IMMUNOGENICITY OF A 3-DOSE PRIMARY SERIES OF THE PNEUMOCOCCAL NON-TYPEABLE HAEMOPHILUS INFLUENZAE PROTEIN-D CONJUGATE VACCINE (PHiD-CV) IN HEALTHY MALAYSIAN AND SINGAPOREAN INFANTS

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Objectives: To demonstrate immunological non-inferiority of the PHiD-CV commercial lot versus the phase III clinical lot and to evaluate the immunogenicity, safety and reactogenicity of PHiD-CV in Malaysian and Singaporean infants.

Methods: Infants (N=466, aged 6–12 weeks at first dose) were randomised 1:1 to receive either the commercial (Com group) or clinical lot (Clin group) of PHiD-CV at 2-3-5 months of age, each co-administered with GSK’s DTPa-combined and human rotavirus vaccines according to local schedules. Immune responses were measured 1 month post-dose 3 using 22F-inhibition ELISA and opsonophagocytic activity (OPA) assays for vaccine pneumococcal serotypes (VT), and ELISA for protein-D. Non-inferiority was achieved if the UL 95%CI of the adjusted antibody GMC ratio (clinical over commercial lot), measured by ELISA, was below 2 for each VT and protein-D.

Results: In both groups, ≥93.6% of infants reached antibody concentrations ≥0.2µg/mL and ≥88.5% reached OPA titres ≥8 for each VT. For cross-reactive serotypes 6A/19A respectively, ≥85.5% and ≥37.7% of infants reached OPA titres ≥8, and ≥60.6% and 54.6% reached antibody concentrations ≥0.2µg/mL; percentages were comparable between groups. All infants except one (Com group) had measurable antibodies against protein-D (≥100 EL.U/mL). Non-inferiority was met for each VT (ULs≤1.45) and protein-D (UL=1.58). Immune responses to co-administered vaccines and safety/reactogenicity profiles were in-line with previous studies.

Conclusion: PHiD-CV in a 3-dose primary series was immunogenic for all VT and protein-D in Malaysian and Singaporean infants. Immune responses induced by a PHiD-CV commercial lot were non-inferior to those induced by the phase III clinical lot.