FDA Grants Priority Review to Merck’s Supplemental Biologics License Application (sBLA) for GARDASIL®9 in Women and Men Ages 27 to 45 for the Prevention of Certain HPV-Related Cancers and Diseases

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KENILWORTH, N.J.--(BUSINESS WIRE)--Merck (NYSE:MRK), known as MSD outside the United States and Canada, today announced that the U.S. Food and Drug Administration (FDA) has accepted for review a new supplemental Biologics License Application (sBLA) for GARDASIL® 9 (Human Papillomavirus 9-valent Vaccine, Recombinant), the company’s 9-valent HPV vaccine. The application is seeking approval for an expanded age indication for GARDASIL 9 for use in women and men ages 27 to 45 for the prevention of certain cancers and diseases caused by the nine human papillomavirus (HPV) types covered by the vaccine. The FDA has granted Priority Review to this sBLA and has set a Prescription Drug User Fee Act (PDUFA), or target action, date of Oct. 6, 2018.

“Women and men ages 27 to 45 continue to be at risk for acquiring HPV, which can lead to cervical cancer and certain other HPV-related cancers and diseases,” said Dr. Alain Luxembourg, director, clinical research, Merck Research Laboratories. “We look forward to working with the FDA on the review of this application for GARDASIL 9, which, if approved, would enable more people to have access to the vaccine.”

GARDASIL 9 is a vaccine indicated in the U.S. in females 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 in males 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].

About GARDASIL® 9 (Human Papillomavirus 9-valent Vaccine, Recombinant)

GARDASIL 9 includes the greatest number of HPV types in any available HPV vaccine. After HPV types 16 and 18, the five additional HPV types in GARDASIL 9 are the most common cervical cancer-causing types worldwide. Seven HPV types in GARDASIL 9 (HPV 16, 18, 31, 33, 45, 52 and 58) cause approximately 90 percent of cervical cancer cases and approximately 80 percent of high-grade cervical lesions (cervical precancers, defined as CIN 2, CIN 3 and AIS) worldwide. These seven HPV types also cause 90 percent of HPV-related vulvar cancers, 85 percent of HPV-related vaginal cancers, and 90 percent of HPV-related anal cancers. HPV types 6 and 11 cause approximately 90 percent of genital warts cases. In addition, approximately 50 percent of cases of low-grade cervical lesions (CIN 1) are caused by the nine HPV types included in the vaccine.

GARDASIL 9 is approved for use in more than 70 countries.

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 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.

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 26 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 United States, human papillomavirus (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 United States each year, half of which occur in people 15 through 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 certain cancers and other diseases in males and females. There is no way to predict who will or won't clear the virus.

HPV causes virtually all cervical cancer cases. Each day, about 36 women are diagnosed with cervical cancer in the United States -- about 13,200 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.

Anal cancer and genital warts affect both men and women. According to the American Cancer Society, an estimated 2,960 men and 5,620 women in the United States will be diagnosed with anal cancer in 2018, 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. Approximately 3 out of 4 people get them after having genital contact with someone who has genital warts.

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. 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 2017 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.


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