

Hib/Meningococcal Combo Effective in Infants

BY PATRICE WENDLING
Chicago Bureau

TORONTO — An investigational combined infant *Haemophilus influenzae* type b and meningococcal conjugate vaccine provided immunity without significant side effects in a phase II single-blind study of 606 infants.

GlaxoSmithKline is developing a conjugate vaccine, for use beginning at age 2 months, containing *Haemophilus influenzae* type b (Hib) polysaccharide and *Neisseria meningitidis* polysaccharides C and Y (MenCY) conjugated to tetanus toxoid.

The investigational vaccine could allow for the inclusion of two meningococcal antigens in the current U.S. infant immunization program without additional in-

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jections, and potentially protect against invasive disease in the first year of life, Dr. Jacqueline Miller and colleagues reported in a poster at the annual meeting of the Pediatric Academic Societies.

An infant meningococcal vaccine is currently not available in the United States, even though the highest rate of meningococcal disease is in infants.

"It's the next big bacterial pathogen in infants to target for vaccination," Dr. Miller, director of clinical research and medical affairs at GlaxoSmithKline in King of Prussia, Penn., said in an interview. "*Neisseria meningitidis* is a pretty invasive and aggressive organism. Infections result in a large public health response and a lot of anxiety in the community.

"I think the untold story is that the highest incidence is actually [in] the youngest kids. But because babies aren't in school, their infections don't receive much media attention. But it's serious in infants and more difficult to recognize in this population because their symptomatology is similar to other, less serious infections."

The investigators randomized healthy infants to a three-dose priming series of the Hib-MenCY study vaccine coadministered at 2, 4, and 6 months of age with Pediarix (diphtheria, tetanus, pertussis, hepatitis B, and polio) and Prevnar (pneumococcal 7-valent conjugate) vaccines; or to ActHIB (Hib conjugate with tetanus toxoid) vaccine coadministered with Pediarix and Prevnar. A third nonrandomized group of 150 3- to 5-year-old children received a single dose of Menomune vaccine, which contains *N. meningitidis* serogroups A, C, W-135, and Y.

The mean age of the children was 64 days in the study vaccine and Hib control groups, and 50 months in the Menomune control group.

At 1 month after the last dose, a statistically higher proportion of the 287 infants in the study vaccine group had anti-polyribosylribitol phosphate antibody

concentrations of at least 1.0 mcg/mL, compared with the 319 infants in the Hib control group (94% vs. 86%), the authors reported.

Overall, 98% of the infants in the Hib-MenCY group had a consolidated serum bactericidal antibody response to *N. meningitidis* serogroup C, compared with 79% of the older children vaccinated with a single dose of Menomune. The difference in responses was statistically significant. "However, the data should be interpreted cau-

tiously given the difference in age of the two treatment groups," the authors wrote.

There was no statistical difference in responses to serogroup Y between the Hib-MenCY study vaccine group and the Menomune group. Serogroups C and Y account for about 94% of all U.S. infections due to serogroups A, C, W-135, and Y.

There was no evidence of interference in the immune responses to the coadministered vaccines in those vaccinated with Hib-MenCY, compared with the Hib con-

control group. A large phase III study is underway in 8,800 infants that will evaluate coadministration of Hib-MenCY with other vaccines and determine how long the vaccine coverage lasts, Dr. Miller said.

Reports of any grade 3 solicited or unsolicited local and systemic adverse events were significantly lower in the Hib-MenCY group, compared with the Hib control group. Dr. Miller called this finding surprising, and had no explanation for why it occurred. ■



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