Merck Statement on FDA Approval of 2-Dose Regimen of GARDASIL® 9 for Girls and Boys 9 through 14 Years of Age

Terms:
Company Statements

Published Date and Time:
10/7/16 5:45 pm EDT

KENILWORTH, N.J. -- Merck (NYSE: MRK), known as MSD outside the United States and Canada, today announced that the U.S. Food and Drug Administration (FDA) has approved a 2-dose vaccination regimen for GARDASIL®9 (Human Papillomavirus 9-valent Vaccine, Recombinant), for use in girls and boys 9 through 14 years of age.

“We are pleased the FDA has approved this 2-dose schedule for GARDASIL 9 in 9-14 year olds,” said Alain Luxembourg, M.D., Ph.D., director, Merck Research Laboratories, and lead for the clinical development program for GARDASIL 9. “We look forward to the CDC’s Advisory Committee on Immunization Practices’ vote on a recommendation for use of two doses of GARDASIL 9 at its committee meeting on October 19.”

GARDASIL 9 can be administered to adolescents 9 through 14 years of age with either 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. In individuals 15 through 26 years of age, GARDASIL 9 is administered with a 3-dose schedule at 0, 2 months and 6 months.

GARDASIL 9 is indicated for use in girls and women 9 through 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 indicated for use in boys and men 9 through 26 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].

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; CIN; VIN; VaIN; or 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.

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 26 years of age, GARDASIL 9 is administered using a 3-dose schedule at 0, 2 months, and 6 months.

About HPV and related cancers and diseases

In the United States, human papillomavirus (HPV) will infect most sexually active males and females in their lifetime. There are approximately 14 million new genital HPV infections in the United States each year, half of which occur in people 15 to 24 years of age. For most people, HPV clears on its own, but for others who don't clear the virus, it could lead to cancer and other diseases in females and males. There is no way to predict who will clear the virus.

HPV causes virtually all cervical cancer cases. Each day, about 35 women are diagnosed with cervical cancer in the United States -- about 12,900 women per year. HPV also causes approximately 70-75 percent of vaginal cancer cases and approximately 30 percent of vulvar cancer cases in females, and approximately 85-90 percent of anal cancers and 90 percent of genital warts in both females and males. Additionally, there are an estimated 3 million abnormal Pap results, many of which are caused by HPV, that require follow-up each year in the United States.

Anal cancer and genital warts affect both men and women. According to the American Cancer Society, an estimated 2,920 men and 5,160 women in the United States will be diagnosed with anal cancer in 2016, and overall rates have been increasing. There is no routine screening recommended for the general population to reduce the risk of anal cancer. Approximately 355,000 cases of genital warts occur each year in the United States. Treatment of genital warts can be painful, and they may recur after treatment, especially in the first three months. Approximately 3 out of 4 people get them after having genital contact with someone who has genital warts.

About Merck

For 125 years, Merck has been a global health care 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 health care through far- reaching policies, programs and partnerships. For more information, visit www.merck.com and connect with us on Twitter, Facebook, 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. There can be no guarantees with respect to pipeline products that the products will receive the necessary regulatory approvals or that they will prove to be commercially successful. 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; 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 2015 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).

Please see Prescribing Information for GARDASIL®9 (Human Papillomavirus 9-valent Vaccine, Recombinant) at http://www.merck.com/product/usa/pi_circulars/g/gardasil_9/gardasil_9_pi.pdf and **Patient Information for GARDASIL 9** at http://www.merck.com/product/usa/pi_circulars/g/gardasil_9/gardasil_9_ppi.pdf.

Language:
English
