

# MenABCWY Meningococcal Vaccine

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# MenABCWY Vaccine Overview

## Indication and dosing being sought for MenABCWY vaccine

- Active immunization of individuals 10 through 25 years of age against invasive meningococcal diseases caused by *Neisseria meningitidis* serogroups A, B, C, W, Y
- Dosing:
  - Administer two doses at least 6 months apart for prevention of meningococcal disease caused by serogroups A, B, C, W and Y.
  - Administer one dose for prevention of meningococcal disease caused by serogroups A, C, W and Y.
  - A booster dose may be administered to individuals who have previously completed a primary series with MenABCWY or MenB-fHbp vaccine or who have previously received MenACWY conjugated vaccines

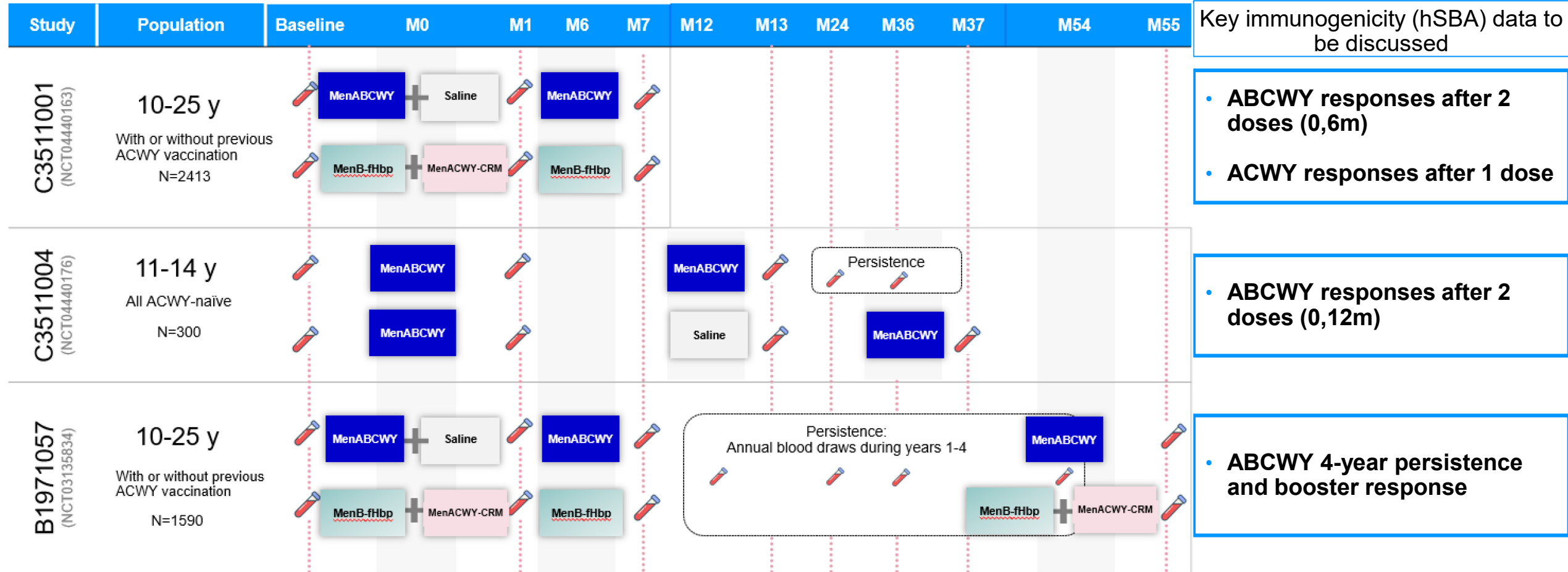
## MenABCWY vaccine composition

- MenABCWY vaccine is composed of drug substance from:
  - Trumenba® (MenB-fHbp): licensed in the US for the prevention of invasive disease caused by *Neisseria meningitidis* group B in individuals 10 through 25 years of age
  - Nimenrix® (MenACWY-TT): licensed ex-US for the prevention of invasive disease caused by *Neisseria meningitidis* serogroups A, C, W, and Y in individuals 6 weeks of age and older.

