



## **IN THE PIPELINE: Vaccine Sought For Virus That Can Hurt Babies**

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Several drug companies are in the race to create a vaccine for a common virus that does no serious harm in most people but can be devastating to babies.

The cytomegalovirus, or CMV, can cause permanent deafness and mental retardation in babies born to mothers infected during pregnancy, and sometimes results in stillbirths. There are no effective treatments for CMV in pregnant women, so a vaccine given to girls before they reach childbearing age could be a way to prevent infection.

In 1999, the Institute of Medicine reported that an effective CMV vaccine would not only save lives and ward off disabilities, but also spare health-care costs. Now, nearly a decade later, a handful of companies are trying to develop them. Sanofi-Aventis (SNY), Vical Inc. (VICL) and AlphaVax Inc. are taking different approaches with their experimental CMV vaccines, in both vaccine design and strategy for conducting human trials.

Early CMV-vaccine studies have shown hints of promise, but more trials will be needed before a CMV vaccine can become available. It's unlikely a vaccine would hit the market in the next few years.

From a financial perspective, the stakes could be big. The companies developing CMV vaccines are closely watching the progress of Gardasil, the fast-selling new cervical-cancer vaccine from Merck & Co. (MRK). They would probably aim to sell the vaccine for use in the same large target population as Gardasil - adolescent girls. And while none of the companies has been specific about potential pricing, Gardasil's hefty price tag of about \$360 for a three-dose regimen could pave the way for an expensive CMV vaccine.

A CMV vaccine is "an absolute necessity," said Michael Katz, a physician and senior vice president for research and global programs at the March of Dimes, the nonprofit group dedicated to improving infant health. "The group who are most vulnerable are the unborn fetuses because if the mother is not immune she becomes infected," and can pass CMV to the fetus, Katz said.

A CMV vaccine might also help people undergoing organ or stem-cell transplants. They're vulnerable to CMV because their immune systems are artificially suppressed to allow their bodies to accept the transplant.

CMV is a type of herpes virus spread by saliva and other bodily fluids. At least half of all Americans are infected with CMV by age 40, but many don't realize it because they have no symptoms. For those with symptoms, the most common include fever, sore throat and swollen lymph glands.

About 40,000 children are born each year in the U.S. with so-called congenital CMV infection, according to the Centers for Disease Control and Prevention, with about 8,000 of these suffering permanent disabilities. Some one-fifth of all cases of congenital deafness are caused by CMV, according to an article in The England Journal of Medicine last year.

Antiviral drugs can be used to treat CMV symptoms in transplant patients and people with AIDS. But they can have serious side effects and aren't approved for use in pregnant women. One antiviral, ganciclovir, is sometimes used in infants with severe CMV disease but can have strong side effects.

Kelly Ponsler of Fishers, Ind., had a baby girl, Katelyn, in August 2006 who was infected with CMV. The virus caused an enlarged liver and spleen, and the infant had to undergo about 45 blood transfusions during more than four months in a neonatal intensive-care unit, Ponsler said. She's now at home after treatment with ganciclovir. The baby has to take formula through a tube inserted in her stomach, but has shown few other signs of permanent CMV-related disabilities.

Sanofi of France is developing what's known as a recombinant CMV vaccine. It uses a genetically engineered, purified version of a protein found on the surface of the CMV virus.

An ongoing mid-stage study in healthy women has shown the Sanofi CMV vaccine to be safe and well tolerated, said Michel de Wilde, senior vice president of research and development for Sanofi's vaccine unit. Results are expected to be released later this year or in 2008. Sanofi would then conduct a large, late-stage trial that would probably last several years, De Wilde said.

Vical of San Diego is working on a DNA-based vaccine, made from a gene sequence found in the virus, but which doesn't include any of the virus itself. Vical is studying its vaccine in stem-cell transplant patients. If that goes well, the company would study the vaccine in girls and women for congenital CMV. Such a trial would be large and expensive, and Vical might try to strike a partnership with a larger drug company to fund it, or seek government support, Chief Executive Vijay Samant said.

The AlphaVax vaccine is derived from inserting CMV genes into a different virus. In a study in guinea pigs, an AlphaVax vaccine was effective in reducing the incidence of stillbirths in mothers infected with a guinea-pig version of CMV, said Jeff Chulay, chief medical officer at AlphaVax. The Research Triangle Park, N.C., company plans to start a small human trial later in March. Like Vical, AlphaVax might seek a large-company partner to help with funding of clinical trials.

A 1999 Institute of Medicine report estimated a CMV vaccine would cost about \$50 a dose, or \$150 for a three-dose regimen. While cheaper than Gardasil, that's pricier than many other vaccines.

The Institute of Medicine estimated it would cost about \$331 million to vaccinate all 12-year-old girls. Still, the institute estimated the vaccine would result in net overall savings because fewer people would incur lifelong health-care costs for permanent disabilities from CMV. Ponsler, the mother of the CMV-infected girl, estimated the medical bills for her daughter have approached \$2 million.

"Even if the vaccine was \$2,000, my goodness it's well worth it in the long run," she said.

Vaccinating boys with a CMV vaccine could help reduce transmission of the virus in the broader population, but the companies developing CMV vaccines didn't have any near-term plans to study them in boys.

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