NEWS RELEASE

Merck Announces Positive Top-line Results from Phase 3 Trial Evaluating Efficacy and Safety of GARDASIL®9 in Japanese Males

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RAHWAY, N.J.--(BUSINESS WIRE)-- Merck (NYSE: MRK), known as MSD outside of the United States and Canada, today announced positive top-line results from its pivotal Phase 3 trial (V503-064) evaluating the company's 9-valent Human Papillomavirus (HPV) vaccine, GARDASIL®9 (Human Papillomavirus 9-valent Vaccine, Recombinant) in Japanese males ages 16 to 26 years. The trial met its primary and secondary endpoints demonstrating that administration of a 3-dose regimen of GARDASIL 9 reduced the combined incidence of anogenital persistent infection caused by 9 types of HPV compared with a placebo.

"A decade after the first approval of GARDASIL 9, Merck continues to evaluate this important vaccine in additional patient populations and remains committed to helping prevent certain HPV-related cancers through broad and equitable access globally," said Dr. Eliav Barr, senior vice president, head of global clinical development and chief medical officer, Merck Research Laboratories. "These data build on the clinical efficacy of GARDASIL 9 for the prevention of persistent infection in males and can potentially make a significant impact in addressing the global burden of certain HPV-related cancers and diseases."

Merck plans to share these data with regulatory authorities in Japan and other countries around the world to support licensure for use in males. The full results also will be presented at an upcoming scientific congress. The clinical development program evaluating GARDASIL 9 in males also includes an ongoing confirmatory Phase 3 trial evaluating efficacy in preventing HPV oral persistent infection to support effectiveness against HPV-related oropharyngeal and other head and neck cancers (**NCT04199689**).

About V503-064

V503-064 is a Phase 3, double-blind, placebo-controlled clinical study (**NCT04635423**) to evaluate the safety/tolerability and efficacy of GARDASIL 9 (V503) in preventing HPV-related anogenital persistent infection in Japanese males 16 to 26 years of age. GARDASIL 9 is commercialized in Japan under the name SILGARD 9.

The primary efficacy objective was to demonstrate reduction in the incidence of HPV 6/11/16/18-related 6-month anogenital persistent infection. The secondary efficacy objective was to demonstrate reduction in the incidence of HPV 31/33/45/52/58-related 6-month anogenital persistent infection. The study enrolled 1,059 participants.

About GARDASIL 9 in the U.S.

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.

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.

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 health care 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 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

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 vaccines 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 (≥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. The duration of immunity of a 2-dose schedule of GARDASIL 9 has not been established.

Dosage and Administration

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 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**).

Please see Prescribing Information for GARDASIL 9 (Human Papillomavirus 9-valent Vaccine, Recombinant) at **https://www.merck.com/product/usa/pi_circulars/g/gardasil_9/gardasil_9_pi.pdf** and Patient Information/Medication Guide for GARDASIL 9 at **https://www.merck.com/product/usa/pi_circulars/g/gardasil_9/gardasil_9_ppi.pdf**

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Media Contacts:

Julie Cunningham
(617) 519-6264
julie.cunningham@merck.com

Muchena Zigomo
(267) 309-5591
muchena.zigomo@merck.com

Investor Contacts:

Peter Dannenbaum
(732) 594-1579
peter.dannenbaum@merck.com

Alexis Constantine
(732) 594-1578
alexis.constantine@merck.com

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