MenABCWY for the prevention of Invasive Meningococcal Disease caused by serogroups A, B, C, W and Y

Wendy Sohn, MD
Global Medical Lead Neisseria Vaccines

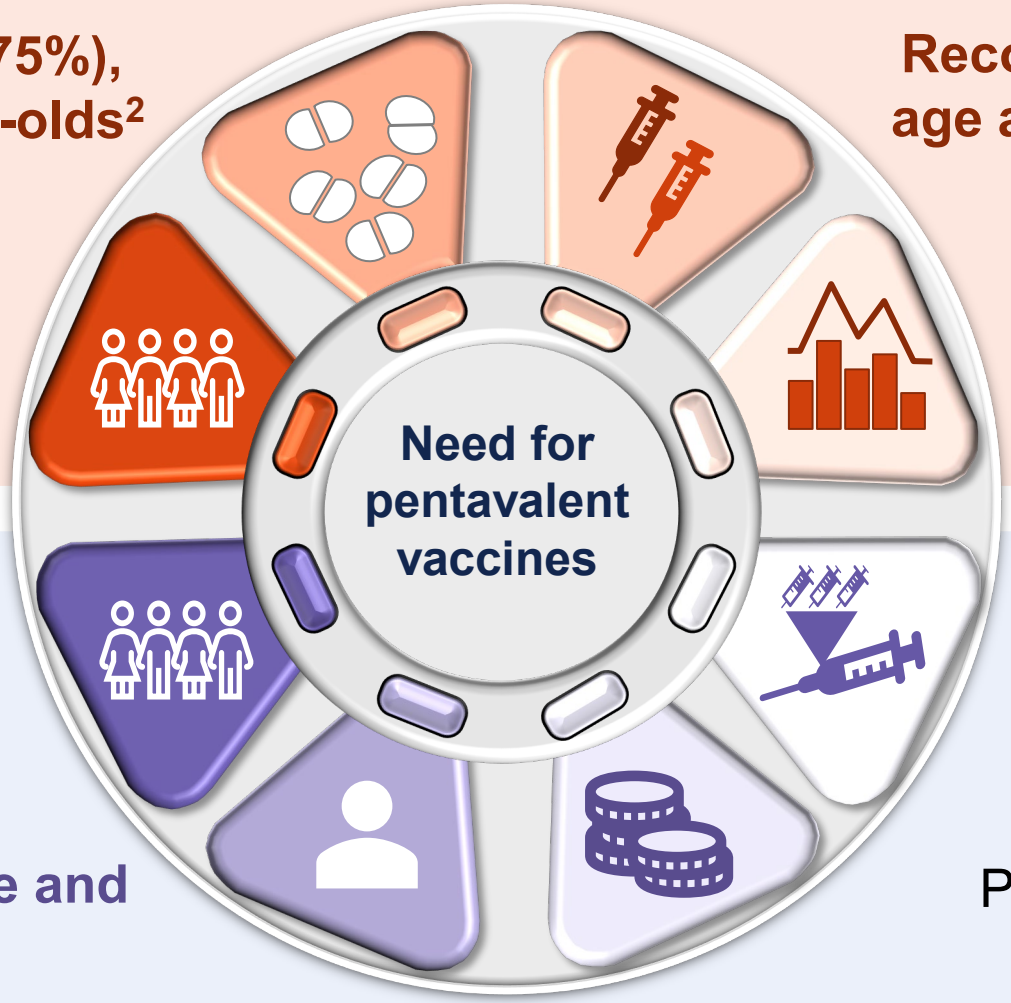
Concerted Prevention of IMD in Adolescents and Young Adults

Out of 5 serogroups: **B (75%), CWY(25%) in 16-23-year-olds**[2]

IMD is an uncommon but potentially **devastating disease**[1]

Recommendations based on age and high-risk conditions[3]

Low vaccination coverage for those at high-risk and **persistent disparities**[4,5]



Reduce **overall burden of pain** and **discomfort**[6]

Improved **convenience and compliance**[6]

Improve **vaccination coverage** rates[5] to meet the greatest medical need

Potentially better overall **economic value**[6]

1. Mbaeyi S, et al. *JAMA Pediatr* 2020; 174 (9):843-851; 2. Enhanced Meningococcal Disease Surveillance Reports 2015-2022; 3. CDC Immunization Schedule 2024; 4. Pingali C, et al. *MMWR Morb Mortal Wkly Rep* 2023; 72(34):912-919; 5. Marshall G, et al. *Clin Infect Dis* 2022, 75(1):155-158; 6. Kroger A, et al. General Best Practice Guidelines for Immunization. [www.cdc.gov/vaccines/hcp/acip-recs/general-recs/downloads/general-recs.pdf]. Accessed on February 28th, 2024.

MenABCWY Program Built on Antigenic Components of MenACWY$_{CRM}$ (Menveo) and MenB-4C (Bexsero)

Lyophilized MenACWY$_{CRM}$ (vial) + **Liquid MenB-4C (prefilled syringe)** = **MenABCWY[1]**

MenACWY$_{CRM}$[2]

2010

Immunogenicity and Safety in Healthy 2 months-55 year-olds[2]

Immunogenicity in high-risk patients[4-6]

Persistence of immune response after 4-6 years[9-11]

Real-world effectiveness[13]

MenB-4C[3]

2015

Immunogenicity and Safety in Healthy 10-25 year-olds[3]

Immunogenicity in high-risk patients[7,8]

Persistence of immune response after 4-7.5 years[12]

Real-world effectiveness[14-16]

Anticipated 2025[1]

Immunogenicity and Safety in Healthy 10-25 year-olds

1. GSK Press Release April 16, 2024. https://www.gsk.com/en-gb/media/press-releases/gsk-s-5-in-1-meningococcal-abcwy-vaccine-candidate-accepted-for-regulatory-review-by-us-fda/; 2. Prescribing Information for MENVEO; 3. Prescribing Information for BEXSERO; 4. Isitt C et al, *HIV Med.* 2023; 24(9):979-989; 5. Kimura A et al, *Clinical and Vaccine Immunology.* 2011; 18(3):483-486; 6. Findlow J et al, *Vaccine.* 2015; 33(29):3322-30; 7.Martinon-Torres F et al, *Pediatrics.* 2018; 142(3): e207174250; 8. Robin C et al, *Clin Microbiol Infect.* 2022, 28(12):1609-1614; 9. Tipton et al, *Vaccine.* 2019; 37(42):6171-6179; 10. Baxter et al, *Pediatr Infect Dis J.* 2014; 33(11):1169-1176; 11. Jacobson et al *Pediatr Infect Dis J.* 2013; 32(4):e170-177; 12. Watson PS et al. *Expert Review of Vaccines.* 2019; 18:4, 343-352; 13. Hyoung Im J et al, *Vaccine.* 2020; 38 (730-732); 14. McMillan M et al, *Clin Infect Dis.* 2021; 73(1):e233–7; 15. Wang B et al *Lancet Infect Dis.* 2022; 22:1011–20; 16. Wang B et al. *J Infect.* 2023; 22:S0163–4453

MenABCWY Program Built on Antigenic Components of $MenACWY_{CRM}$ (Menveo) and MenB-4C (Bexsero)

Lyophilized $MenACWY_{CRM}$ (vial) + **Liquid MenB-4C (prefilled syringe)** = **MenABCWY**[1]

MenABCWY Proposed Indication[2]

*Vaccine indicated for active immunization to prevent invasive disease caused by Neisseria meningitidis serogroups A, B, C, W, and Y in individuals **10 through 25 years** of age*

