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Merck's HPV Vaccine, GARDASIL®9, now indicated in boys and men 9 - 45 years of age

Helps Protect Against Nine HPV types – Including Types that Cause Anal Cancer and Genital Warts

- HPV is estimated to infect over 550,000 Canadians each yearⁱ
- Among HPV-related cases, HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58 cause approximately 90-95% of anal cancers and HPV types 6 and 11 cause 90% of genital warts.ⁱⁱ

Kirkland, Quebec – August, 27 2020 – Merck (NYSE: MRK), known as MSD outside the United States and Canada, announced today that GARDASIL®9 (Human Papillomavirus 9-valent Vaccine, Recombinant), Merck's 9-valent human papillomavirus (HPV) vaccine, is now indicated for use in boys and men 9 to 45 years of age for the prevention of anal cancer, abnormal and precancerous anal lesions, and genital warts. Previously, the vaccine was indicated in boys and men 9 to 26 years of age and girls and women 9 to 45 years of age.

"I am very proud of another key milestone in the importance of GARDASIL®9's role in helping to protect yet more Canadians" said AnnA Van Acker, President of Merck Canada. "At Merck Canada, we are very committed to our portfolio of vaccines to help prevent infections and diseases in children and adults. With this new achievement in HPV prevention, we are now extending indications to a new male population."

This new indication brings parity with GARDASIL®9's indications for use in girls and women 9 to 45 years of age for the prevention of cervical, vulvar, vaginal, and anal cancers as well as abnormal and precancerous lesions and genital warts caused by nine types of HPV.

"This development represents a new clinical tool, further contributing to cancer prevention for men," explained Dr. Christine Palmay, MD and women's health expert from Toronto. "The nonavalent HPV vaccine is now approved for men in their 30s and 40s, as has been the case for women for several years. This new indication marks an advancement in male health and the fight against cancer."

About HPV and related cancers and diseases

HPV is a common virus. Without vaccination, the majority of sexually active people will catch HPV during their lifetime. 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. This means that they can transmit (pass on) the virus to others without knowing it.ⁱⁱⁱ

HPV causes nearly 100% of cervical cancers. HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58 specifically cause approximately 90% of cervical cancers and 75-85% of cervical precancers. These 9 types of HPV also cause at least 75% of HPV-related vulvar, vaginal and anal cancers, and precancers. Over 90% of genital warts are caused by HPV types 6 and 11.^{iv}

About GARDASIL®9

GARDASIL®9 is a vaccine (injection/shot) that helps protect against some diseases caused by some types of Human Papillomavirus (HPV). GARDASIL®9 contains the same 4 HPV types (6, 11, 16, 18) as in GARDASIL®* with 5 additional HPV types (31, 33, 45, 52, 58).^v

Boys and Men

GARDASIL®9 helps protect boys and men 9 through 45 years of age against infection caused by HPV types 6, 11, 16, 18, 31, 33, 45, 52 and 58 and the following diseases caused by HPV:

- Anal cancer caused by HPV types 16, 18, 31, 33, 45, 52, and 58
- Genital warts caused by HPV types 6 and 11
- Abnormal and precancerous anal lesions caused by HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58.^{vi}

Girls and Women

GARDASIL®9 helps protect girls and women 9 through 45 years of age against the following diseases caused by an infection with Human Papillomavirus (HPV) types 6, 11, 16, 18, 31, 33, 45, 52, and 58:

- Cervical cancer (cancer of the lower end of the uterus or womb) caused by HPV types 16, 18, 31, 33, 45, 52, and 58
- Vulvar (the outside of the female genital area) and vaginal cancers caused by HPV types 16, 18, 31, 33, 45, 52, and 58
- Anal cancer caused by HPV types 16, 18, 31, 33, 45, 52, and 58
- Genital warts (condyloma acuminata) caused by HPV types 6 and 11
- Abnormal and precancerous cervical lesions (changes in cells of the cervix that have a risk of turning into cancer) as found in a Pap test caused by HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58
- Abnormal and precancerous vaginal, vulvar (outside of the female genital area) and anal lesions caused by HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58

These diseases have many causes. Most of the time, these diseases are caused by the following nine types of HPV: 6, 11, 16, 18, 31, 33, 45, 52, and 58. GARDASIL®9 only protects against diseases caused by these nine types of HPV. People cannot get HPV or any of these diseases from GARDASIL®9.

GARDASIL[®]9 does not remove the need for cervical cancer screening; women should still get routine cervical cancer screening; Does not protect the person getting GARDASIL[®]9 from a disease that is caused by other types of HPV, other viruses or bacteria; Does not treat HPV infection; Does not protect the person getting GARDASIL[®]9 from HPV types that he/she may already have; but most people do not have all types contained in the vaccine. GARDASIL[®]9 may not fully protect each person who gets it.

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. Side effects and allergic reactions can occur.^{vii}

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 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. 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 consult GARDASIL®9 Product Monograph at

https://www.merck.ca/static/pdf/GARDASIL_9-PM_E.pdf

GARDASIL®9 Consumer Information is also available at

https://www.merck.ca/static/pdf/GARDASIL_9-CI_E.pdf.

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- i Merck Canada. GARDASIL®9 Monograph. Available at: https://www.merck.ca/static/pdf/GARDASIL_9-PM_E.pdf Page 17. Accessed on August 21, 2020
 - ii Merck Canada. GARDASIL®9 Monograph. Available at: https://www.merck.ca/static/pdf/GARDASIL_9-PM_E.pdf Page 17. Accessed on August 21, 2020
 - iii Merck Canada. GARDASIL®9 Part III Consumer Information. Available at: https://www.merck.ca/static/pdf/GARDASIL_9-CI_E.pdf. Page 42. Accessed on August 21, 2020
 - iv Merck Canada. GARDASIL®9 Part III Consumer Information. Available at https://www.merck.ca/static/pdf/GARDASIL_9-CI_E.pdf. Page 42. Accessed on August 21, 2020
 - v Merck Canada. GARDASIL®9 Part III Consumer Information. Available at: https://www.merck.ca/static/pdf/GARDASIL_9-CI_E.pdf. Page 42. Accessed on August 21, 2020
 - vi Merck Canada. GARDASIL®9 Part III Consumer Information. Available at https://www.merck.ca/static/pdf/GARDASIL_9-CI_E.pdf. Page 42. Accessed on August 21, 2020
 - vii Merck Canada. GARDASIL®9 Part III Consumer Information. Available at https://www.merck.ca/static/pdf/GARDASIL_9-CI_E.pdf. Page 43. Accessed on August 21, 2020

*GARDASIL® is no longer marketed/available in Canada

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