



News Release

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Health Canada Approves GARDASIL®9 (Human Papillomavirus 9-valent Vaccine, Recombinant) for the Prevention of Oropharyngeal and Other Head and Neck Cancers

GARDASIL®9 is the first vaccine in Canada approved for the prevention of HPV-Related Oropharyngeal and other Head and Neck Cancers caused by HPV types 16, 18, 31, 33, 45, 52, and 58

KIRKLAND, QC – April 11, 2022 - Merck, (NYSE: MRK), known as MSD outside Canada and the United States, announced today that Health Canada has approved an expanded indication of GARDASIL®9 in individuals 9 through 45 years of age for the prevention of infection caused by the Human Papillomavirus (HPV) types 6, 11, 16, 18, 31, 33, 45, 52 and 58 and the following diseases associated with the HPV types included in the vaccine: Oropharyngeal and other head and neck cancers caused by HPV types 16, 18, 31, 33, 45, 52, and 58.¹ This market authorization has been issued with conditions pending the results of trials to verify its clinical benefit.

“Head and neck cancers can be extremely debilitating for survivors. Although curative treatment of HPV induced oropharyngeal cancer is usually successful, the treatment and cancer itself can cause significant morbidities, dysfunction, and lowered patient qualities of life moving forward. A vaccine that can actually help prevent certain HPV-related head and neck cancers is an important scientific advancement,” said Dr. Peter Spafford, College of Medicine Division of Otolaryngology – Head and Neck Surgery, Department of Surgery, University of Saskatchewan.

“No screening program exists for HPV-related oropharyngeal cancers. This approval represents the first clinical tool to help prevent oropharyngeal and head and neck cancer caused by HPV infection in men and women,” said Dr. Vivien Brown, Past President of the Federation of Medical Women of Canada (FMWC) and co-founder of HPV Prevention Week in Canada.

It is estimated that 75% of sexually active Canadians will have an HPV infection at some point if not immunized² and that more than 550,000 Canadians become infected with HPV each year.³ While most infected people clear the virus, those who do not can develop HPV-related cancers and precancers, or genital warts. Many people who have HPV may not show any signs or symptoms, which means they can infect others without knowing it.⁴

According to the Public Health Agency of Canada, about 25% to 35% of mouth and throat cancers are related to oral HPV infection and in 2012, the incidence rate of HPV-associated oropharyngeal cancer was more than 4.5 times higher in males and females. The proportion of tonsillar cancers in Canada in which HPV has been detected increased from 25% (1993–1999) to 62% (2006–2011).⁵

“Scheduling regular dentist check-ups can allow your dental professional to detect signs of head and neck cancers including oropharyngeal cancers at their earliest stage. Canadians should

speak to their dental professional about a thorough evaluation, as there is currently no screening program that exists for head and neck cancers,” said Dr. Cheryl Cable, Maxillofacial Prosthodontist, President of Canadian Association of Women Dentists, Lead of the Alberta Head and Neck Cancer Dental Leadership Team, and Associate Professor of the University of Alberta.

“Today’s expanded approval for GARDASIL®9 is a key milestone in the prevention of HPV-related oropharyngeal and other head and neck cancers. It is a clear testament to Merck Canada’s mission of saving and improving the lives of Canadians,” said Marwan Akar, President and Managing Director of Merck Canada.

About Head and Neck Cancers

Head and neck cancers can occur in various areas of the mouth, the space inside and around the nose and throughout the throat or the salivary glands.⁶ In 2012, the incidence rate of HPV-associated oropharyngeal cancer was more than 4.5 times higher in males than females;⁷ however, the rate for women has been rising for several decades.⁸ People over the age of 40 are also at higher risk for head and neck cancers.⁹ In addition to HPV, other factors that can raise the risk of developing head and neck cancers include tobacco use and alcohol consumption.¹⁰

