1350. Vaccination Response to an Ongoing Meningitis Outbreak: Uptake and Attitudes among Men Who Have Sex with Men in Los Angeles, CA

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Session: 135. Bivalent Norovirus VLP Vaccine Candidate in Older Adults: Impact of MPL and a Second Dose in a Randomized, Controlled, Double-Blind Clinical Trial

Friday, October 6, 2017: 12:30 PM

Background. Acute norovirus (NoV) gastroenteritis may cause significant morbidity in healthy adults and can prove fatal in older subjects. We investigated the safety and immunogenicity in older adults of one or two doses of an intramuscular bivalent virus-like particle (VLP) vaccine candidate (genotypes G1 and G2 multivalent consensus GIL4c) formulated with alum and with and without MPL (3-O-deacyl-4\'-monophosphoryl lipid A) adjuvant.

Methods. In a phase II, double-blind, controlled trial, 294 healthy adults ≥ 60 years of age randomized to 4 equal groups received one or two immunizations 28 days apart. One dose groups received placebo (saline) on Day 1. Vaccine formulated with 50μg AK0851 and 50μg GIL4c VLP antigens, with or without 15μg MPL adjuvant. A fifth group of 26 healthy 18–49 year-olds received one dose of MPL-free vaccine. Humoral immunity was assessed as ELISA pan-Ig and histo-blood group antigen blocking (HBGA) antibody titers at Days 1, 8, 29 and 57. Cell-mediated immunity (CMI) and avidity indices (AI) were also measured. Safety was assessed as solicited local and systemic adverse events (AE) for 7 days, and unsolicited AEs until Day 28 after each vaccination.

Results. Marked increases in pan-Ig and HBGA to both genotypes occurred by Day 28 after first vaccination. Similar increases were seen at Day 57 in antibody avidity in all groups. Similar increases in CMI responses or changes in antibody avidity were observed between vaccine dose on Day 29 or with the formulations containing MPL. Responses were similar in magnitude when assessed by age groups (60–74, 75–84 and ≥ 85 years of age) and vaccine dose. Responses were similar between the 15μg MPL and saline formulations. No vaccine-related SAEs were reported.

Conclusion. No reported disclosures.