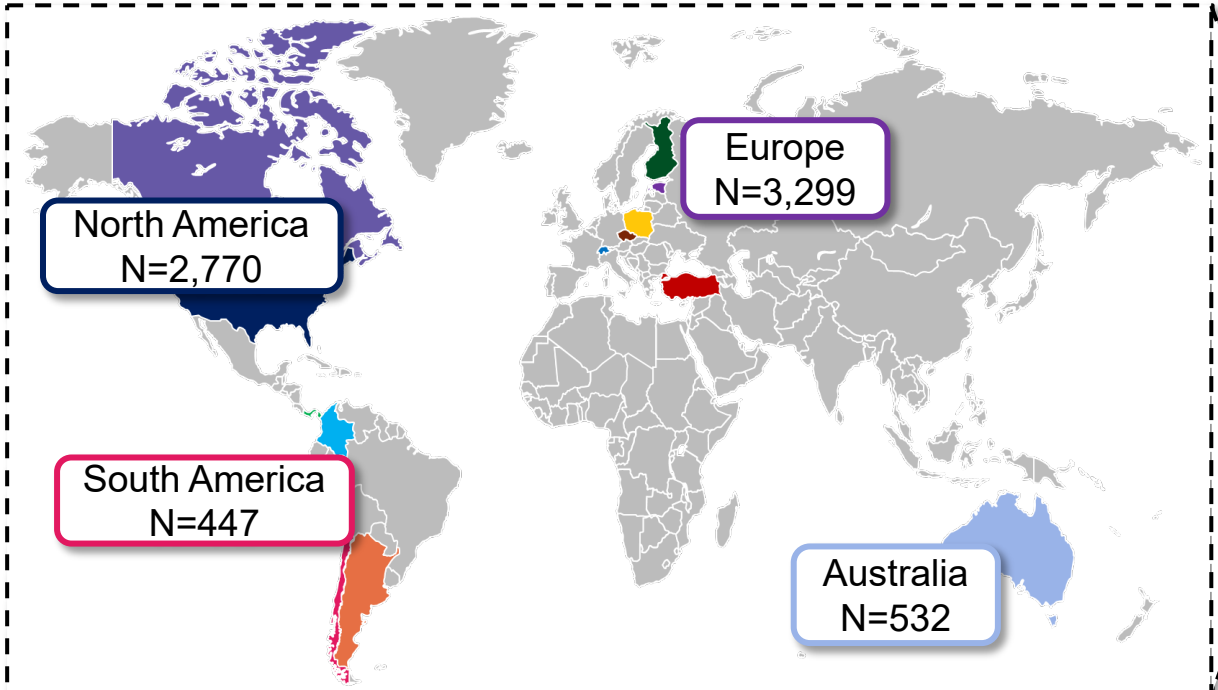
*Administer **2 doses** (0.5 mL each) intramuscularly at least **6 months apart***

1. GSK Press Release April 16, 2024. https://www.gsk.com/en-gb/media/press-releases/gsk-s-5-in-1-meningococcal-abcwy-vaccine-candidate-accepted-for-regulatory-review-by-us-fda/;
2. MenABCWY Candidate Vaccine Draft Prescribing Information, February 2024

Comprehensive MenABCWY Clinical Development Program

12 Studies, >7,000 Participants, 13 Countries

- 10 completed Ph1-2 studies: different formulations and administration schedules in ages 9 – 42 years[1]
- 2 completed Ph3 studies: safety and immunogenicity of MenABCWY in MenACWY-naïve and primed 10-25 yrs[2-3]
- 1 ongoing Phase 2 study: evaluating 2 doses administered 2 or 4 years apart in ages 11 – 14 years[4]

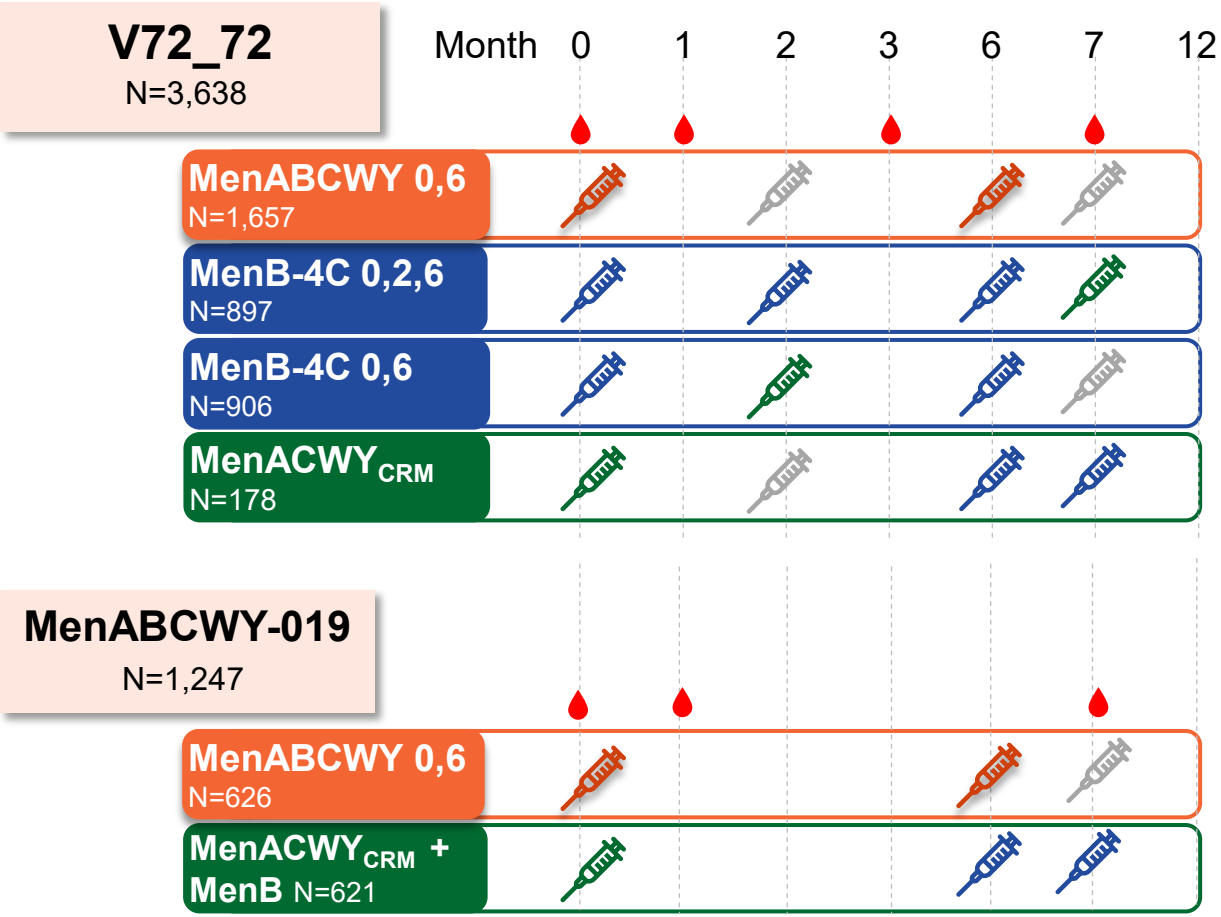


Vaccine exposed set[1]	N
MenABCWY (Total)	**3,718**
MenABCWY	**→ 1,216**
MenB-4C	**2,969**
$MenACWY_{CRM}$	**361**
TOTAL receiving ≥ 1 dose of study vaccine	**7,048**

1. GSK, Data on File 2024N555071; 2. Clinicaltrials.gov identifier NCT04502693, accessed May 31st, 2024; 3. Clinicaltrials.gov identifier NCT04707391, accessed May 31st, 2024; 4. Clinicaltrials.gov identifier NCT05087056, accessed May 31st, 2024.

Phase 3 Studies Assessed Safety and Immunogenicity of MenABCWY

Compared to MenB-4C, MenACWY$_{CRM}$ Administered per CDC Schedule at Study Onset



Study populations

10-25 years of age
MenACWY-naïve

15-25 years of age
MenACWY-primed*

Healthy participants, without progressive, unstable or uncontrolled clinical conditions (including abnormal immune function)

MenB-naïve

MenABCWY MenB-4C MenACWY$_{CRM}$ Placebo

N for each study arm depicts the exposed set. *MenACWY-primed participants received dose of licensed MenACWY vaccine ≥ 4 years prior to study start
Clinicaltrials.gov identifier NCT04502693, accessed May 31st, 2024 and Clinicaltrials.gov identifier NCT04707391, accessed May 31st, 2024.