# Adolescent meningococcal vaccination platform options for MenABCWY vaccine



# MenABCWY vaccine clinical program overview



- All participants were meningococcal serogroup B vaccine naïve prior to study entry
- 80% of participants in the Phase 3 study were Caucasian; 10% black and African Americans; 25% of participants being Hispanic or Latino

An abstract, three-dimensional graphic composed of several overlapping, curved blue planes. The planes are rendered with a gradient from light blue to dark blue, creating a sense of depth and movement. The overall shape is reminiscent of a stylized wave or a series of connected, curved segments.

# Immunogenicity

# Immunogenicity objectives and endpoints

## FDA agreement for licensure

### ACWY evaluation (non-inferiority after 1 and 2 doses of MenABCWY vaccine versus MenACWY-CRM)

- hSBA seroresponse\* (4-fold)
- Naïve and primed participants

### B evaluation (non-inferiority after 2 doses of MenABCWY vaccine versus MenB-fHbp)

- hSBA seroresponse\* (4-fold)
- Composite response<sup>†</sup>

### ABCWY evaluation (Other endpoints)

- hSBA thresholds (1:4, 1:8, 1:16)
- GMTs

**MenB immunogenicity analysis:** Same approach taken as for Trumenba licensure in the US

- **4 MenB test strains utilized**, 2 from Factor H Binding Protein (fHbp) subfamily A (A22, A56) and 2 from subfamily B (B24, B44)
- **hSBA results provide information on breadth of coverage against MenB strains**
- All strains express **vaccine-heterologous fHbp variants**
- **Strains and fHbp variants** expressed are representative of known genetic diversity; strains were randomly selected
- hSBA seropositivity defined as titers  $\geq 1:8$  or  $\geq 1:16$ , which is greater than the 1:4 correlate of protection

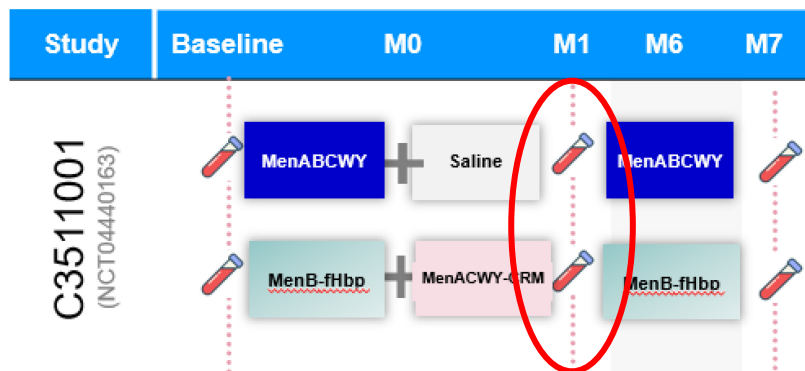
Abbreviations: hSBA=human serum bactericidal assay; GMT=geometric mean titer; MenB=serogroup B

\*For participants with a baseline hSBA titer  $< 1:4$ , seroresponse is defined as a titer  $\geq 1:16$ . For those with a baseline hSBA titer  $\geq 1:4$  and  $< 1:8$  ( $< 1:16$  for A22), seroresponse is a titer  $\geq 4$  times the 1:8 (1:16 for A22). For those with a baseline hSBA titer  $\geq 1:8$  ( $\geq 1:16$  for A22), seroresponse is a titer  $\geq 4$  times the baseline titer. <sup>†</sup>hSBA titer  $\geq 1:8$  (1:16 for A22) for all 4 primary strains 1 month after Dose 2.



