FDA Approves Expanded Age Indication for GARDASIL® 9 in Males

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GARDASIL 9 Now Approved for Males 16 through 26 Years of Age for the Prevention of Anal Cancers and Genital Warts Caused by Nine HPV types

KENILWORTH, N.J.--(BUSINESS WIRE)--Merck (NYSE: MRK), known as MSD outside the United States and Canada, announced today that the U.S. Food and Drug Administration (FDA) approved an expanded age indication for GARDASIL® 9 (Human Papillomavirus 9-valent Vaccine, Recombinant), Merck's 9-valent human papillomavirus (HPV) vaccine, to now include use in males 16 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 already approved for use in boys 9 through 15 years of age for the prevention of these diseases. GARDASIL 9 is also approved for use in girls and young women 9 through 26 years of age for the prevention of cervical, vulvar, vaginal, and anal cancers caused by HPV 16, 18, 31, 33, 45, 52 and 58, precancerous or dysplastic lesions caused by HPV 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].

"This is an important approval that now aligns the indication for GARDASIL 9 in males and females ages 9 through 26 to that of GARDASIL, and also supports the CDC's HPV vaccine recommendations for use in males," said Jacques Cholat, M.D., president, Merck Vaccines. "We are pleased that males 16 through 26 years of age will now have access to GARDASIL 9, which includes the most HPV types, to help further reduce the burden of HPV-related diseases."

GARDASIL 9 (Human Papillomavirus 9-valent Vaccine, Recombinant) includes the greatest number of HPV types in any available HPV vaccine. GARDASIL 9 adds protection against five additional HPV types -- 31, 33, 45, 52 and 58 -- in addition to the four original HPV types covered by GARDASIL [Human Papillomavirus Quadrivalent (Types 6, 11, 16, and 18) Vaccine, Recombinant]. Seven HPV types in GARDASIL 9 (HPV 16, 18, 31, 33, 45, 52 and 58) cause approximately 90-95 percent of HPV-related anal cancers, approximately 90 percent of cervical cancers, and approximately 85 percent of HPV-related vaginal cancers. HPV types 6 and 11 cause approximately 5 percent of genital warts cases in males and females. 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.

CDC's ACIP Recommendations

Following its February 2015 meeting, the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP) included GARDASIL 9 in the HPV vaccination recommendations, which added it to the routine recommendations for vaccination of males and females 11 and 12 years of age. The HPV vaccination series can be started at age nine. Only GARDASIL 9 and GARDASIL are indicated and recommended for use in males in the United States. The ACIP also recommends HPV vaccination for females 13 through 26 years of age and for males 13 through 21 years of age who have not been vaccinated previously or who have not completed the 3-dose series.

GARDASIL 9 is covered under 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, underinsured, American Indian or Alaska Native.

"While it is important to remember that the CDC's ACIP recommends routine HPV vaccination at age 11 or 12, before exposure to the HPV virus, this expanded indication for GARDASIL 9 is exciting because now 16- through 26-year-old young men can get this HPV vaccine," said Anna Giuliano, Ph.D., founding director, Center for Infection Research in Cancer, H. Lee Moffitt Cancer Center & Research Institute, Tampa, and clinical investigator for GARDASIL 9. "It's important that we collectively work to increase HPV vaccination rates to help prevent HPV-related cancers and diseases."
CDC Reports Low HPV Vaccination Rates, Especially for Males

In 2014, the CDC made increasing HPV vaccination rates a public health priority. According to the CDC, HPV vaccination rates are unacceptably low compared to rates for other adolescent vaccines, and vaccination coverage is especially low in males. In 2014, for boys 13 through 17 years of age, coverage with at least one dose of HPV vaccine was just 41.7 percent, and receipt of the recommended three doses was even lower—just 21.6 percent.

A health care provider recommendation is very important in helping a parent decide to get their son or daughter vaccinated against HPV-related cancers and diseases, and the CDC encourages health care providers to routinely recommend HPV vaccination at 11 or 12 years of age with the same sense of importance used to recommend other adolescent vaccines in order to increase vaccination rates and help protect more individuals against HPV-related cancers and other diseases.

Availability and market transition information for GARDASIL 9 (Human Papillomavirus 9-valent Vaccine, Recombinant)

GARDASIL 9 is available, and most managed care plans have already made decisions to cover the cost of GARDASIL 9, including for males 16 through 26 years of age, making the number of plans covering GARDASIL 9 similar to the number covering the cost of GARDASIL [Human Papillomavirus Quadrivalent (Types 6, 11, 16, and 18) Vaccine, Recombinant]. The approval of GARDASIL 9 for males 16 through 26 years of age is a milestone in the planned transition from GARDASIL to GARDASIL 9, as both products are now approved for the same populations.

The goal in the United States is to fully transition from use of GARDASIL to GARDASIL 9. Merck will ensure availability of and communication around GARDASIL and GARDASIL 9 to allow for a smooth transition.

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

Clinical Program for Immunogenicity and Safety of GARDASIL 9 (Human Papillomavirus 9-valent Vaccine, Recombinant) in Males 16 through 26 Years of Age

The clinical trial program for GARDASIL 9 was designed to build upon the safety and efficacy established in clinical trials with GARDASIL [Human Papillomavirus Quadrivalent (Types 6, 11, 16, and 18) Vaccine, Recombinant]. The pivotal efficacy study in females 16 through 26 years of age evaluated the efficacy of GARDASIL 9 to prevent HPV-related cervical, vulvar, and vaginal disease using GARDASIL as a comparator. Effectiveness of GARDASIL 9 against persistent infection and disease related to the nine vaccine HPV types in males 16 through 26 years of age was inferred from a non-inferiority comparison of type-specific antibody geometric mean titers (GMTs) following vaccination with GARDASIL 9 among heterosexual males 16 through 26 years of age with those among females 16 through 26 years of age.

A total of 1,106 heterosexual males and 1,101 females were enrolled in the study. The primary analyses were conducted in the per-protocol population, in which study participants received all three vaccinations within pre-defined day ranges, did not have major deviations from the study protocol, and were seronegative to the relevant HPV type(s) prior to dose one. The analyses found that anti-HPV GMTs at Month 7 among males 16 through 26 years of age were non-inferior to anti-HPV GMTs among females 16 through 26 years of age.

In the clinical studies with GARDASIL 9 in males 16 through 26 years of age, the most common (≥10%) local and systemic adverse reactions reported were injection-site pain (63.4%), injection-site swelling (20.2%) and injection-site erythema (20.7%).

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 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 AIIN.

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 (Human Papillomavirus 9-valent Vaccine, Recombinant)

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.
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 at the following schedule: 0, 2 months, 6 months.

About HPV and related cancers and diseases

In the United States, 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 significant cancers and other diseases in males as well as females, and there is no way to predict who will clear the virus.

HPV causes approximately 85-90 percent of anal cancers in both males and females. According to the American Cancer Society, an estimated 2,600 men and 4,600 women in the United States will be diagnosed with anal cancer in 2015, and overall rates have been increasing. There is no routine screening recommended for the general population to reduce the risk of anal cancer.

HPV causes approximately 90 percent of genital warts in both males and females. There are approximately 360,000 cases of genital warts 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.

In women, HPV also causes virtually all cervical cancer cases. Each day another 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. 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.

About Merck

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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 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 2014 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).