Demographics and Baseline Characteristics of Phase 3 Studies

		V72_72			MenABCWY-019	
		MenABCWY N=1,657	MenB-4C 0-6 N=906	$MenACWY_{CRM}$ N=178	MenABCWY N=626	$MenACWY_{CRM}$ N=621
Median age	**At 1st vaccination, years (range)**	**16** (9–26)	**16** (9–26)	**16** (10–25)	**16** (15–25)	**16** (15–25)
Age group	**10–11 years**	320 **(19%)**	172 **(19%)**	27 **(15%)**	0	0
	12–17 years	666 **(40%)**	368 **(41%)**	76 **(43%)**	450 **(72%)**	441 **(71%)**
	18–25 years	671 **(40%)**	366 **(40%)**	75 **(42%)**	176 **(28%)**	180 **(29%)**
Region	**US**	491 **(30%)**	270 **(30%)**	52 **(29%)**	366 **(59%)**	365 **(59%)**
Sex	**Female**	933 **(56%)**	446 **(49%)**	100 **(56%)**	343 **(55%)**	325 **(52%)**
Race	**White**	1492 **(90%)**	791 **(87%)**	162 **(91%)**	474 **(76%)**	467 **(75%)**
	Asian	71 **(4%)**	60 **(7%)**	9 **(5%)**	22 **(4%)**	33 **(5%)**
	Black or African American	59 **(4%)**	29 **(3%)**	6 **(3%)**	94 **(15%)**	86 **(14%)**
	Other	35 **(2%)**	26 **(3%)**	1 **(1%)**	36 **(6%)**	38 **(6%)**
Ethnicity	**Not Hispanic or Latino**	1546 **(93%)**	852 **(94%)**	172 **(97%)**	447 **(71%)**	432 **(69%)**
	Hispanic or Latino	92 **(6%)**	41 **(5%)**	6 **(3%)**	179 **(29%)**	192 **(31%)**
	Not reported	19 **(1%)**	13 **(1%)**	0	0	0

N for each study arm depicts the exposed set.
Clinicaltrials.gov identifier NCT04502693, accessed May 31st, 2024 and Clinicaltrials.gov identifier NCT04707391, accessed May 31st, 2024.

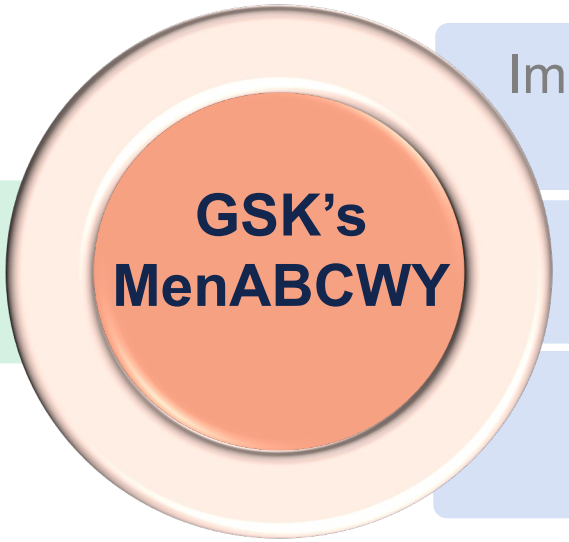
Evidence Supporting Safety and Immunogenicity of MenABCWY

Serogroups A C W Y

Serogroup B

Solicited and unsolicited adverse events after each dose of MenABCWY, MenB-4C or MenACWY$_{CRM}$

Non-inferiority vs MenACWY$_{CRM}$ in MenACWY-naïve and -primed



Immunogenicity of MenABCWY against 110 serogroup B strains

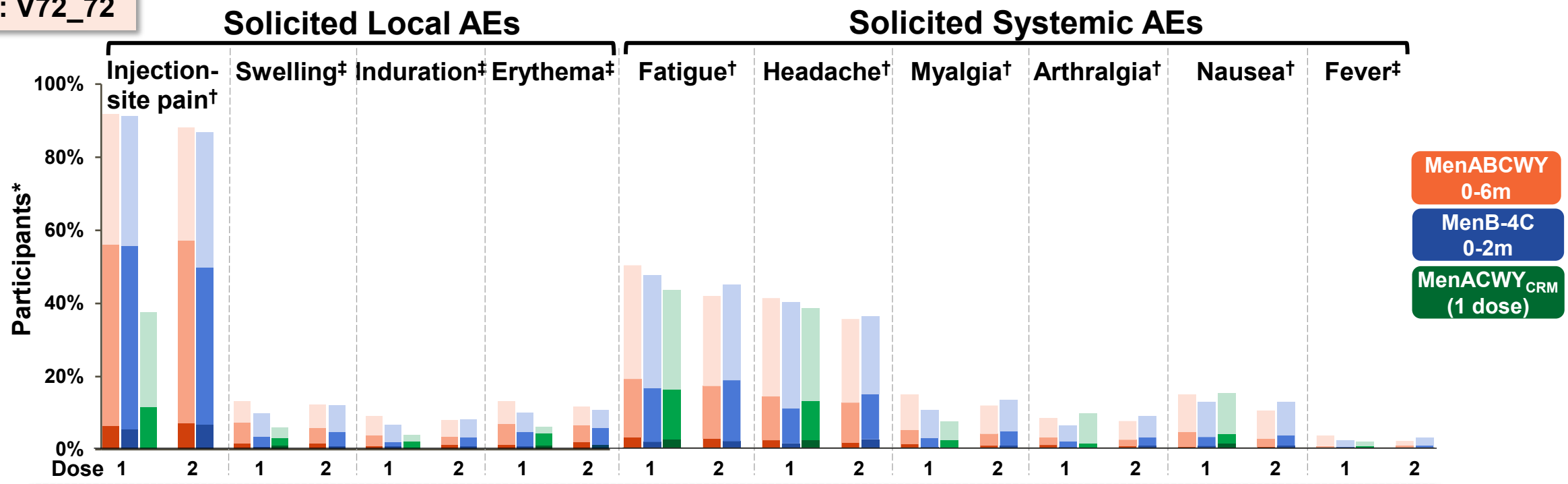
Immunological noninferiority of MenABCWY vs MenB-4C

Persistence and booster immune response up to 24 months

Clinicaltrials.gov identifier NCT04502693, accessed May 31st, 2024; Clinicaltrials.gov identifier NCT04707391, accessed May 31st, 2024; Vesikari T et al. *Hum Vaccin Immunother* 2021;17(11):4689-4700

Solicited Local and Systemic AEs within 7 Days, after Each Vaccination with MenABCWY, MenB-4C or MenACWY$_{CRM}$

Phase 3: V72_72



→ Generally **mild-to-moderate**, with mean **duration of 1-4 days**, depending on AE

→ Occurred at similar rates after MenABCWY and MenB-4C, and higher than after MenACWY$_{CRM}$

→ No observed difference between 1st and 2nd dose MenABCWY

†Severity of symptom	‡Size (mm)	‡Fever (°C)
Mild – easily tolerated	25–50	38.0–38.9
Moderate – interferes with normal activity	51–100	39.0–39.9
Severe – prevents normal activity	>100	≥ 40.0

AE: adverse event; *Number of participants varies by study vaccination: 1428-1638 for MenABCWY arm, 823-835 for MenB-4C and 178 for MenACWY.
GSK, Data on File 2024N555060

MenABCWY Demonstrated a Well-Tolerated Safety Profile Comparable to MenB-4C

Integrated Safety Analysis (Pooled) N =7,048	MenABCWY N=3,718 n (%)	MenB-4C N=2,969 n (%)	MenACWY$_{CRM}$ N=361 n (%)
Unsolicited AEs (within 30 days of any vaccination)	1,072 **(29%)**	736 **(25%)**	47 **(13%)**
Related*	256 **(7%)**	155 **(6%)**	10 **(3%)**
AEs leading to withdrawal	8 **(0.2%)**	4 **(0.1%)**	0
Medically attended AEs†	416 **(12%)**	302 **(11%)**	8 **(4%)**
Related medically attended AEs†	22 **(0.6%)**	15 **(0.5%)**	0
SAEs (entire study period)	70 **(1.9%)**	58 **(2%)**	5 **(1.4%)**
Related*	3 **(0.1%)**	2‡ **(0.1%)**	0
Deaths (all unrelated)	1§	2¶	1§

*Assigned as related by investigator; †Medically attended flags for AEs are not available in studies V102P1, V102_02, V102_02E1 and V102_03. Participants from these studies are not included. Therefore, the denominator is different for the 3 groups (MenABCWY N=3488, MenB N=2861, MenACWY N=213); ‡2 SAEs occurred in the MenB-4C arms of the studies included in the pooled safety analysis: 1 SAE followed a MenB-4C and 1 followed a MenACWY-CRM vaccination; §Suicide; ¶Deaths by poisoning and drug overdose; AE: adverse event; SAE: serious adverse event
GSK, Data on File 2024N555058.

