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FDA News

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FDA Licenses New Vaccine for Prevention of Cervical Cancer and Other Diseases in Females Caused by Human Papillomavirus

Rapid Approval Marks Major Advancement in Public Health

The Food and Drug Administration (FDA) today announced the approval of Gardasil, the first vaccine developed to prevent cervical cancer, precancerous genital lesions and genital warts due to human papillomavirus (HPV) types 6, 11, 16 and 18. The vaccine is approved for use in females 9-26 years of age. Gardasil was evaluated and approved in six months under FDA's priority review process--a process for products with potential to provide significant health benefits.

"Today is an important day for public health and for women's health, and for our continued fight against serious life-threatening diseases like cervical cancer," said Alex Azar, Deputy Secretary, U.S. Department of Health and Human Services (HHS). "HHS is committed to advancing critical health measures such as the development of new and promising vaccines to protect and advance the health of all Americans."

HPV is the most common sexually-transmitted infection in the United States. The Centers for Disease Control and Prevention estimates that about 6.2 million Americans become infected with genital HPV each year and that over half of all sexually active men and women become infected at some time in their lives. On average, there are 9,710 new cases of cervical cancer and 3,700 deaths attributed to it in the United States each year. Worldwide, cervical cancer is the second most common cancer in women; and is estimated to cause over 470,000 new cases and 233,000 deaths each year.

For most women, the body's own defense system will clear the virus and infected women do not develop related health problems. However, some HPV types can cause abnormal cells on the lining of the cervix that years later can turn into cancer. Other HPV types can cause genital warts. The vaccine is effective against HPV types 16 and 18, which cause approximately 70 percent of cervical cancers and against HPV types 6 and 11, which cause approximately 90 percent of genital warts.

"This vaccine is a significant advance in the protection of women's health in that it strikes at the infections that are the root cause of many cervical cancers," said Andrew C. von Eschenbach, MD, Acting Commissioner of Food and Drugs. "The development of this vaccine is a product of extraordinary work by scientists as well as by FDA's review teams to help facilitate the development of very novel vaccines to address unmet medical needs. This work has resulted in the approval of a number of new products recently, including Gardasil, which address significant public health needs."

Gardasil is a recombinant vaccine (contains no live virus) that is given as three injections over a six-month period. Immunization with Gardasil is expected to prevent most cases of cervical cancer due to HPV types included in the vaccine. However, females are not protected if they have been infected with that HPV type(s) prior to vaccination, indicating the importance of immunization before potential exposure to the virus. Also, Gardasil does not protect against less common HPV types not included in the vaccine, thus routine and regular pap screening remain critically important to detect precancerous changes in the cervix to allow treatment before cervical cancer develops.

"This is the first vaccine licensed specifically to prevent cervical cancer. Its rapid approval underscores FDA's commitment to help make safe and effective vaccines available as quickly as possible. Not only have vaccines dramatically reduced the toll of diseases in infants and children, like polio and measles, but they are playing an increasing role protecting and improving the lives of adolescents and adults," said Jesse Goodman, MD, MPH, Director of FDA's Center for Biologics Evaluation and Research.

Four studies, one in the United States and three multinational, were conducted in 21,000 women to show how well Gardasil worked in women between the ages of 16 and 26 by giving them either the vaccine or placebo. The results showed that in women who had not already been infected, Gardasil was nearly 100 percent effective in preventing precancerous cervical lesions, precancerous vaginal and vulvar lesions, and genital warts caused by infection with the HPV types against which the vaccine is directed. While the study period was not long enough for cervical cancer to develop, the prevention of these cervical precancerous lesions is believed highly likely to result in the prevention of those cancers.

The studies also evaluated whether the vaccine can protect women already infected with some HPV types included in the vaccine from developing diseases related to those viruses. The results show that the vaccine is only effective when given prior to infection.

Two studies were also performed to measure the immune response to the vaccine among younger females aged 9-15 years. Their immune response was as good as that found in 16-26 year olds, indicating that the vaccine should have similar effectiveness when used in the 9-15 year age group.

The safety of the vaccine was evaluated in approximately 11,000 individuals. Most adverse experiences in study participants who received Gardasil included mild or moderate local reactions, such as pain or tenderness at the site of injection.

The manufacturer has agreed to conduct several studies following licensure, including additional studies to further evaluate general safety and long-term effectiveness. The manufacturer will also monitor the pregnancy outcomes of women who receive Gardasil while unknowingly pregnant. Also, the manufacturer has an ongoing study to evaluate the safety and effectiveness of Gardasil in males.

Gardasil is manufactured by Merck & Co., Inc., of Whitehouse Station, NJ.

For more information, see:

- <http://www.fda.gov/cber/products/hpvmer060806.htm>
- <http://www.fda.gov/womens/getthefacts/hpv.html>

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