NEWS RELEASE

Merck Announces Plans to Conduct Clinical Trials of a Novel Investigational Multi-Valent Human Papillomavirus (HPV) Vaccine and Single-Dose Regimen for GARDASIL® 9

3/13/2024

Company reaffirms commitment to reduce the global burden of HPV-related diseases, including certain cancers

RAHWAY, N.J.--(BUSINESS WIRE)-- Merck (NYSE: MRK), known as MSD outside of the United States and Canada, today, at the EUROGIN 2024 HPV Congress, announced plans to initiate clinical development of a new investigational multi-valent HPV vaccine designed to provide broader protection against multiple HPV types. Separately, the company also plans to conduct clinical trials in both females and males to evaluate the efficacy and safety of a single-dose regimen of GARDASIL®9 (Human Papillomavirus 9-valent, recombinant), compared to the approved three-dose regimen.

“Evidence continues to emerge showing the importance of GARDASIL and GARDASIL 9 to public health,” said Dr. Eliav Barr, senior vice president, head of global clinical development and chief medical officer, Merck Research Laboratories. “These significant investments build upon our leadership and importantly provide the opportunity to further impact the global burden of certain HPV-related cancers and disease.”

In the U.S., GARDASIL 9 is indicated for use in females 9 through 45 years of age for the prevention of cervical, vulvar, vaginal, anal, oropharyngeal and other head and neck cancers caused by HPV Types 16, 18, 31, 33, 45, 52, and 58; cervical, vulvar, vaginal, and anal 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 9
through 45 years of age for the prevention of anal, oropharyngeal and other head and neck cancers caused by HPV Types 16, 18, 31, 33, 45, 52, and 58; anal 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. The oropharyngeal and head and neck cancer indication is approved under accelerated approval based on effectiveness in preventing HPV-related anogenital disease. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial. The confirmatory trial is ongoing. 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].

**Multivalent HPV vaccine research**

Merck vaccine researchers continue to build on the development of GARDASIL and GARDASIL 9 to identify new candidates with the potential to extend protection against a broader array of HPV types. The latest addition to the pipeline employs the company’s proprietary virus-like particle (VLP) technology to incorporate additional VLPs for expanded HPV type coverage. This includes several types known to have more impact in African and Asian populations and individuals of African and Asian descent. First-in-human studies (Phase 1) are scheduled to start in the fourth quarter of 2024.

**Assessing the potential efficacy and durability of a single dose regimen of GARDASIL 9**

In response to calls from scientific leaders for more clinical data concerning alternative dosing regimens for GARDASIL 9, Merck, pending regulatory input, plans to conduct two prospective clinical trials, one in females (16-26 years old) and one in males (ages 16-26 years old). These randomized, double-blind, multi-year clinical trials will examine the short and long-term efficacy and immunogenicity of a single-dose of GARDASIL 9 versus the currently approved three-dose regimen. The goal of these large, randomized trials is to generate data that clearly determines whether or not a single dose of GARDASIL 9 provides comparable long-term protection to the approved three-dose regimen, while also satisfying the high standards required by regulatory authorities. The clinical trials are anticipated to start enrolling participants in the fourth quarter of 2024.

**HPV vaccine supply**

To address the increasing global demand for GARDASIL and GARDASIL 9 and support broader and equitable access, Merck has made significant investments in manufacturing to help increase supply. Starting in 2019, the company committed to expand manufacturing capacity by increasing production at existing plants as well as constructing new facilities. Between 2017 and 2020 this resulted in a near doubling of supply which has subsequently been doubled again between 2020 and 2024. Merck expects to supply sufficient quantities of HPV vaccines to meet anticipated demand for 2025 and will continue to expand our supply capacity in the future.
Indication for GARDASIL and GARDASIL 9

GARDASIL 9 is a vaccine indicated in females 9 through 45 years of age. GARDASIL is a vaccine indicated in females 9 through 26 years of age. GARDASIL 9 is indicated for the prevention of cervical, vulvar, vaginal, anal, oropharyngeal and other head and neck cancers caused by human papillomavirus (HPV) Types 16, 18, 31, 33, 45, 52, and 58; and precancerous or dysplastic lesions caused by HPV Types 6, 11, 16, 18, 31, 33, 45, 52, and 58. GARDASIL is indicated for the prevention of cervical, vulvar, vaginal, and anal cancers caused by HPV Types 16 and 18, and precancerous or dysplastic lesions caused by HPV Types 6, 11, 16, and 18. Both are indicated for the prevention of genital warts caused by HPV Types 6 and 11.

GARDASIL 9 is indicated in males 9 through 45 years of age. GARDASIL is indicated in males 9 through 26 years of age. GARDASIL 9 is indicated for the prevention of anal, oropharyngeal and other head and neck cancers caused by HPV Types 16, 18, 31, 33, 45, 52, and 58; and precancerous or dysplastic lesions caused by HPV Types 6, 11, 16, 18, 31, 33, 45, 52, and 58. GARDASIL is indicated for the prevention of anal cancer caused by HPV Types 16 and 18, and precancerous or dysplastic lesions caused by HPV Types 6, 11, 16, and 18. Both are indicated for the prevention of genital warts caused by HPV Types 6 and 11.

The GARDASIL 9 oropharyngeal and head and neck cancer indication is approved under accelerated approval based on effectiveness in preventing HPV-related anogenital disease. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

Indication - Limitations of Use

GARDASIL 9 and GARDASIL do not eliminate the necessity for vaccine recipients to undergo screening for cervical, vulvar, vaginal, anal, oropharyngeal and other head and neck cancers as recommended by a health care provider.

GARDASIL 9 and GARDASIL have not been demonstrated to provide protection against diseases caused by:

- HPV types not covered by the vaccine
- HPV types to which a person has previously been exposed through sexual activity

Not all vulvar, vaginal, anal, oropharyngeal and other head and neck cancers are caused by HPV, and GARDASIL 9 and GARDASIL protect only against those vulvar, vaginal, anal, oropharyngeal and other head and neck cancers caused by HPV types contained in the vaccines.

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

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

**Select Safety Information**

GARDASIL 9 and GARDASIL are 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 and GARDASIL have not been established in pregnant women.

For GARDASIL 9, 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. For GARDASIL, the most common (≥1.0%) adverse reactions were headache, fever, nausea, dizziness; and injection-site pain, swelling, erythema, pruritus, and bruising.

The duration of immunity for a 2-dose regimen of GARDASIL 9 is unknown.

**Dosage and Administration**

Administer either GARDASIL 9 or GARDASIL intramuscularly in the deltoid or anterolateral area of the thigh.

For GARDASIL 9, a complete vaccination regimen consists of:

- 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.

For GARDASIL, complete vaccination regimen for individuals aged 9 through 26 years of age consists of 3 doses at the following schedule: 0, 2 months, 6 months.

About Merck

At Merck, known as MSD outside of the United States and Canada, we are unified around our purpose: We use the power of leading-edge science to save and improve lives around the world. For more than 130 years, we have brought hope to humanity through the development of important medicines and vaccines. We aspire to be the premier research-intensive biopharmaceutical company in the world – and today, we are at the forefront of research to deliver innovative health solutions that advance the prevention and treatment of diseases in people and animals. We foster a diverse and inclusive global workforce and operate responsibly every day to enable a safe, sustainable and healthy future for all people and communities. For more information, visit www.merck.com and connect with us on X (formerly Twitter), Facebook, Instagram, YouTube and LinkedIn.

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

This news release of Merck & Co., Inc., Rahway, 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 candidates that the candidates 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 Annual Report on Form 10-K for the year ended December 31, 2023 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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