Table 1. Humoral and cellular immune responses (ATP cohort for humoral immunogenicity and ATP sub-cohort for CMI, respectively)

	Time point	HZ/su-PreC (HZ/su)		Pl-PreC (placebo)		HZ/su-OnC (HZ/su)		Pl-OnC (placebo)	
		N	Value	N	Value	N	Value	N	Value
Humoral immune responses (ATP cohort for humoral immunogenicity)									
VRR*, % (95% CI)	M2	65	93.8 (**85.0**–98.3)	76	0.0 (0.0–4.7)	22	63.6 (40.7–82.8)	18	0.0 (0.0–18.5)
	M13	51	52.9 (38.5–67.1)	55	0.0 (0.0–6.5)	17	47.1 (23.0–72.2)	14	0.0 (0.0–23.2)
GMC, mIU/ml (95% CI)	M2	65	22974.3 (19080.0–27663.5)	78	1120.9 (903.9–1390.0)	22	9328.0 (4492.5–19368.2)	20	854.6 (534.1–1367.2)
	M13	51	4563.0 (3532.8–5893.7)	56	1178.9 (923.3–1505.1)	17	4229.5 (2073.8–8626.0)	14	708.5 (376.9–1331.8)
Adjusted GMC ratio (HZ/su: placebo)** (95% CI)	M2	23.2 (**17.9**–30.0) p <0.0001				–			
CMI responses (ATP sub-cohort for CMI)									
VRR*, % (95% CI)	M2	22	50.0 (28.2–71.8)	27	0.0 (0.0–12.8)	–			
	M13	17	17.6 (3.8–43.4)	16	0.0 (0.0–20.6)	–			
Freq., GM 95% CI	M2	22	781.8 (535.2–1110.4)	27	78.7 (13.7–162.9)	–			
Freq., mean	M13	18	523.83	19	125.78	–			
Adjusted GM frequency ratio (HZ/su:placebo)** (95% CI)	M2	9.94 (**3.63**–27.19) p <0.0001				–			

ATP, according-to-protocol; **CMI,** cell-mediated immunogenicity; **HZ/su-PreC,** first of 2 HZ/su vaccinations at 8–30 days prior to the start of a chemotherapy cycle; **Pl-PreC,** first of 2 placebo administrations at 8–30 days prior to the start of a chemotherapy cycle; **HZ/su-OnC,** first of 2 HZ/su vaccinations at the start of a chemotherapy cycle (±1 day); **Pl-OnC,** first of 2 placebo administrations at the start of a chemotherapy cycle (±1 day); **N,** number of subjects with available results; **VRR** vaccine response rate; **GM,** geometric mean; **GMC,** geometric mean anti-gE antibody ELISA concentrations; **Freq.,** frequency of gE-specific CD4[2+] T-cells (per 10^6 total CD4+ T-cells); **%,** percentage of subjects; **CI,** confidence interval; **IU,** international unit; **M2,** Month 2, 1 month post-dose 2; **M13,** Month 13, 12 months post-dose 2. The **p-value** is relative to the null hypothesis H_0: HZ/su:placebo =1. **Bolded values** indicate that immunogenicity success criteria of the primary objective (lower limit [LL] of 95% CI for GMC HZ/su:placebo ratio ≥60% – humoral immunogenicity) and secondary objectives (LL of 95% CI for VRR ≥3 – humoral immunogenicity and for GM frequency HZ/su: placebo ratio ≥1 – CMI) were met.
***humoral VRR,** percentage of subjects with vaccine response: for initially seronegative subjects (anti-gE antibody concentration below the cut-off [97 mIU/ml]), at least a 2-fold increase as compared to the cut-off; for initially seropositive subjects (anti-gE antibody concentration above the cut-off), at least a 4-fold increase as compared to the pre-vaccination antibody concentration; **CMI VRR,** percentage of subjects with vaccine response: for subjects with pre-vaccination T-cell frequencies below the threshold (320 gE-specific CD4[2+] T-cells/10^6 CD4+ T-cells), at least a 2-fold increase as compared to the threshold; for subjects with pre-vaccination T-cell frequencies above the threshold, at least a 2-fold increase as compared to pre-vaccination T-cell frequencies. **, adjusted for baseline values.

