CDC Advisory Committee on Immunization Practices (ACIP) Votes to Provisionally Recommend Shared Clinical Decision-Making for Vaccination of Adults Ages 27-45 with GARDASIL®9 & Harmonization of Catch-up Vaccination for Males and Females Through Age 26

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KENILWORTH, N.J.--(BUSINESS WIRE)--Merck (NYSE: MRK), known as MSD outside the United States and Canada, today announced the U.S. Centers for Disease Control and Prevention's (CDC's) Advisory Committee on Immunization Practices (ACIP) voted to recommend HPV vaccination with GARDASIL®9 (Human Papillomavirus 9-valent Vaccine, Recombinant) based on shared clinical decision making for individuals 27 through 45 years of age who are not adequately vaccinated. The ACIP also voted to expand routine and catch-up recommendations for males through 26 years of age who are not adequately vaccinated. The CDC currently recommends routine vaccination of females and males 11-12 years of age, and vaccination can begin at age 9. If approved by the CDC, GARDASIL 9 recommendations would be expanded to include females and males 13-26 years of age who have not previously been vaccinated, and for adults 27-45 years of age the decision to vaccinate would be made between an individual and their healthcare provider.

Details of the ACIP recommendations for GARDASIL 9 will be available from the CDC. The provisional recommendations are reviewed by the director of the CDC and the Department of Health and Human Services and final recommendations will become official when published in the CDC's Morbidity and Mortality Weekly Report (MMWR).

GARDASIL 9 is indicated for use in females aged 9-45 for the prevention of cervical, vulvar, vaginal and anal cancers 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 also indicated for use in males aged 9-45 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].

In the U.S., almost half of new HPV infections occur in adults 25 years of age or older. Approximately 23,000 Americans are diagnosed with cervical, vaginal, vulvar, and anal cancers associated with HPV every year, according to latest published incidence from 2015. The nine types of HPV covered in GARDASIL 9 cause the majority of HPV-related cancers and other diseases in women and men. Even though adults may have already been exposed to some types of HPV covered by the vaccine, GARDASIL 9 may help protect against certain cancers and diseases caused by any of the nine HPV types to which someone has not yet been exposed.

"With more than a 100-year legacy in vaccines, Merck is deeply passionate about impacting public health through providing our broad portfolio of vaccines to people around the world," said Dr. Richard M. Haupt, vice president and head of vaccines and infectious diseases, Global Medical Affairs at Merck. "We applaud the ACIP and the CDC for their continued efforts to address the significant burden of HPV-related cancers by continuously evaluating vaccination recommendations utilizing a comprehensive body of scientific evidence."

About the ACIP and CDC recommendations

The ACIP develops written recommendations for the routine administration of vaccines to children and adults. The ACIP, 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 CDC reviews advice from the ACIP and publishes final recommendations in the MMWR. The Affordable Care Act (ACA) generally requires coverage for all vaccines administered in accordance with final CDC recommendations. This requirement applies to all non-grandfathered commercial plans and Medicaid expansion beneficiaries. Individuals, or their healthcare providers, should contact their health insurance plan to determine vaccine coverage and reimbursement requirements as well as adoption timeframes.

Important information about GARDASIL 9
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 professional.

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

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.

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 HPV vaccination. When syncope is associated with tonic-clonic movements, the activity is usually transient and typically responds to restoring cerebral perfusion.

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

The most common (≥10%) local and systemic adverse reactions in females were injection-site pain, swelling, erythema, and headache. The most common (≥10%) local and systemic reactions in males were injection-site pain, swelling, and erythema.

The duration of immunity of GARDASIL 9 has not been established.

Dosage and administration for GARDASIL 9

GARDASIL 9 should be administered intramuscularly in the deltoid region of the upper arm or in the higher anterolateral area of the thigh.

- For individuals 9 through 14 years of age, GARDASIL 9 can be administered using a 2-dose or 3-dose schedule. For the 2-dose schedule, the second dose should be administered 6-12 months after the first dose. If the second dose is administered less than 5 months after the first dose, a third dose should be given at least 4 months after the second dose. For the 3-dose schedule, GARDASIL 9 should be administered at 0, 2 months, and 6 months.
- For individuals 15 through 45 years of age, GARDASIL 9 is administered using a 3-dose schedule at 0, 2 months, and 6 months.

About HPV and HPV-related cancers and diseases

In the U.S., based upon modeled data, it is estimated that HPV will infect most sexually active males and females in their lifetime. According to the CDC, there are approximately 14 million new genital HPV infections in the U.S. each year, with roughly half occurring in people 25 years of age and older. For most people, HPV clears on its own, but for others who do not clear the virus it could lead to cervical, vaginal, and vulvar cancers in women, and anal cancer and genital warts in men and women. The majority of these cancers and diseases are caused by the nine types of HPV covered by GARDASIL 9. Studies suggest that sexually active adults remain at risk for acquiring new HPV infections, and for men in particular, the rate of new infection remains relatively constant, irrespective of age. There is no way to know which people who have HPV will develop cancer or other health problems.

According to the American Cancer Society, the number of new anal cancer cases has been rising for many years. There is no routine screening recommended for the general population to reduce the risk of anal cancer. Approximately three out of four people get genital warts after having genital contact with someone who has them. Treatment of genital warts can be painful, and they can recur after treatment, especially in the first three months. Persistent HPV infection can also lead to abnormal Pap results that may require additional follow-up procedures.

About Merck

For more than a century, Merck, a leading global biopharmaceutical company known as MSD outside of the United States and Canada, has been inventing for life, bringing forward medicines and vaccines for many of the world’s most challenging diseases. 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 health care through far-reaching policies, programs and partnerships. Today, Merck continues to be at the forefront of research to advance the prevention and treatment of diseases that threaten people and communities around the world - including cancer, cardio-metabolic diseases, emerging animal diseases, Alzheimer’s disease and infectious diseases including HIV and Ebola. For more information, visit www.merck.com and connect with us on Twitter, Facebook, Instagram, YouTube and LinkedIn.

Forward-Looking Statement of Merck & Co., Inc., Kenilworth, N.J., USA

This news release of Merck & Co., Inc., Kenilworth, N.J., USA (the “company”) includes “forward-looking statements” within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. These statements are based upon the current beliefs and expectations of the company’s management and are subject to significant risks and uncertainties. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ.
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; the company’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 the company’s patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

The company 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 the company’s 2018 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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