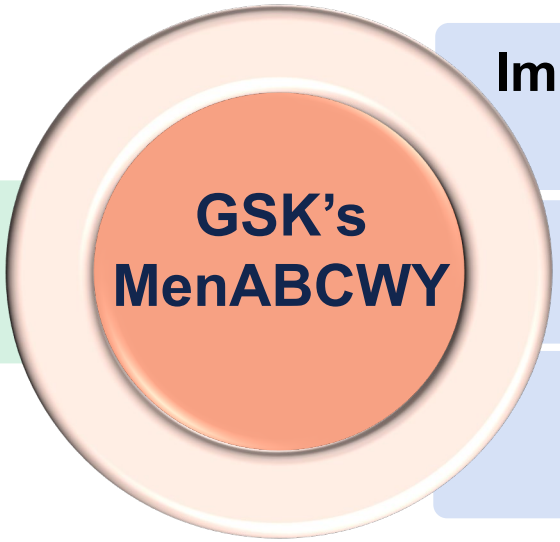
Evidence Supporting Safety and Immunogenicity of MenABCWY

Serogroups A C W Y

Serogroup B

Solicited and unsolicited adverse events after each dose of MenABCWY, MenB-4C or MenACWY$_{CRM}$

Non-inferiority vs MenACWY$_{CRM}$ in MenACWY-naïve and -primed



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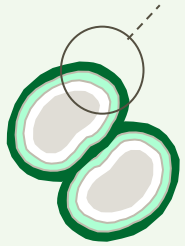
Assays Used to Infer Meningococcal Vaccine Protection

	Vaccine targets	Traditional hSBA	
MenACWY Vaccines	*N. meningitidis* **capsule polysaccharide**  Highly abundant, conserved antigens[1]	hSBA against serogroup-specific polysaccharide capsule reference strain **infers protection against all strains in serogroup[2]**	**Surrogate of protection:** titer ≥4 threshold for protection[2,3,4,5,6]

hSBA, human serum bactericidal assay

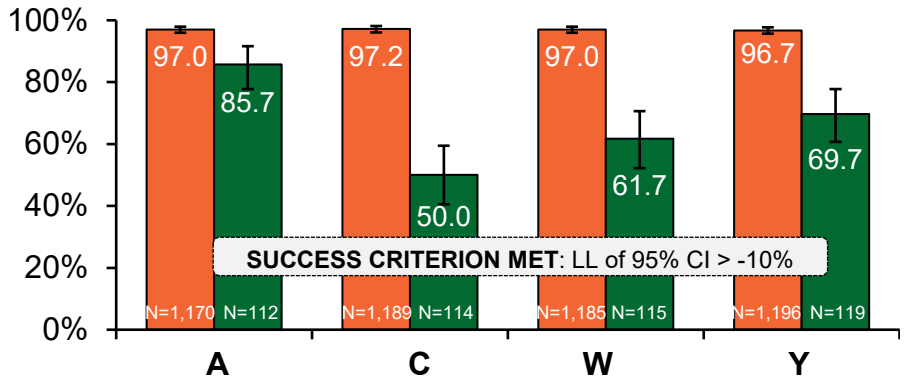
1. CDC, 2022. About meningococcal vaccines. https://www.cdc.gov/vaccines/vpd/mening/hcp/about-vaccine.html; 2. Donald RGK *et al. Hum Vaccin Immunother.* 2017;13:255–265; 3. Balmer P *et al. Postgrad Med.* 2020;132:184–191;
4. Goldschneider I, et al. *J Exp Med.* 1969;129(6):1307-1348; 5. Bröker M et al. *Vaccine*. 2009;27:5574–5580; 6.Ferlito et al. *Clin Exp Immunol.* 2018;194(3): 361-370; 6. Muzzi A et al. *MSphere.* 2022;e00385223

MenABCWY Non-Inferior to MenACWY$_{CRM}$ in MenACWY-Naïve and MenACWY-Primed Participants

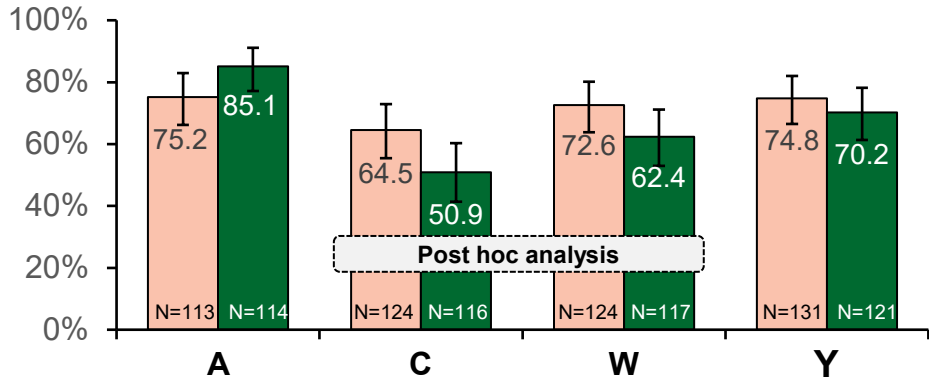
V72_72: MenACWY-Naïve

% with 4-fold Rise in hSBA Titers*† (95% CI)

2 doses MenABCWY non-inferior to 1 dose MenACWY$_{CRM}$‡,1



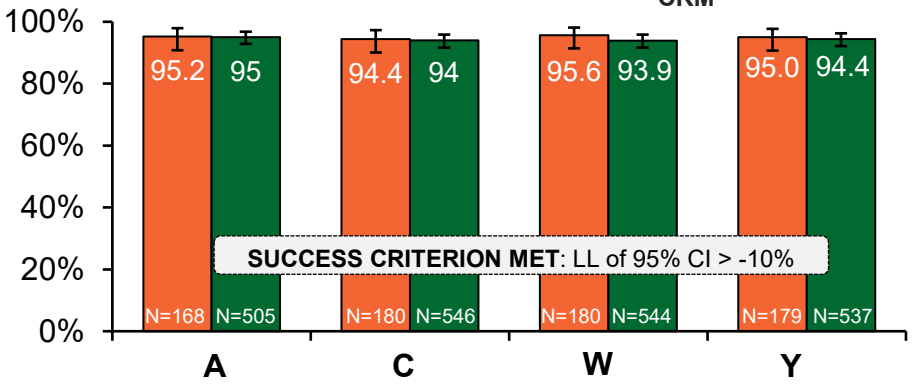
1 dose MenABCWY compared to 1 dose MenACWY$_{CRM}$#,3



