2719. Immunogenicity and Safety of a Quadrivalent Meningococcal Conjugate Vaccine (MenACYW-TT) Administered in Adults 18–55 Years of Age

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Background: The MenACYW-TT conjugate vaccine is a quadrivalent meningococcal vaccine that contains tetanus toxoid as carrier protein. The vaccine is intended for global use in all age groups (i.e., individuals 6 weeks of age and older). This Phase III study evaluated the immune lot consistency, and safety and immunogenicity of the vaccine when compared with a licensed quadrivalent meningococcal conjugate vaccine in individuals 10–55 years of age.

Methods: A randomized, modified double-blind, multi-center study (NCT02842853) was conducted in the United States. The study evaluated 3344 meningococcal vaccine naïve adolescents and adults, who were randomly assigned to receive either a single dose of one of the three lots of MenACYW-TT conjugate vaccine or single dose of Menactra® [MenACYW-D]. Serum bactericidal assay with human complement (hSBAC) and rabbit complement (rSBAC) was used to measure antibodies against serogroups A, C, W, and Y at baseline before vaccination (Day 0) and 30 days post-vaccination. Safety data were collected up to 6 months post-vaccination. Herein we report the performance of MenACYW-TT in adults 18 through 55 years of age (n = 1,807).

Results: Immune equivalence was demonstrated across all 3 lots of MenACYW-TT conjugate vaccine based on geometric mean titers (GMTs) for all serogroups. Non-inferiority of immune responses, based on percentages of participants achieving hSBAC vaccine serosponse, was demonstrated between MenACYW-TT and MenACYW-D for all four serogroups at Day 30 compared with baseline. The proportion of individuals (18–55 years) with hSBAC ≥ 1:8 following MenACYW-TT administration were higher than those after MenACYW-D administration for all four serogroups (A: 93.5% vs. 88.1%; C: 93.5% vs. 77.8%; W: 94.5% vs. 80.2%; Y: 98.6% vs. 81.2%). A similar trend was observed for post vaccination GMTs in adult participants. Reactogenicity profiles were comparable across study groups. Most unsolicited adverse events were of grade 1 or grade 2 intensity. No vaccine-related serious adverse events were reported.

Conclusion: MenACYW-TT vaccine was well tolerated and demonstrated a non-inferior immune response compared with the licensed MenACYW-D vaccine when administered as a single dose to meningococcal vaccine naïve adults.

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