

# Menveo Shown Immunogenic in All Age Groups

BY MIRIAM E. TUCKER

ATLANTA — An investigational meningococcal conjugate vaccine was immunogenic in all age groups tested down to 2 months of age, and more immunogenic in adolescents than the currently licensed quadrivalent meningococcal conjugate vaccine in tests conducted by Novartis.

The vaccine, Menveo, contains *Neisseria meningitidis* serotypes A, C, Y, and W-135 and is conjugated with the carrier protein cross-reactive material 197 (MenACWY-CRM). Novartis submitted a Biologics License Application in August 2008 for its use in persons aged 11-55 years, and received a Complete Response letter from the Food and Drug Administration on July 1, 2009, stating that no new clinical trials would be required, a Novartis statement said.

The currently licensed meningococcal conjugate vaccine, Sanofi Pasteur's Menactra, contains the same four serotypes conjugated to diphtheria toxoid protein (MenACYW-D). It is licensed for routine immunization of 11- to 12-years-olds and for individuals aged 2-55 years who are at increased risk for invasive meningococcal disease.

At a meeting of the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention, Dr. Peter Dull presented phase III data on MenACWY-CRM use in adolescents.

To date, there are a total of 24 clinical trials completed or ongoing, with more than 16,000 subjects having received MenACWY-CRM, said Dr. Dull, head of meningococcal vaccine development at Novartis.

At 1 month post vaccination, a significantly greater proportion of the 1,483 MenACWY-CRM recipients seroresponded than of 501 recipients of MenACYW-D for serotypes A (75% vs. 66%), W-135 (75% vs. 63%), and Y (68% vs. 41%). Responses to serotype C did not differ significantly (75% vs. 73%). The proportions with titers of serogroup-specific serum bactericidal activity using human complement (hSBA) greater than or equal

to 1:8 were also significantly greater for MenACWY-CRM for A (75% vs. 67%), W-135 (96% vs. 88%), and Y (88% vs. 69%) but not C (84% for both vaccines).

Both vaccines were well tolerated, with comparable reactogenicity. The incidences of local injection-site reactions and of systemic symptoms were similar between groups. There were no serious adverse events deemed to be vaccine related, and no subjects in either group withdrew be-

cause of adverse events, Dr. Dull said.

In a separate investigation, similar safety profiles were seen when MenACWY-CRM was administered concomitantly with human papillomavirus and combined tetanus, diphtheria, and pertussis vaccines as with administration of MenACWY-CRM alone. Noninferior immune responses were also seen with concomitant administration, as measured by the percentage with hSBA titers

of 1:8 or greater for all meningococcal serogroups, the percentage with diphtheria and tetanus antibody concentrations of 1.0 IU/mL or greater, the percentage with human papillomavirus seroconversion and geometric mean titers, and the responses to all pertussis antigens.

Phase III studies are in progress to support licensure in infants beginning from 2 months of age, Dr. Dull said. ■

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\*IMS NPA data. December 2007-November 2008.

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