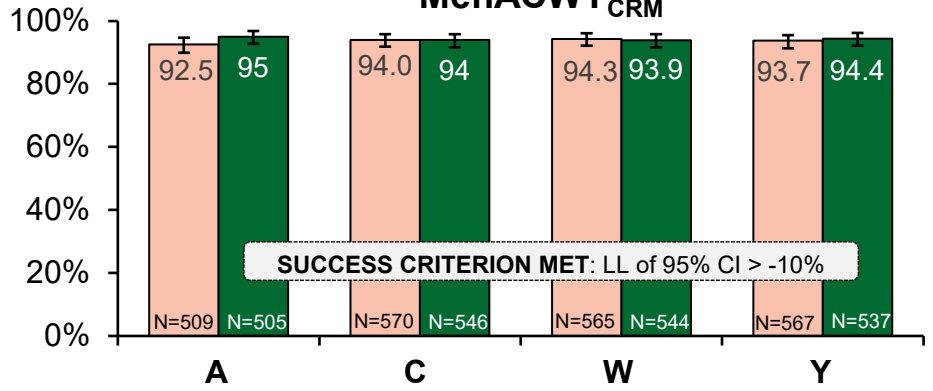
MenABCWY-019: MenACWY-Primed**

% with 4-fold Rise in hSBA Titers*† (95% CI)

2 doses MenABCWY non-inferior to 1 dose MenACWY$_{CRM}$‡,2



1 dose MenABCWY non-inferior to 1 dose MenACWY$_{CRM}$2



MenABCWY (2 doses)

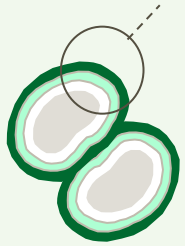
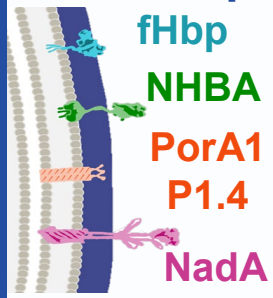
MenABCWY (1st dose)

MenACWY (1 dose)

*At 1 month after 1 or 2 doses of MenABCWY or after single MenACWY vaccination; †Defined as a post-vaccination titer ≥4-fold the LOD or ≥LLOQ, whichever is greater if pre-vaccination titer <LOD, a post-vaccination titer ≥4-fold the LLOQ if pre-vaccination titer ≥LOD and <LLOQ, and a post-vaccination titer ≥4-fold the pre-vaccination titer if pre-vaccination titer ≥LLOQ. LOD: 4 for MenA, MenC, MenW, and MenY. LLOQ = 12 for MenA; 8 for MenC; 8 for MenW; 10 for MenY, except for the post-hoc analysis for which LLOQs were 8 for MenA and 11 for MenC; ‡Licensure criteria agreed with CBER; #full set analysis; **Primed participants had received a dose of MenACWY vaccine at least 4 years prior. CI – confidence interval, hSBA - human serum bactericidal assay, LOD – limit of detection; LLOQ – lower limit of quantitation

1. Clinicaltrials.gov identifier NCT04502693, accessed May 31st, 2024; 2. Clinicaltrials.gov identifier NCT04707391, accessed May 31st, 2024; 3. GSK, Data on File 2024N555056.

Assays Used to Infer Meningococcal Vaccine Protection

Vaccine targets	Traditional hSBA	enc-hSBA
MenACWY Vaccines *N. meningitidis* **capsule polysaccharide**  Highly abundant, conserved antigens[1]	hSBA against serogroup-specific polysaccharide capsule reference strain **infers protection against all strains in serogroup**[2]	➢ GSK developed **enc-hSBA**[5] to test against multiple serogroup B strains ➢ **110 strains** randomly selected from 2000-2008 IMD cases, that continue to represent **95% of US disease causing serogroup B strains**[5] collected up to 2017
MenB Vaccines *N. meningitidis* **subcapsular* proteins**  **fHbp** **NHBA** **PorA1 P1.4** **NadA** Variable expression among disease-causing serogroup B strains[3]	hSBA **does not assess vaccine induced immune response** against many **diverse strains** expressing more than 1 antigen[4]	

hSBA, human serum bactericidal activity; enc-hSBA, endogenous complements human serum bactericidal activity, Men, meningococcal serogroup; fHbp – factor H binding protein; NHBA – Neisserial Heparin Binding Antigen; NadA – Neisseria Adhesin A; PorA1 P1.4 – porin A1 P1.4. *A MenB capsular vaccine was poorly immunogenic due to structural similarity between the capsule and human tissue[5]

1.CDC, 2022. About meningococcal vaccines. https://www.cdc.gov/vaccines/vpd/mening/hcp/about-vaccine.html; 2. Donald RGK *et al. Hum Vaccin Immunother.* 2017;13:255–265; 3. Balmer P *et al. Postgrad Med.* 2020;132:184–191; 4. Kleinschmidt A *et al. NPJ Vaccines.* 2021;6:29; 5. Muzzi A et al. *MSphere.* 2022;e00385223

enc-hSBA: Immune Response Against Diverse Serogroup B Strains in MenABCWY vs MenB-4C Arms

Immunological Vaccine Effectiveness (IVE)

Test-Based

IVE = (1 – relative risk) x 100

Relative risk defined as the percentage of tests without bactericidal activity in the group receiving MenB-containing vaccine compared to controls

→ informs on breadth of MenB vaccine strain coverage at a population level

Responder-Based

Percentage of participants whose sera killed ≥70% of strains tested†

→ percentage of participants achieving broad protection against serogroup B strains

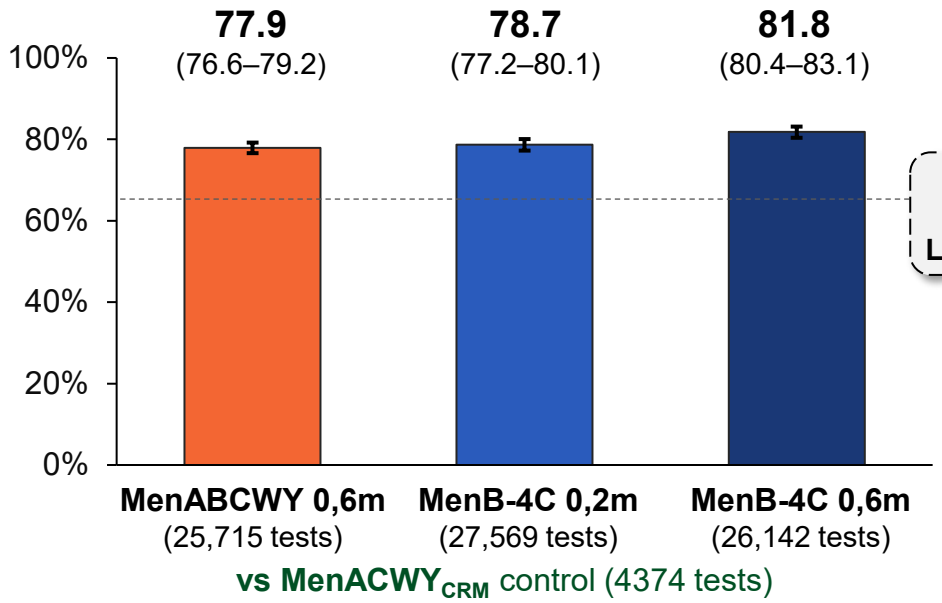
*relative risk = ratio between % of tests lacking bactericidal activity against 110-strain panel in group receiving MenB-containing vaccine and control (MenACWY vaccine); †Target number of strains tested for each participant was 35 strains out of the 110 strains panel. MenB: meningococcal serogroup B; enc-hSBA: endogenous complement serum bactericidal activity; IVE: immunological vaccine effectiveness

Welsch et al, *Vaccine*. 2018;36(15): 5309-5317; Clinicaltrials.gov identifier NCT04502693, accessed May 31st, 2024

enc-hSBA: Immune Response against Diverse Serogroup B Strains after 2 doses of MenABCWY or MenB-4C

