



NEWS RELEASE

# FDA Approves Merck's GARDASIL 9 for the Prevention of Certain HPV-Related Head and Neck Cancers

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**GARDASIL®9 (Human Papillomavirus 9-valent Vaccine, Recombinant) Now Approved for the Prevention of HPV-Related Cervical, Vaginal, Vulvar, Anal, Oropharyngeal and Other Head and Neck Cancers**

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 approved an expanded indication for GARDASIL9 for the prevention of oropharyngeal and other head and neck cancers caused by HPV Types 16, 18, 31, 33, 45, 52, and 58. 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 trial is currently underway.

"At Merck, working to help prevent certain HPV-related cancers has been a priority for more than two decades," said Dr. Alain Luxembourg, director, clinical research, Merck Research Laboratories. "Today's approval for the prevention of HPV-related oropharyngeal and other head and neck cancers represents an important step in Merck's mission to help reduce the number of men and women affected by certain HPV-related cancers."

GARDASIL 9 is a vaccine indicated 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 human papillomavirus (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 indicated 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.

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

Both men and women can be at risk for HPV-attributable oropharyngeal cancer; however, this cancer affects men five times more than women.<sup>1</sup> For most people, HPV clears on its own. But, for those who don't clear the virus, it can cause certain cancers. Oropharyngeal cancer can arise as a result of HPV infection in the oropharynx, which includes the soft palate, side and back wall of the throat, tonsils, and back one-third of the tongue. According to a recent model published by the U.S. Centers for Disease Control and Prevention (CDC), HPV-attributable oropharyngeal cancer has surpassed cervical cancer as the most prevalent type of HPV-related cancer in the U.S.<sup>1</sup>

<sup>1</sup> The CDC analyzed data from the U.S. Cancer Statistics (USCS) to assess the incidence of HPV-associated cancers and to estimate the annual number of cancers caused by HPV, overall and by state, during 2012 to 2016.

The estimated number of HPV-attributable cancers was calculated by multiplying the average number of HPV-associated cancers by the percentage of HPV-attributable cancers diagnosed from 1993 to 2005, before HPV vaccination was available in the U.S.

The detection of HPV DNA in an HPV study is not enough to determine that HPV caused the cancer.

Not all cervical and oropharyngeal cancers are caused by HPV.

## Important Information About GARDASIL 9

GARDASIL 9 does 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 healthcare provider.

GARDASIL 9 has 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 protects only against those vulvar, vaginal, anal, oropharyngeal and other head and neck cancers caused by HPV

Types 16, 18, 31, 33, 45, 52, and 58.

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

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

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

According to the CDC, an estimated 14 million new HPV infections occur every year in the United States. HPV is so common that 80% of people who are sexually active get HPV at some point in their life. For most people, HPV clears on its own; but for those who don't clear the virus, it could cause certain cancers and diseases. There is no way to know which people who have HPV will develop cancer or other health problems. GARDASIL®9 (Human Papillomavirus 9-valent Vaccine, Recombinant) helps protect against seven HPV types that cause the majority of HPV-related cancers in the United States. Persistent HPV infection can also lead to pre-cancerous lesions that may require additional follow-up procedures. With the exception of cervical cancer, there is no routinely recommended screening for the detection of HPV-related cancers.

## About Merck

For more than 125 years, Merck, 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 in pursuit of our mission to save and improve lives. We demonstrate our commitment to patients and population health by increasing access to health care through far-reaching policies, programs and partnerships. Today, Merck continues to be at the forefront of research to prevent and treat diseases that threaten people and animals – including cancer, infectious diseases such as HIV and Ebola, and emerging animal diseases – as we aspire to be the premier research-intensive biopharmaceutical company in the world. For more information, visit [www.merck.com](http://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 the recent global outbreak of novel coronavirus disease (COVID-19); 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 2019 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](http://www.sec.gov)).

Please see the 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](http://www.merck.com/product/usa/pi_circulars/g/gardasil_9/gardasil_9_pi.pdf) and the Patient Information for GARDASIL9 at [http://www.merck.com/product/usa/pi\\_circulars/g/gardasil\\_9/gardasil\\_9\\_ppi.pdf](http://www.merck.com/product/usa/pi_circulars/g/gardasil_9/gardasil_9_ppi.pdf).

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