FDA panel backs Glaxo's cervical vaccine for women

September 9 2009, By MATTHEW PERRONE , AP Business Writer

(AP) -- Drugmaker Merck likely will face U.S. competition for its vaccine Gardasil, after federal experts recommended rival GlaxoSmithKline's Cervarix also be approved to prevent the virus that causes most cervical cancers.

The FDA's panel of vaccine experts voted overwhelmingly Wednesday that Cervarix appears safe and effective for girls and women ages 10 to 25. If the FDA follows the group's advice as it usually does, Glaxo would begin competing against Merck's Gardasil, which has controlled the U.S. market since 2006.

But Merck won its own small victory at the meeting, as the same panel recommended Gardasil be expanded to prevent genital warts in boys, a new use for a vaccine that already posts sales of more than $1 billion.

While panelists favored the expanded approval, they questioned how widely the vaccine would be used, since genital warts are not a serious medical condition.

"Genital warts are a nuisance, they're ugly and can sometimes be stigmatizing," said Dr. Kenneth Noller, of Tufts University. "But in men and women with healthy immune systems they go away by themselves."

The human papilloma virus, or HPV, infects about 6 million people in the U.S. each year, and is mainly spread through sexual contact. It usually causes no symptoms and goes away within two years, though rare

cases can develop into warts and cancer in both men and women.

Last year nearly 4,000 women died of cervical cancer in the U.S., less than 1 percent of all cancer related deaths.

London-based drugmaker Glaxo already has won approval for Cervarix in Europe, but its U.S. launch was delayed in 2007 when the FDA said it needed more data.

Panelists said newer studies suggest the vaccine is safe, but they recommended follow-up studies to monitor miscarriages and inflammatory-muscular problems reported by a small number of patients.

The group said it was unlikely those problems were related to the vaccine, but said the issues should still appear on product labeling.

"I think this could be marketed with the usual caveat that it's not to be used during pregnancy," Noller said.

Even if the FDA grants approval, Glaxo will face an uphill battle against competitor Merck. Besides an established brand in the U.S., Gardasil also boasts an extra degree of protection against sexually transmitted diseases.

Gardasil and Cervarix both defend against HPV strains 16 and 18, which cause about 70 percent of cervical cancer cases. But Merck's vaccine also defends against two other HPV types that cause 90 percent of genital warts, something Cervarix does not target.

Leerink Swan analyst Seamus Fernandez estimates Cervarix will eventually make up 25-30 percent of the total market for HPV-blocking vaccines. Cervarix global sales were $231 million last year.

In separate votes Wednesday, FDA's panel ruled that Gardasil successfully prevents genital warts in boys and men ages 9 to 26.

While an approval decision from the FDA could theoretically double the market opportunity for Gardasil, analysts don't expect much use among males.

"If it's not preventing something serious like cervical cancer and there are questions about safety, I think a parents' acceptance of the vaccine in young boys might be less urgent than for their girls," Fernandez said in an interview last week.

Gardasil became an early success story for Merck after its launch, with sales growing to over $1.4 billion last year.

But momentum has slowed amid questions about the longevity of the vaccine's effect and its cost effectiveness, considering its price tag of nearly $400.

Merck has tracked HPV immunity out to five years in women, and just three years in boys and men. Public health advocates argued Gardasil should not be approved for boys without evidence of its long-term effectiveness.

"The boys of America are not facing an epidemic of genital warts," said Diana Zuckerman, of the National Research Center for Women and Families in Washington, during a public comment period. "We have time to wait for better data before approval."

Dr. Richard Haupt, Whitehouse Station, N.J.-based Merck's head researcher for Gardasil, said the company plans long term studies to track the vaccine's effectiveness over time.

"Our long term evaluations will look at immune response, but more importantly they will look at disease prevention over time," said Haupt.