Test-Based IVE

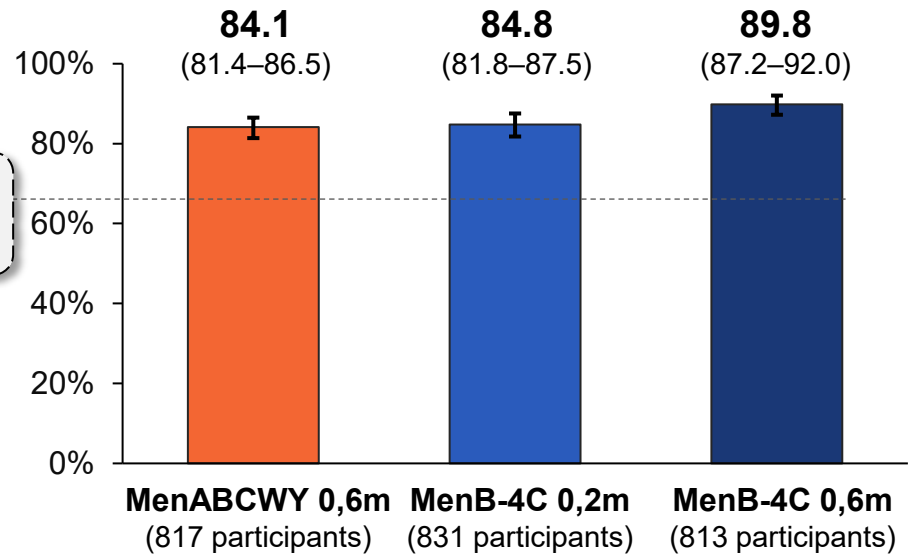
→ Informs breadth of MenB vaccine strain coverage at a population level



SUCCESS CRITERION MET: LL of 97.5% CI > 65%

Responder-Based IVE

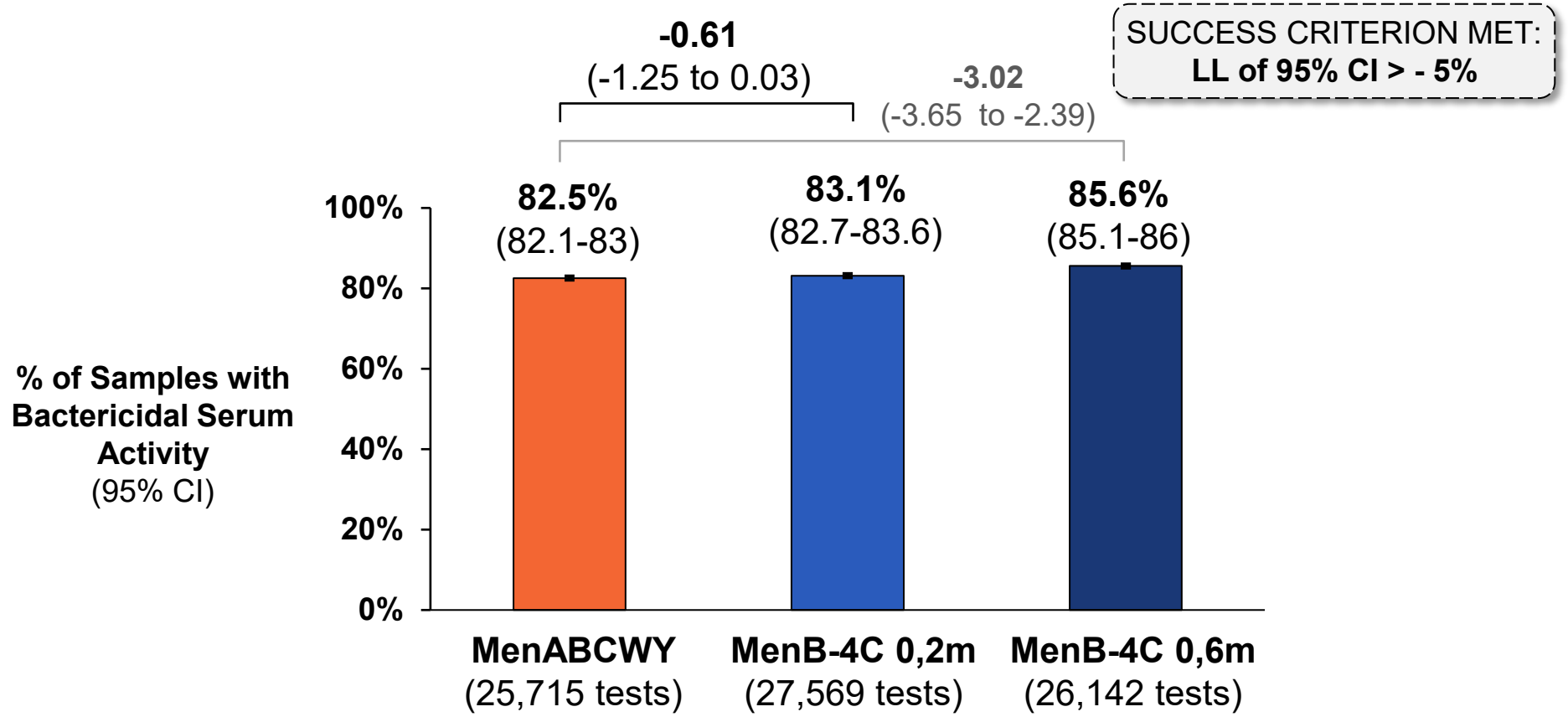
→ % participants achieving broad protection against serogroup B strains



MenABCWY achieved breadth of bactericidal effect against a diverse and broad panel of serogroup B strains, similar to MenB-4C 2-dose administered 2 or 6 months apart

The 3 MenB-4C schedules were hierarchically tested for IVE in the order: MenB-4C 0-2-6m → MenB-4C 0-6m→MenB-4C 0-2m. The 0-2m schedule was the last schedule to meet the predefined success criterion (**LL of 95% CI > 65%**) and was hence chosen as the comparator for the MenABCWY 0-6m schedule for all subsequent statistical analyses. LL, lower limit; IVE: immunological vaccine effectiveness
Clinicaltrials.gov identifier NCT04502693, accessed May 31st, 2024

enc-hSBA: Noninferiority of Immune Response against Diverse Serogroup B Strains in MenABCWY vs MenB-4C



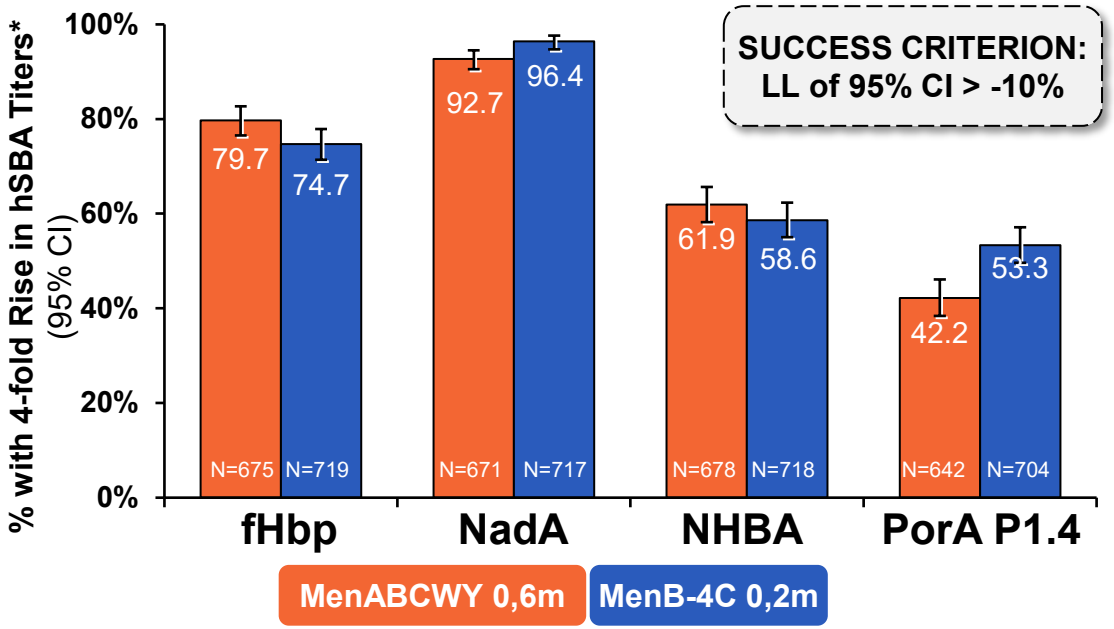
MenABCWY was noninferior to MenB-4C, based on bactericidal effects against diverse strains assessed by enc-hSBA assay