# Immunogenicity ACWY-naive

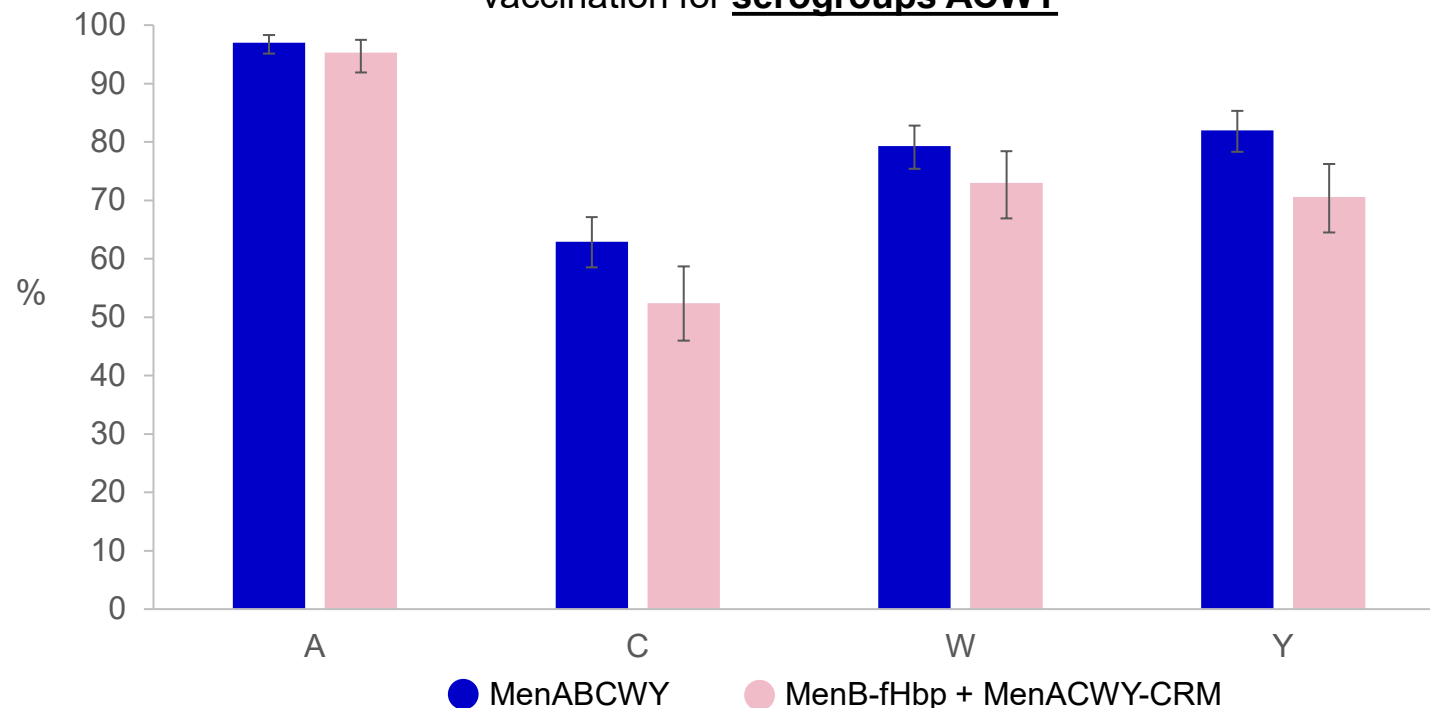
# A single dose of MenABCWY vaccine can be used as an alternative to ACWY vaccines in ACWY-naïve adolescents



Comparisons (ACWY-naïve participants):

- MenABCWY vaccine 1 month after first dose
- MenACWY-CRM 1 month after single dose

Percentage of participants achieving hSBA seroresponse\* 1 month after vaccination for **serogroups ACWY**



- 1 dose of MenABCWY vaccine was **noninferior** to 1 dose of MenACWY-CRM in ACWY-naïve participants
- 82.4%-99.4% of participants had serogroups ACWY hSBA titers  $\geq 1:8$  after 1 dose of MenABCWY vaccine

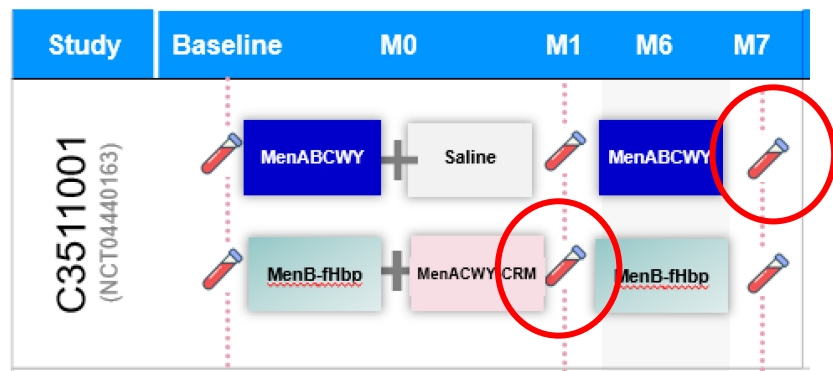
Abbreviations: hSBA=serum bactericidal assay using human complement.

