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Development of a pentavalent meningococcal conjugate vaccine, NmCV-5 (ACWYX)

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### Background

After introduction of MenAfriVac®, there has been elimination of serogroup A disease in the African meningitis belt. However, serogroups W, X and C still cause outbreaks in the region. Building upon the MenAfriVac experience, a world's first pentavalent meningococcal conjugate vaccine, NmCV-5, for serogroups A, C, W, Y and X has been developed in India.

### Aim/Methods

NmCV-5 was evaluated in 4 clinical studies in individuals aged 1-85 years: Phase 1 single-dose study in adults (USA), Phase 2 in toddlers to evaluate two doses (Mali), Phase 3 single dose study in 2-29 years (Mali and The Gambia) and Phase 3 single dose study in 18-85 years (India). The non-inferiority of the seroresponse rate and Geometric Mean Titres of NmCV-5 versus MenACWY-D was evaluated in 2 to 85 years age group. In all studies, safety follow up was for 6 months. Immunogenicity was assessed by baby rabbit serum bacterial antibody assay (rSBA) at baseline and 28 days after vaccination. In Phase 1 and 2 studies adjuvanted and non-adjuvanted formulations were evaluated.

### Results

In all studies, the solicited AEs were mostly mild and transient, with incidence similar between NmCV-5 and MenACWY-D groups except for injection site pain which was higher in NmCV-5 in Phase 2/3 studies. No causally related SAEs were reported. In the Phase 2 study, a single dose of NmCV-5 elicited rSBA responses that were similar to or higher than those observed with two doses of MenACWY-D. Immune responses to the non-adjuvanted and adjuvanted formulations were similar. Non-inferiority of NmCV-5 against MenACWY-D was demonstrated in each age-group [(2-10, 11-17 and 18-29 years in Africa) and (18-85 years in India)] for all 5 serogroups. In the Phase 2/3 Indian study, lot-to-lot consistency of NmCV-5 was demonstrated for all serogroups.

### Conclusions

NmCV-5 elicited robust immune responses to all serogroups in 3 different geographic settings. NmCV-5 was also safe and well tolerated. Introduction of NmCV-5 has the potential to eliminate all disease-causing meningococcal serogroups in the African meningitis belt. NmCV-5 can also be used in other endemic countries, for travellers to sub-Saharan Africa, Hajj or Umrah. The vaccine was recently approved in India.