

Wyeth seeking approval for advanced infant vaccine

March 31 2009, By LINDA A. JOHNSON , AP Business Writer

(AP) -- Drugmaker Wyeth on Tuesday sought U.S. approval to sell a new version of its blockbuster infant vaccine Prevnar that protects against more strains of a bacteria that causes pneumonia and other diseases.

Prevnar, on the market since 2000, currently protects against seven of the most common strains of a strep bacteria, *Streptococcus pneumoniae*. The bacteria can cause ear infections, [pneumonia](#) and more-dangerous, invasive conditions including [bloodstream infections](#) and meningitis.

The new version, called Prevnar 13, protects against those seven pneumococcal strains, plus six others - the next-most common ones - that cause the same diseases. The six new strains include one, dubbed 19A, that has become more prevalent around the world the past seven years and often is antibiotic-resistant.

"It's now become the predominant cause of serious invasive disease, including in babies," said Peter Paradiso, vice president for scientific affairs at Wyeth Vaccines. "It's important (to target) because of the number of cases and the severe disease it causes."

Madison, N.J.-based Wyeth is hoping for a decision in about six months from the [Food and Drug Administration](#), which already has allowed the company to submit some study results as they became available. Wyeth's application includes all the final data from 13 late-stage studies involving more than 7,000 babies and toddlers in the U.S., Canada and several European countries.

Meanwhile, Wyeth has been testing the vaccine in adults and expects next year to apply for approval to market Prevnar 13 for them.

According to Wyeth, since Prevnar became part of the routine vaccine schedule in this country, there's been a huge drop in invasive pneumococcal disease such as blood infections and meningitis, which is caused when the brain or spinal cord is infected. Invasive infections among children under 5 dropped 77 percent by 2005, and plunged 98 percent for the strains targeted by the vaccine.

In addition, kids often infect adults around them, and invasive pneumococcal infections of the strains in Prevnar fell 55 percent in the same period among adults never vaccinated with Prevnar, Wyeth said.

Currently, babies need four doses of Prevnar before 15 months of age. Without health insurance, each costs about \$83.

About 35 countries have Prevnar in their national vaccination programs, Paradiso said, and it had sales of \$2.7 billion last year. It's on its way to becoming the first \$3 billion-a-year vaccine. It is Wyeth's second-best-selling product behind the antidepressant Effexor.

Drugmaking giant Pfizer Inc. is acquiring Wyeth in deal worth \$68 billion when announced. The deal is expected to close this fall.

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