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 because 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. ■