Table 2. Overall frequency of solicited AEs (Days 0–6 post each dose) per subject (TVC)

AE		HZ/su-PreC % (95% CI)	Pl-PreC % (95% CI)	HZ/su-OnC % (95% CI)	Pl-OnC % (95% CI)
		N=86	N=86	N=26	N=24
Local	**Pain**	83.7% (74.2–90.8)	4.7% (1.3–11.5)	69.2% (48.2–85.7)	12.5% (2.7–32.4)
	Redness	39.5% (29.2–50.7)	0% (0.0–4.2)	23.1% (9.0–43.6)	0% (0.0–14.2)
	Swelling	17.4% (10.1–27.1)	1.2% (0.0–6.3)	11.5% (2.4–30.2)	0% (0.0–14.2)
General	**Fatigue**	66.3% (55.3–76.1)	60.5% (49.3–70.8)	80.8% (60.6–93.4)	66.7% (44.7–84.4)
	GI	38.4% (28.1–49.5)	39.5% (29.2–50.7)	69.2% (48.2–85.7)	62.5% (40.6–81.2)
	Headache	34.9% (24.9–45.9)	30.2% (20.8–41.1)	50.0% (29.9–70.1)	58.3% (36.6–77.9)
	Myalgia	58.1% (47.0–68.7)	25.6% (16.8–36.1)	38.5% (20.2–59.4)	37.5% (18.8–59.4)
	Shivering	33.7% (23.9–44.7)	18.6% (11.0–28.4)	38.5% (20.2–59.4)	37.5% (18.8–59.4)
	Fever	17.4% (10.1–27.1)	2.3% (0.3–8.1)	19.2% (6.6–39.4)	12.5% (2.7–32.4)

TVC, total vaccinated cohort; **AEs,** any grade adverse events; **N,** number of subjects with ≥1 documented dose; **%,** percentage of subjects with the respective AE; **CI,** confidence interval; **HZ/su-PreC,** first of 2 HZ/su vaccinations at 8–30 days prior to the start of a chemotherapy cycle; **Pl-PreC,** first of 2 placebo administrations at 8–30 days prior to the start of a chemotherapy cycle; **HZ/su-OnC,** first of 2 HZ/su vaccinations at the start of a chemotherapy cycle (±1 day); **Pl-OnC,** first of 2 placebo administrations at the start of a chemotherapy cycle (±1 day); **GI,** gastrointestinal symptoms (nausea, vomiting, abdominal pain, diarrhea); **Fever,** temperature ≥37.5°C.

Table 3. Overall frequency of AEs per subject (TVC)

AEs	Reporting period	HZ/su-PreC % (95% CI)	Pl-PreC % (95% CI)	HZ/su-OnC % (95% CI)	Pl-OnC % (95% CI)
		N=86	N=86	N=26	N=24
Solicited local	**D0–6 after each dose**	88.4% (79.7–94.3)	4.7% (1.3–11.5)	69.2% (48.2–85.7)	12.5% (2.7–32.4)
Solicited general		79.1% (69.0–87.1)	65.1% (54.1–75.1)	88.5% (69.8–97.6)	70.8% (48.9–87.4)
		N=90	N=91	N=27	N=24
Unsolicited	**D0–29 after each dose**	82.2% (72.7–89.5)	89.0% (80.7–94.6)	96.3% (81.0–99.9)	91.7% (73.0–99.0)
MAEs		21.1% (13.2–31.0)	30.8% (21.5–41.3)	44.4% (25.5–64.7)	20.8% (7.1–42.2)
		N=90	N=91	N=27	N=24
pIMDs	**Dose 1 to study end**	0% (0.0–4.0)	0% (0.0–4.0)	0% (0.0–12.8)	4.2% (0.1–21.1)
SAEs		30.0% (20.8–40.6)	37.4% (27.4–48.1)	33.3% (16.5–54.0)	33.3% (15.6–55.3)
Fatal SAEs		10.0% (4.7–18.1)	11.0% (5.4–19.3)	11.1% (2.4–29.2)	4.2% (0.1–21.1)

TVC, total vaccinated cohort; **AEs,** any grade adverse events; **%,** percentage of subjects with the respective AE; **CI,** confidence interval; **HZ/su-PreC,** first of 2 HZ/su vaccinations at 8–30 days prior to the start of a chemotherapy cycle; **Pl-PreC,** first of 2 placebo administrations at 8–30 days prior to the start of a chemotherapy cycle; **HZ/su-OnC,** first of 2 HZ/su vaccinations at the start of a chemotherapy cycle (±1 day); **Pl-OnC,** first of 2 placebo administrations at the start of a chemotherapy cycle (±1 day); **MAEs,** medically-attended AEs; **pIMDs,** potential immune-mediated diseases; **SAEs,** serious AEs; **D,** day; **N,** number of subjects with ≥1 documented (solicited AEs) or administered (other AEs) dose.

