

FDA says Glaxo vaccine blocks cancer-causing virus

September 4 2009, By MATTHEW PERRONE , AP Business Writer

(AP) -- A vaccine from GlaxoSmithKline successfully blocks the virus that causes most cases of cervical cancer, the Food and Drug Administration said Friday.

In documents posted online, the FDA said Cervarix - Glaxo's [vaccine](#) against [human papilloma virus](#) or HPV - successfully blocked the two most cancerous strains of the virus nearly 93 percent of the time.

The main study of the vaccine enrolled more than 18,000 [women](#) who either received Cervarix or a sham treatment. The FDA said the vaccine appears to fight the HPV virus for more than six years, based on company data. Side effects were minor, such as pain and swelling at the injection site.

The agency will ask a panel of vaccine experts next week whether Cervarix should be approved for girls and women ages 10 to 25. The FDA is not required to follow the group's advice, though it usually does.

A positive review from the agency will clear the British drugmaker's vaccine to compete in the U.S., though it could face an uphill battle against Merck's blockbuster vaccine Gardasil, which has been on the market here since 2006.

Besides having a three-year head start, Gardasil also defends against two more HPV types that cause 90 percent of genital warts, something Cervarix does not target.

Cervarix already is approved in nearly 100 other countries, but has been delayed in the U.S. since 2007 when the FDA said it needed additional data.

Earlier studies of Cervarix showed a higher number of muscular and neurological problems among patients who used the vaccine compared with the alternate treatment.

The FDA said Friday it asked outside experts to examine more recent data from the company to see if Cervarix could have caused those problems.

"The conclusion in the case of each of these efforts was that the data are not sufficient to establish a link," the agency said in its review.

The FDA said it would ask Glaxo to report any continuing problems in a follow-up study planned for after the vaccine's launch.

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.

Last year nearly 4,000 women died of [cervical cancer](#).

"Protection against cervical cancer is a very important health need for girls and young women, and we believe Cervarix has an important role to play in addressing this," said Glaxo spokeswoman Lisa Behrens.

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