and disease related to HPV types 31, 33, 45, 52, and 58, in individuals previously vaccinated with GARDASIL [Human Papillomavirus Quadrivalent (Types 6, 11, 16, and 18) Vaccine, Recombinant] has not been assessed.

GARDASIL 9 (Human Papillomavirus 9-valent Vaccine, Recombinant) added to CDC’s Vaccines for Children program

During today's meeting, the ACIP also voted to include GARDASIL 9 in the CDC’s Vaccines for Children (VFC) program for both boys and girls.

Since 1994, the VFC program has provided vaccines to children through the age of 18 who are Medicaid-eligible, uninsured, underserved1, American Indian or Alaska Native. After the ACIP has made a recommendation for the use of a given vaccine, the Committee votes on whether the vaccine should be included in the VFC program. Eligible children may receive recommended vaccines through VFC once the CDC contracts for the purchase of the vaccine have been completed.

GARDASIL 9 is also available through Merck’s patient assistance program for vaccines. Through this program, Merck will provide free vaccines to adults who are uninsured and who are unable to afford vaccines. More information can be found at www.MerckHelps.com.

About the ACIP

The ACIP develops written recommendations for the routine administration of vaccines to children and adults, along with schedules regarding the appropriate dosage and dosing frequency, and contraindications applicable to the vaccines. The
Committee, which consists of 15 experts in immunization and related fields, provides advice to assist the CDC and the nation in reducing the incidence of diseases that may be prevented with vaccines and to increase the safe usage of vaccines and related biological products. The ACIP recommendations do not result in requirements for vaccine administration by individual states or coverage by insurance companies. However, state health authorities and private insurers typically follow the Committee’s guidance.

Details of the ACIP recommendations for GARDASIL 9 will be available from the CDC. The recommendations are under review by the director of the CDC and the Department of Health and Human Services and will become official when published in the CDC’s Morbidity and Mortality Weekly Report.

**Important Information about GARDASIL 9 (Human Papillomavirus 9-valent Vaccine, Recombinant)**

GARDASIL 9 does not eliminate the necessity for women to continue to undergo recommended cervical cancer screening.

Recipients of GARDASIL 9 should not discontinue anal cancer screening if it has been recommended by a health care provider.

GARDASIL 9 has not been demonstrated to provide protection against disease from vaccine HPV types to which a person has previously been exposed through sexual activity.

GARDASIL 9 has not been demonstrated to protect against diseases due to HPV types other than 6, 11, 16, 18, 31, 33, 45, 52, and 58.

GARDASIL 9 is not a treatment for external genital lesions; cervical, vulvar, vaginal, and anal cancers; or cervical intraepithelial neoplasia (CIN), vulvar intraepithelial neoplasia (VIN), vaginal intraepithelial neoplasia (VaIN), or anal intraepithelial neoplasia (AIN).

Not all vulvar, vaginal, and anal cancers are caused by HPV, and GARDASIL 9 protects only against those vulvar, vaginal, and anal cancers caused by HPV 16, 18, 31, 33, 45, 52 and 58.

Vaccination with GARDASIL 9 may not result in protection in all vaccine recipients.

**Select Safety Information for GARDASIL 9**

GARDASIL 9 is contraindicated in individuals with hypersensitivity, including severe allergic reactions to yeast, or after a previous dose of GARDASIL 9 or GARDASIL [Human Papillomavirus Quadrivalent (Types 6, 11, 16, and 18) Vaccine, Recombinant].

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 HPV vaccination. When syncope is associated with tonic-clonic movements, the activity is usually transient and typically responds to restoring cerebral perfusion by maintaining a supine or Trendelenburg position.

Safety and effectiveness of GARDASIL 9 have not been established in pregnant women.

The most common (≥10%) local and systemic adverse reactions in females 16 through 26 years of age were injection-site pain, swelling, erythema, and headache. The most common (≥10%) local and systemic reactions in boys 9 through 15 years of age were injection-site pain, swelling, and erythema.

**Dosage and administration for GARDASIL 9 (Human Papillomavirus 9-valent Vaccine, Recombinant)**

GARDASIL 9 should be administered intramuscularly in the deltoid region of the upper arm or in the higher anterolateral area of the thigh at the following schedule: 0, 2 months, 6 months.

**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 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 and connect with us on Twitter, Facebook and YouTube.

**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; 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 2013 Annual Report on Form 10-K and the company’s other filings with the SEC available at the SEC’s Internet site (www.sec.gov).


1 Underinsured children receive VFC vaccines at Federally Qualified Health Centers.

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