

FDA: Merck's Gardasil stops genital warts in boys

September 4 2009, By MATTHEW PERRONE , AP Business Writer

(AP) -- Merck's blockbuster vaccine Gardasil, which is already used to prevent cervical cancer in women, also stops viruses that cause genital warts in men, the Food and Drug Administration said Friday.

In documents posted online, the FDA said the [vaccine](#) prevented [genital warts](#) in males 90 percent of the time.

The vaccine works by blocking the two strains of the [human papilloma virus](#), or HPV, which causes irregular growths and rare types of cancer in male genitals.

Merck has asked the FDA to approve Gardasil for boys and men ages 9 to 26.

A panel of vaccine advisers will weigh in on the new use next week. The FDA is not required to follow the group's advice, though it usually does.

A 4,000-patient study conducted by Merck compared patients taking Gardasil to patients taking a sham treatment for three years.

Merck had originally asked the FDA to approve the vaccine for prevention of both genital warts and precancerous growths on the penis and anus. However, reviewers said the number of those growths was too small to evaluate.

The Whitehouse Station, N.J.-based company and the FDA agreed to

"evaluate a less broad indication focusing only on genital warts," the FDA documents state.

Side effects with the vaccine were mild, such as pain and swelling at the injection site.

Gardasil was approved for women in 2006 and had sales over \$1 billion last year.

About 6 million people in the U.S. each year contract HPV, which usually causes no symptoms and clears up by itself. While there are about 40 strains of the virus that are spread through sexual contact, only about 15 cause cancer in men and women.

Cancer of the penis and anus are extremely rare, with less than 2,000 cases reported annually.

"When I talk to people I often say the burden of these diseases in men is understated and unrecognized," said Dr. Richard Haupt, Merck's head researcher for Gardasil. "Gardasil is highly efficacious and we should see an impact on men's health because of that."

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