About GARDASIL®9

GARDASIL®9 is a vaccine indicated for individuals 9 through 45 years of age for the prevention of infection caused by the Human Papillomavirus (HPV) types 6, 11, 16, 18, 31, 33, 45, 52 and 58 and the following diseases associated with the HPV types included in the vaccine: cervical, vulvar, vaginal, and anal cancer (without conditions), and oropharyngeal and other head and neck cancers (with conditions) caused by HPV types 16, 18, 31, 33, 45, 52, and 58; genital warts caused by HPV types 6 and 11 (without conditions); and the following precancerous or dysplastic lesions caused by HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58 (without conditions): cervical adenocarcinoma *in situ* (AIS), cervical intraepithelial neoplasia (CIN) grade 2 and grade 3, cervical intraepithelial neoplasia (CIN) grade 1, vulvar intraepithelial neoplasia (VIN) grade 2 and grade 3, vaginal intraepithelial neoplasia (VaIN) grade 2 and grade 3, and anal intraepithelial neoplasia (AIN) grades 1, 2, and 3.¹¹

The oropharyngeal and other head and neck cancer indication for GARDASIL®9 has been issued market authorization with conditions, pending the results of trials to verify its clinical benefit. Healthcare practitioners should advise patients of the nature of the authorization.¹²

Health Canada’s approval for the prevention of HPV-related oropharyngeal and other head and neck cancers caused by HPV types 16, 18, 31, 33, 45, 52 and 58 is based on the effectiveness of GARDASIL®* and GARDASIL®9 to prevent persistent infection and anogenital disease caused by HPV types covered by the vaccine.¹³

GARDASIL®9 should not be used in anyone with an allergic reaction to a previous dose of GARDASIL®9 or GARDASIL®* or to any of the ingredients in the vaccine. GARDASIL®9 does not treat HPV infection and may not protect everyone who gets vaccinated. Side effects and allergic reactions can occur.¹⁴ GARDASIL®9 is not recommended for use in pregnant women.

About Merck

For over 130 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 about our operations in Canada, visit www.merck.ca and connect with us on [YouTube](#) and Twitter [@MerckCanada](#).

Forward-Looking Statement of Merck & Co. Inc., Kenilworth, NJ, 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 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 the 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 2021 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).

*GARDASIL® is no longer marketed in Canada

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References

¹ GARDASIL®9 Product Monograph. Merck & Co. Inc. Updated April 6, 2022.

² Public Health Agency of Canada. Human Papillomavirus Vaccine: Canadian Immunization Guide. Available at <https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/page-9-human-papillomavirus-vaccine.html>. Accessed on February 24, 2022.

³ GARDASIL®9 Product Monograph. Merck & Co. Inc. Updated April 6, 2022.

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- ⁴ GARDASIL[®] 9 Product Monograph. Merck & Co. Inc. Updated April 6, 2022.
- ⁵ GARDASIL[®] 9 Product Monograph. Merck & Co. Inc. Updated April 6, 2022.
- ⁶ National Cancer Institute. Head and Neck Cancers. Available at <https://www.cancer.gov/types/head-and-neck/head-neck-fact-sheet>. Accessed on February 18, 2022.
- ⁷ Office of the Chief Dental Officer of Canada. Human papillomavirus and oral health. Can Commun Dis Rep 2020;46(11/12):380–3. <https://doi.org/10.14745/ccdr.v46i1112a03>. Available at <https://www.canada.ca/en/public-health/services/reports-publications/canada-communicable-disease-report-ccdr/monthly-issue/2020-46/issue-11-12-november-5-2020/human-papillomavirus-oral-health.html>.
- ⁸ Cancer.net. Head and Neck Cancer: Risk Factors and Prevention. Available at <https://www.cancer.net/cancer-types/head-and-neck-cancer/risk-factors-and-prevention>. Accessed on February 18, 2022.
- ⁹ Cancer.Net. Head and Neck Cancer: Risk Factors and Prevention. Available at <https://www.cancer.net/cancer-types/head-and-neck-cancer/risk-factors-and-prevention>. Accessed on March 16, 2022.
- ¹⁰ Cancer.Net. Head and Neck Cancer: Risk Factors and Prevention. Available at <https://www.cancer.net/cancer-types/head-and-neck-cancer/risk-factors-and-prevention>. Accessed on March 16, 2022.
- ¹¹ GARDASIL[®] 9 Product Monograph. Merck & Co. Inc. Updated April 6, 2022.
- ¹² GARDASIL[®] 9 Product Monograph. Merck & Co. Inc. Updated April 6, 2022.
- ¹³ GARDASIL[®] 9 Product Monograph. Merck & Co. Inc. Updated April 6, 2022.
- ¹⁴ GARDASIL[®] 9 Product Monograph. Merck & Co. Inc. Updated April 6, 2022.