Disclosures. **P. Vink**, GSK group of companies: Employee, Salary and stock options and stock granted

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

Ian Holloway, PhD, MSW, MPH[1]; Elizabeth Wu, MPH[2]; Jennifer Gildner, MSPH[2]; Vincent Fenimore, PhD, M.Ed.[2,3] and Paula Frew, PhD, MA, MPH[3,4,5]; [1]Department of Social Welfare, 3250 Charles Young Drive, Los Angeles, California, [2]Department of Social Welfare, Luskin School of Public Affairs, University of California, Los Angeles, Los Angeles, California, [3]Department of Medicine, Division of Infectious Diseases, Emory University School of Medicine, Atlanta, Georgia, [4]Hubert Department of Global Health, Rollins School of Public Health, Emory University, Atlanta, Georgia, [5]Department of Behavioral Sciences and Health Education, Rollins School of Public Health, Emory Univeristy, Atlanta, Georgia

Session: 152. Herpes Zoster Vaccine
Friday, October 6, 2017: 12:30 PM

Background. Men who have sex with men (MSM) are at high risk for invasive meningococcal disease (IMD). Following a 2016 IMD outbreak in Southern California, public health officials issued an advisory that urged at-risk adult gay and bisexual men, and all people with HIV, to obtain immunizations. Despite public health efforts to increase MCV4 coverage, uptake and acceptance among MSM remains unknown. Thus, our study sought to: (1) estimate reported MCV4 immunization among MSM in Los Angeles, CA; and (2) document the facilitators and barriers to the newest vaccination recommendation following the recent outbreak.

Methods. From November 2016 through February 2017, we used venue-based sampling to recruit MSM in Los Angeles (N = 513). Eligible participants completed a 30-minute iPad survey that included items on MCV4 status, sexual behavior, vaccination knowledge and behaviors among other factors. Chi-square and independent sample t-tests were used to determine bivariate associations. Statistically significant variables from bivariate analyses were included in a multivariate logistic regression model predicting MCV4 uptake.

Results. Participants were young (M=33, SD=10) and racially/ethnically diverse: White (35.7%), Black/African American (14.6%), Hispanic (36.5%), Asian/Pacific Islander (4.1%), Other (9.2%). Reported MCV4 immunization among MSM (25.4%) and MSM living with HIV (37.7%) was low. Statistically significant correlates of MCV4 uptake in our multivariate model included: younger age (aOR=2.51), prior STI diagnosis (aOR=2.21), believing MCV4 vaccination was important (aOR=3.45), having confidence in the MCV4 vaccine (aOR=5.43), and knowing someone who had received the vaccination (aOR=5.79).

Conclusion. MSM's perceived health risk, vaccine confidence, and knowledge of someone who received the MCV4 vaccine were important indicators of meningitis immunization in this outbreak context. Provider and public health education efforts may be enhanced by messages that emphasize personal health risks, the safety and efficacy of MCV4, and the importance of meningococcal vaccines for men's health. Popular opinion leader programs facilitated by someone who had been vaccinated are warranted to enhance MCV4 uptake.

Disclosures. **All authors:** No reported disclosures.

1351. Bivalent Norovirus VLP Vaccine Candidate in Older Adults: Impact of MPL and a Second Dose in a Randomized, Controlled, Double-Blind Clinical Trial

Jim Sherwood, BA[1]; Jakob Cramer, MD[1]; Nancy Bouveret Le Cam, MD[1]; Stella Lin, PhD[2]; Frank Baehner, MD[1]; Paul Mendelman, MD[2] and Astrid Borkowski, MD[1]; [1]Takeda Pharmaceuticals International AG, Zurich, Switzerland, [2]Takeda Development Center Americas, Inc., Deerfield, Illinois

Session: 152. Herpes Zoster Vaccine
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 GI.1 and multivalent consensus GII.4c) 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 formulations contained 500µg $Al(OH)_3$adjuvant with 15µg GI.1 and 50µg GII.4c 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 8 after first vaccination. Geometric mean titers were similar in magnitude in all groups and persisted at similar levels through Day 56. No increases were observed with a second 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 when compared with those to a single vaccine dose in 18–49 year-olds. No clinically relevant differences in CMI responses or changes in antibody avidity were observed between formulations. Both formulations were generally well tolerated, the most frequent reaction being mild pain at the injection site. No vaccine-related SAEs were reported.

Conclusion. Older adults aged over 60 years displayed immune responses to NoV VLP vaccines that were similar to those in younger adults with no apparent signs of immunosenescence. These data support the further development of the MPL-free vaccine candidate in older adults.

Disclosures. **J. Sherwood**, Takeda Pharmaceuticals International AG: Employee, Salary; **J. Cramer**, Takeda Pharmaceuticals International AG: Employee, Salary; **N. Bouveret Le Cam**, Takeda Vaccines Inc.: Employee, Salary; **S. Lin**, Takeda Vaccines Inc.: Employee, Salary; **F. Baehner**, Takeda Pharmaceuticals International AG: Employee, Salary; **P. Mendelman**, Takeda Vaccines Inc.: Employee, Salary; **A. Borkowski**, Takeda Pharmaceuticals International AG: Employee, Salary