*The 3 MenB-4C schedules were hierarchically tested for IVE in the order: MenB-4C 0-2-6m → MenB-4C 0-6m→MenB-4C 0-2m. The 0-2m schedule was the last schedule to meet the predefined success criterion (LL of 97.5% CI > 65%) and was hence chosen as the comparator for the MenABCWY 0-6m schedule for all subsequent statistical analyses. LL, lower limit
Clinicaltrials.gov identifier NCT04502693, accessed May 31st, 2024

hSBA: MenABCWY Immune Response Against Serogroup B Reference Strains

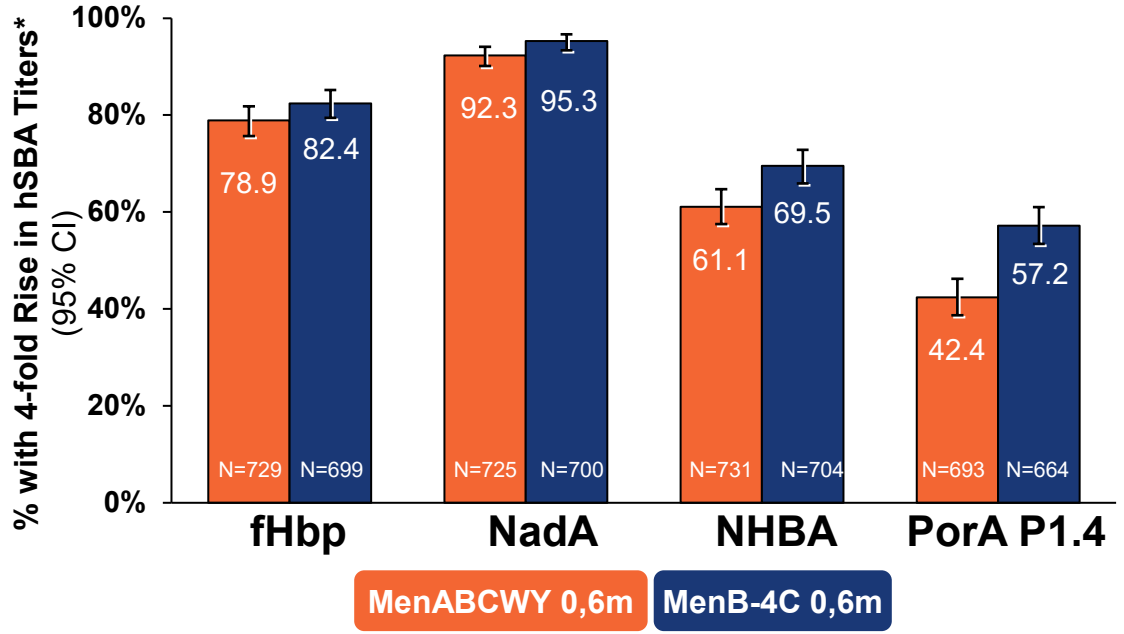
MenABCWY 0,6m vs MenB-4C 0,2 m

Group difference: (95%CI)	fHbp	NadA	NHBA	PorA P1.4
	5.02 (0.6 to 9.4)	–3.68 (–6.2 to –1.3)	3.31 (–1.8 to 8.4)	–11.06 (–16.3 to –5.7)



MenABCWY 0,6m vs MenB-4C 0,6 m

Group difference: (95%CI)	fHbp	NadA	NHBA	PorA P1.4
	-3.53 (-7.6 to 0.6)	–3.01 (–5.6 to –0.5)	-8.31 (–13.2 to -3.4)	–14.80 (–20.0 to –9.5)



- Secondary endpoint not met because success criterion not met for all 4 strains
- MenABCWY elicited comparable immune responses for 3 reference strains vs MenB-4C 0,2 and 2 reference strains vs MenB-4C 0,6m.

*At 1 month after 2nd MenABCWY or 2nd MenB-4C vaccination, relative to baseline. 4-fold rise in hSBA titer for each strain was defined as a post-vaccination titer ≥4-fold the LOD or ≥LLOQ, whichever is greater if pre-vaccination titer <LOD, a post-vaccination titer ≥4-fold the LLOQ if pre-vaccination titer ≥LOD and <LLOQ, and a post-vaccination titer ≥4-fold the pre-vaccination titer if pre-vaccination titer ≥LLOQ. LOD – limit of detection; LLOQ – lower limit of quantitation; LOD: fHbp: 3; NadA: 6; NHBA: 4; PorA P1.4: 4. LLOQ: fHbp: 5; NadA: 15; NHBA: 4; PorA P1.4: 6. fHbp, factor H binding protein; hSBA, human serum bactericidal assay; LL, lower limit; LOD – limit of detection; LLOQ – lower limit of quantitation; NadA, *Neisseria* adhesin A; NHBA, Neisserial heparin-binding antigen; Por A P1.4, porin A

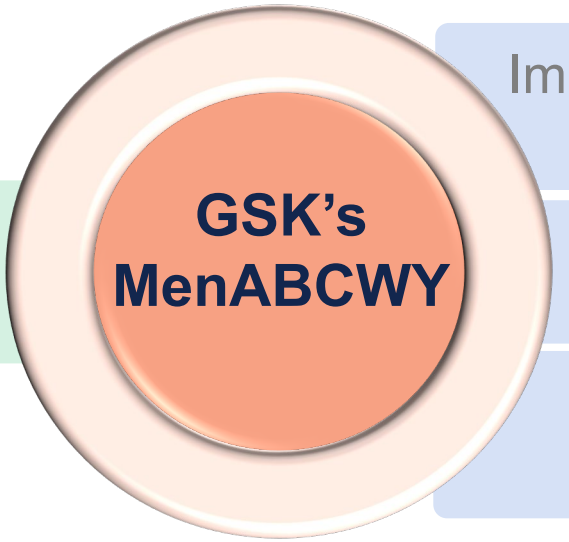
Clinicaltrials.gov identifier NCT04502693, accessed May 31st, 2024

Evidence Supporting Safety and Immunogenicity of MenABCWY

Serogroups A C W Y

Solicited and unsolicited adverse events after each dose of MenABCWY, MenB-4C or MenACWY$_{CRM}$

