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Rationale for a Pentavalent Meningococcal Serogroup ABCWY Vaccine: A Review of Epidemiologic and Clinical Data

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Background

Invasive meningococcal disease (IMD) is dominated by serogroups A, B, C, W, and Y; currently available vaccines target serogroups ACWY or B only using different schedules.

Aim/Methods

We present the utility of a pentavalent MenABCWY vaccine to address the challenges of evolving IMD epidemiology. Global IMD burden was assessed through review of surveillance reports and PubMed articles published January 2010–June 2020 in 77 countries. Clinical data were from the MenABCWY clinical development program covering 3 phase I/IIb/III studies in >4000 adolescents/young adults. Immunogenicity evaluations utilized serum bactericidal assays using human complement (hSBA) against serogroup A/C/W/Y strains and 4 diverse, vaccine-heterologous B strains. hSBA titers were defined by the proportion of participants achieving seroprotective hSBA titers (≥1:8 or ≥1:16 depending on strain) and ≥4-fold rise from baseline (seroresponse). Safety was also evaluated.

Results

IMD incidence during 2010–2019 was low (< 3 per 100,000) but characterized by unpredictable shifts in disease-causing serogroups and sporadic outbreaks. Incidence peaked among infants/young children, with secondary peaks in adolescents/young adults and sometimes older adults. Serogroups ABCWY caused most IMD; serogroup B dominated in many regions and in some regions serogroups W and Y increased. After 2 MenABCWY doses at 0,6-month, 93.3%–97.8% of ACWY-naïve and 68.1%–95.9% of all participants achieved hSBA seroresponses for serogroups A/C/W/Y and serogroup B test strains, respectively, which were noninferior to 1 MenACWY-CRM dose and 2 MenB-FHbp doses (0,6-month) respectively. Most (78.3%) achieved noninferior seroprotective hSBA titers against all 4 B strains combined. Noninferior A/C/W/Y hSBA seroresponses were observed in ACWY-experienced participants. Four-year immunopersistence was similar to the comparator. After the 4-year booster dose, 100% achieved seroprotective hSBA titers for A/C/W/Y and greater percentages achieved seroprotective hSBA titers for B test strains than after the primary series. Seroresponses for all 5 serogroups were higher on a 0,12-month schedule compared to the 0,6-month schedule. One MenABCWY dose was noninferior to one MenACWY-CRM dose. MenABCWY was well-tolerated. No safety concerns were identified.

Conclusions

MenABCWY was safe, highly immunogenic, and could help address challenges in evolving IMD epidemiology and existing vaccination schedules by providing adolescents/young adults with comprehensive protection using a single vaccine. Funded by Pfizer.