Merck Presentations at EUROGIN 2018 Show Data on HPV Disease and Vaccination in Multiple Study Populations

Terms:
- Company Statements

Subtitle:
Oral session dedicated entirely to HPV research in the male population

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KENILWORTH, N.J., Dec. 2, 2018 – Merck (NYSE: MRK), known as MSD outside the United States and Canada, will present new research from its human papillomavirus (HPV) vaccine research program at the European Research Organization on Genital Infection and Neoplasia (EUROGIN) 2018 Congress taking place in Lisbon, Portugal from December 2-5. More than 30 abstracts will be presented, including 21 oral presentations and 10 poster presentations, about GARDASIL and GARDASIL 9 in both women and men across age groups, and other HPV-related topics.

“HPV does not discriminate by age or gender, with about 65 people around the world diagnosed with certain HPV-related cancers every hour,” said Dr. Alain Luxembourg, director, clinical research, Merck Research Laboratories. “The breadth of data being presented at EUROGIN builds on our 20-year history of HPV vaccine research and development to support use of GARDASIL and GARDASIL 9 in inappropriate males and females.”

A complete list of abstract titles and presentation dates and times can be found at the EUROGIN website at: https://www.eurogin.com/2019/405-interactive-scientific-program.html.

Key presentations at EUROGIN 2018:

- An entire session dedicated to data on understanding and preventing HPV-related cancer and disease among men, including data from long-term follow-up studies with GARDASIL and GARDASIL 9. [FC 04 – Free Communications: Vaccines 1: Male Vaccines: Monday, December 3, 14:15 – 15:45 WET]
  - Abstract #583: Efficacy, immunogenicity and safety of the quadrivalent HPV L1 Virus-Like Particle (VLP) vaccine in 16- to 26-year-old Japanese men. A. Luxembourg.
  - Abstract #626: Long-term follow-up study of immunogenicity and effectiveness of the 9-Valent HPV (9vHPV) vaccine in preadolescents and adolescents (9-15 y.o.). E. Joura.
  - Abstract #500: Comparison of Immunogenicity of 2-dose and 3-dose regimens of 9-valent HPV vaccine (3 year LTFU). J. Bornstein.
  - Abstract #611: Human papillomavirus (HPV) seroprevalence and anogenital HPV detection among HIV-negative men who have sex with men (MSM). S. Goldstone.
  - Abstract #501: Identifying facilitators and barriers associated with expanding HPV vaccination programs to males. E. Morais.
  - Abstract #508: A systematic literature review of cost-effectiveness studies assessing the nonavalent HPV vaccine in a gender neutral population. S. Kothari.
  - Additional presentations of note include:
    - Abstract #526: Type-specific data on human papillomavirus infection in oropharyngeal squamous cell carcinoma in Europe. N. Kanibir. [HN 04 – Head and Neck Forum: Free Communications 1: Sunday, December 2, 17:00 – 17:08 WET]
    - Abstract #523: Type-specific data on human papillomavirus infection in oropharyngeal squamous cell carcinoma in the Asia-Pacific Region. T. Nda. [FC 06 – Free Communications: Vaccines 2: Tuesday, December 4, 10:15 – 10:26 WET]
    - Abstract #625: 14 years of follow up on the long-term effectiveness and immunogenicity of the quadrivalent HPV vaccine in 4 Nordic countries. M. Nygård. [FC 12 – Free Communications: Vaccines 4: Tuesday, December 4, 17:00 – 17:12 WET]
    - Abstract #496: A systematic literature review update of the impact and effectiveness of the quadrivalent HPV vaccine on cervical abnormalities. B. Kuter. [P 05 – HPV Prophylactic Vaccines]
    - Abstract #106: Impact and effectiveness of the quadrivalent human papillomavirus vaccine on oral and anal HPV infections and recurrent respiratory papillomatosis. R. Drury. [P 05 – HPV Prophylactic Vaccines]
    - Abstract #510: Evolution of gender-neutral HPV vaccination in National Immunization Programs around the world...
GARDASIL 9 is a vaccine indicated in females 9 through 45 years of age for the prevention of cervical, vulvar, vaginal, and anal cancers caused by HPV types 16, 18, 31, 33, 45, 52, and 58, 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 now also indicated in males 9 through 45 years of age for the prevention of anal cancer caused by HPV types 16, 18, 31, 33, 45, 52, and 58, 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 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].

Important information about GARDASIL 9

GARDASIL 9 does not eliminate the necessity for women to continue to undergo recommended cervical cancer screening. Recipients of GARDASIL 9 should not discontinue anal cancer screening if it has been recommended by a health care professional.

GARDASIL 9 has not been demonstrated to provide protection against diseases from vaccine HPV types to which a person has previously been exposed through sexual activity.

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

Not all vulvar, vaginal, and anal cancers are caused by HPV, and GARDASIL 9 protects only against those vulvar, vaginal, and anal cancers caused by HPV 16, 18, 31, 33, 45, 52, and 58.

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.

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 (≥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 GARDASIL 9 has not been established.

Dosage and administration for GARDASIL 9

GARDASIL 9 should be administered intramuscularly in the deltoid region of the upper arm or in the higher 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

In the United States, human papillomavirus (HPV) will infect most sexually active males and females in their lifetime. According to the CDC, there are approximately 14 million new genital HPV infections in the United States each year, with roughly half occurring in people 25 years of age and older. For most people, HPV clears on its own, but for others who don't clear the virus it could lead to certain cancers and other diseases. Studies suggest that sexually active adults remain at risk for acquiring new HPV infections, and for men in particular, the rate of new infection remains relatively constant, irrespective of age. There is no way to predict who will or won't clear the virus.

Each year in the United States, approximately 26,100 men and women are diagnosed with certain HPV-related cancers. HPV causes virtually all cervical cancer cases. Each day, about 36 women are diagnosed with cervical cancer -- about 13,200 women per year. It is estimated that approximately half of all cervical cancer cases are caused by HPV infections acquired after the age of 20.

Worldwide, HPV also causes approximately 70-75 percent of vaginal cancer cases and approximately 30 percent of vulvar cancer cases.
cancer cases in females, and approximately 85-90 percent of anal cancers in both females and males. Persistent HPV infection can lead to abnormal Pap results that may require additional follow-up procedures. Anal cancer and genital warts affect both men and women. According to the American Cancer Society, an estimated 2,960 men and 5,620 women in the United States will be diagnosed with anal cancer in 2018, and overall rates have been increasing. There is no routine screening recommended for the general population to reduce the risk of anal cancer.

Approximately 355,000 cases of genital warts occur each year in the United States, and one study in Brazil published in 2017 showed that the incidence of genital warts in men 31-44 years old was similar to men ages 18-30. Treatment of genital warts can be painful, and they can recur after treatment, especially in the first three months. Approximately 3 out of 4 people get them after having genital contact with someone who has genital warts.

About Merck

For more than a century, Merck, a leading global biopharmaceutical company 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. Through our prescription medicines, vaccines, biologic therapies and animal health products, we work with customers and operate in more than 140 countries to deliver innovative health solutions. We also demonstrate our commitment to increasing access to health care through far-reaching policies, programs and partnerships. Today, Merck continues to be at the forefront of research to advance the prevention and treatment of diseases that threaten people and communities around the world - including cancer, cardio-metabolic diseases, emerging animal diseases, Alzheimer's disease and infectious diseases including HIV and Ebola. For more information, visit 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. 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).