Non-inferiority vs MenACWY$_{CRM}$ in MenACWY-naïve and -primed



Serogroup B

Immunogenicity of MenABCWY against 110 serogroup B strains

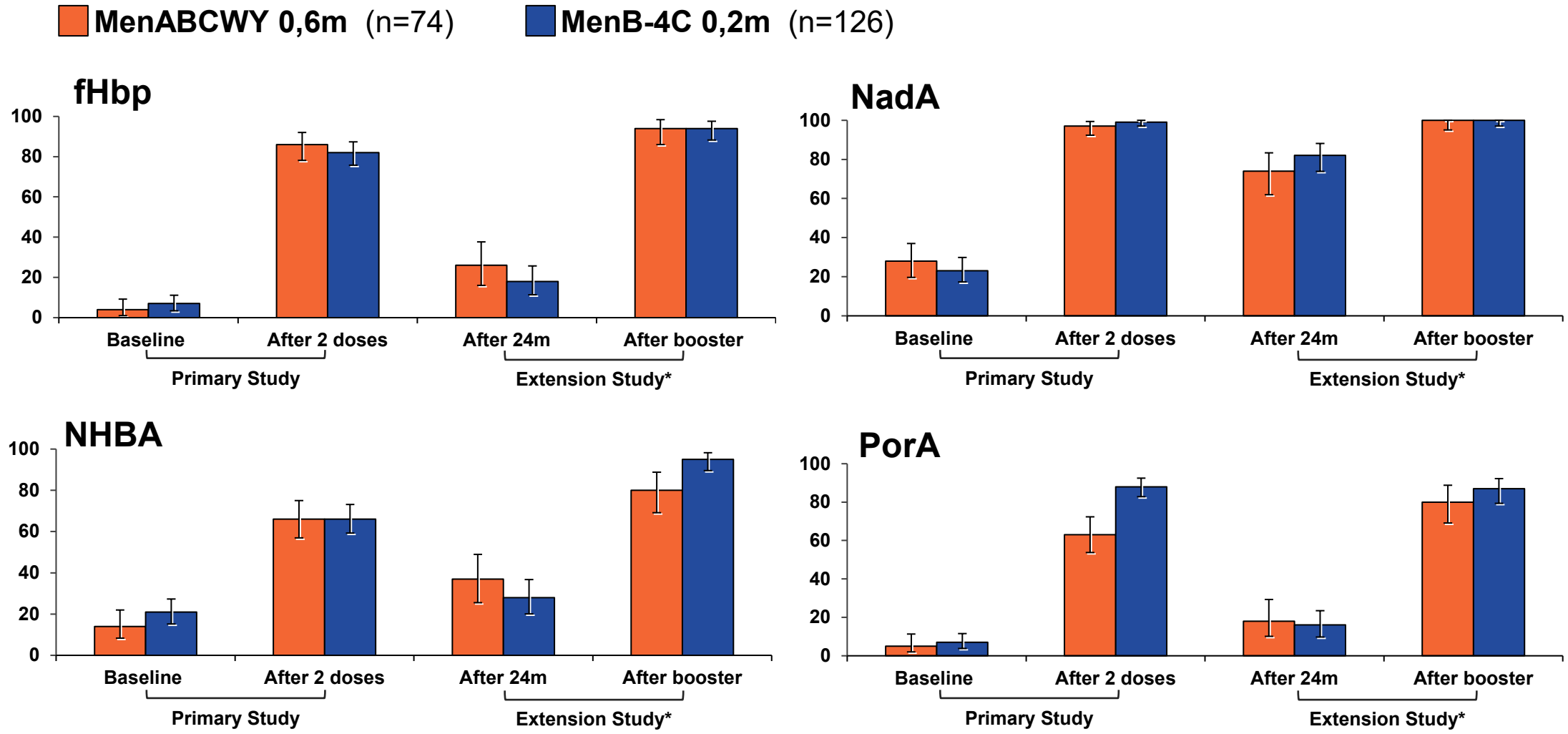
Immunological noninferiority of MenABCWY vs MenB-4C

Persistence and booster immune response up to 24 months

Clinicaltrials.gov identifier NCT04502693, accessed May 31st, 2024; Clinicaltrials.gov identifier NCT04707391, accessed May 31st, 2024; Vesikari T et al. *Hum Vaccin Immunother.* 2021;17(11):4689-4700

Persistence After 24 months and Booster Response of MenABCWY Demonstrated Against Serogroup B Reference Strains

Study 15E1



*For follow-on group: blood draws were done at baseline and 5 days after booster dose. For the Matched Naive group: blood draws were baseline (prevaccination), 1 month after 1st dose and 5 days after 2nd dose. fHbp, factor H binding protein; hSBA, serum bactericidal assay using human complement; LLOQ, lower limit of quantitation; NadA, Neisseria adhesin A; NHBA, Neisseria heparin binding antigen; PorA, porin A. The LLOQs were 8.0 (fHbp), 8.6 (NadA), 8.9 (NHBA), 8.2 (PorA).

Vesikari T et al. *Hum Vaccin Immunother.* 2021;17(11):4689-4700

MenABCWY Summary

→ Combines two well-established vaccines licensed in the US - MenB-4C, MenACWY$_{CRM}$

→ Clinical program demonstrated safety and immunogenicity in adolescents and young adults

→ Tested against a broad panel of 110 serogroup B strains, representing 95% of US serogroup B disease-causing strains

→ Demonstrated persistence of immune response up to 24 months

Summary of Data for Policy Considerations

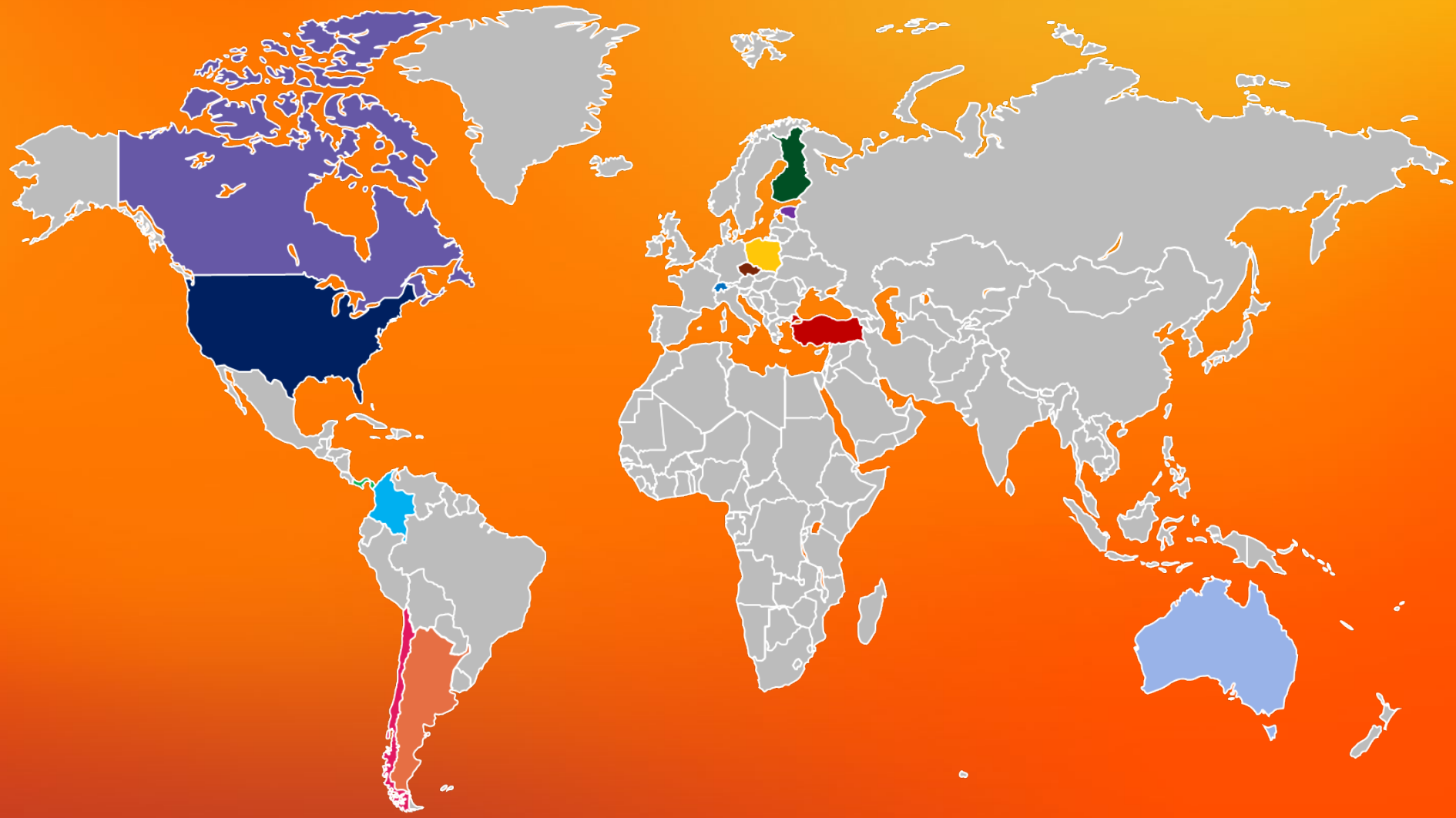
2 doses of MenABCWY can protect against serogroups A,B,C W,Y

- → Achieves broad coverage against strains causing endemic and outbreak disease, to meet the current and evolving US epidemiology
- → Offers the opportunity to improve vaccination coverage in adolescents and young adults
- → Represents the evolution of IMD as **one vaccine-preventable disease**

MenABCWY allows for prevention of IMD with one vaccine

Thank you!

Investigators, study site personnel, study participants, and their families



GSK