

## FDA grants priority review to Merck's sBLA for HPV vaccine

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**Merck's HPV vaccine GARDASIL 9 includes the greatest number of HPV types in any available HPV vaccine**



Merck, known as MSD outside the United States and Canada, has announced that the US Food and Drug Administration (FDA) has accepted for review a new supplemental Biologics License Application (sBLA) for GARDASIL 9 (Human Papillomavirus 9-valent Vaccine, Recombinant), the company's 9-valent HPV vaccine.

The application is seeking approval for an expanded age indication for GARDASIL 9 for use in women and men ages 27 to 45 for the prevention of certain cancers and diseases caused by the nine human papillomavirus (HPV) types covered by the vaccine. The FDA has granted Priority Review to this sBLA and has set a Prescription Drug User Fee Act (PDUFA), or target action, date of Oct. 6, 2018.

"Women and men ages 27 to 45 continue to be at risk for acquiring HPV, which can lead to cervical cancer and certain other HPV-related cancers and diseases," said Dr. Alain Luxembourg, director, clinical research, Merck Research Laboratories. "We look forward to working with the FDA on the review of this application for GARDASIL 9, which, if approved, would enable more people to have access to the vaccine."

GARDASIL 9 is a vaccine indicated in the U.S. in females 9 through 26 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; pre-cancerous 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 also indicated in males 9 through 26 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

According to the CDC, there are approximately 14 million new genital HPV infections in the United States each year, half of which occur in people 15 through 24 years of age.

HPV causes virtually all cervical cancer cases. Each day, about 36 women are diagnosed with cervical cancer in the United States -- about 13,200 women per year. HPV also causes approximately 70-75 percent of vaginal cancer cases and approximately 30 percent of vulvar cancer cases in females, and approximately 85-90 percent of anal cancers and 90 percent of genital warts in both females and males.