

**1083. Comparative Evaluation of Two Different Investigational Meningococcal ABCWY Vaccine Formulations in Adolescents and Young Adults**

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**Background.** Novartis has licensed meningococcal vaccines against serogroups A, C, W and Y (MenACWY-CRM) and serogroup B (4CMenB). We evaluated 2 investigational formulations of MenABCWY vaccines, with primary objectives to assess their noninferiority compared with the licensed vaccine for ACWY serogroups and formulation selection based on a desirability index (DI) (Clinicaltrials.gov NCT01272180).

**Methods.** 480 healthy subjects, aged 10–25 years, were randomized to four groups and received either: one of two MenABCWY formulations with full or quarter doses of outer membrane vesicles (OMV), 4CMenB, or Placebo/MenACWY-CRM. Each was given as a 2-dose series at 0 and 2 months. A serum bactericidal assay with human complement (hSBA) was used to measure antibodies against serogroups A, C, W, Y and serogroup B test strains at baseline and 30 days after dose 2; seroresponses and hSBA GMTs were assessed. For MenABCWY vaccines we also compared a

DI based on immunogenicity (post-vaccine hSBA GMT ratios) and reactogenicity parameters (percentages of doses associated with severe local and severe systemic reactions).

**Results.** Percentages of subjects with seroresponses to A, C, W and Y were significantly higher after 2 doses of either MenABCWY formulation (with full and quarter OMV) than after a single dose of MenACWY; respectively 90/92% vs 73% for A; 95/93% vs 63% for C; 80/84% vs 65% for W; and 92/90% vs 75% for Y. Prespecified non-inferiority criteria were met. Both MenABCWY vaccines induced robust immune responses against serogroup B test strains, comparable with 4CMenB. Among the three serogroup B-containing formulations, DI analyses were comparable, although the full dose OMV vaccine induced higher GMTs than the quarter dose vaccine against most of the serogroup B test strains. Reactogenicity profiles of the MenABCWY vaccines were similar to each other and to that of 4CMenB. No vaccine-related serious adverse events were reported.

**Conclusion.** The MenABCWY vaccines had comparable immunogenicity for serogroups ACWY and for serogroup B, although GMT responses against B test strains appeared to be higher for the full OMV formulation. Reactogenicity was comparable between the investigational and the 4CMenB vaccine.

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