\*For participants with a baseline hSBA titer  $< 1:4$ , seroresponse is defined as a titer  $\geq 1:16$ . For those with a baseline hSBA titer  $\geq 1:4$  and  $< 1:8$ , seroresponse is a titer  $\geq 4$  times the 1:8. For those with a baseline hSBA titer  $\geq 1:8$ , seroresponse is a titer  $\geq 4$  times the baseline titer.

N=492-501 for MenABCWY group; N=244-254 for MenB-fHbp + MenACWY-CRM group.  
Data on File, Study C3511001 (NCT04440163) Aug 2022, Pfizer Inc.



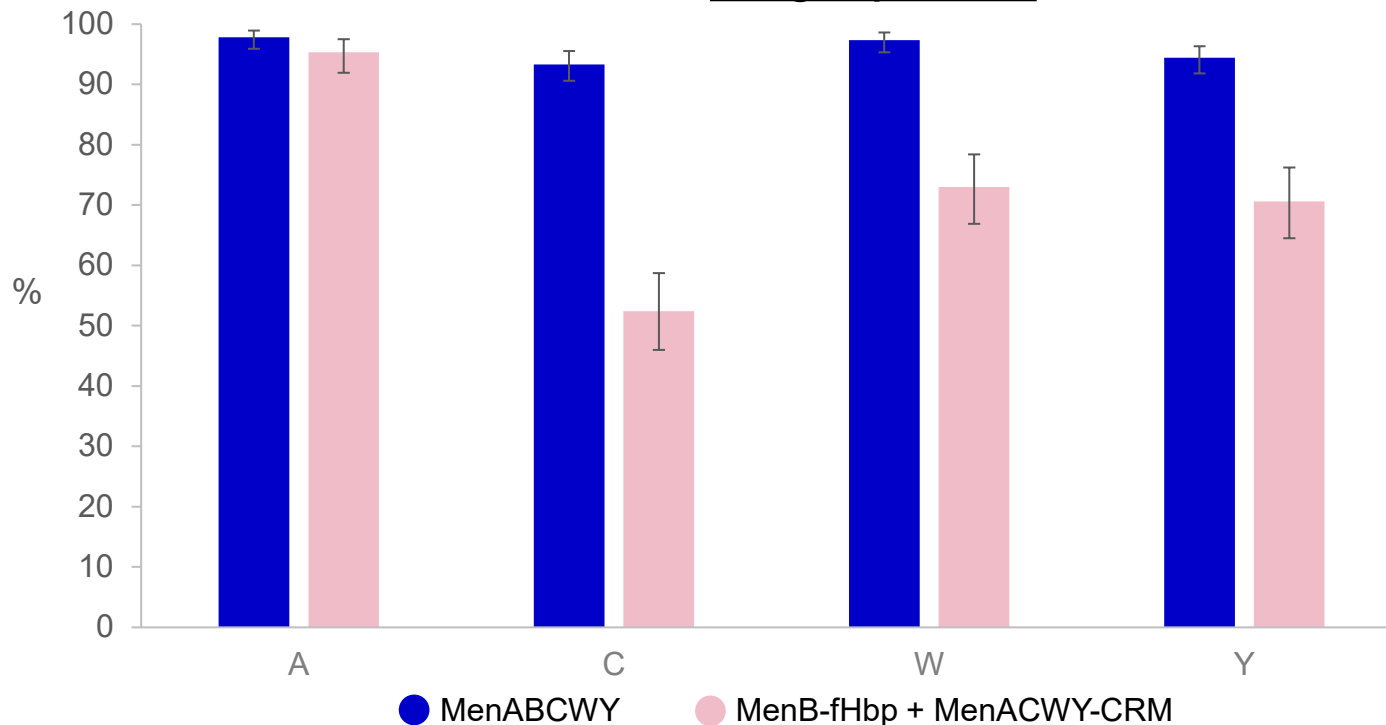
# 2 doses of MenABCWY vaccine elicit higher responses versus a single dose of MenACWY-CRM in ACWY-naïve participants



Comparisons (ACWY-naïve participants):

- MenABCWY vaccine 1 month after second dose
- MenACWY-CRM 1 month after single dose

Percentage of participants achieving hSBA seroresponse\* 1 month after vaccination for **serogroups ACWY**



- 2 doses of MenABCWY vaccine were **noninferior** to 1 dose of MenACWY-CRM in ACWY-naïve participants
- 99.1-99.8% of participants had serogroups ACWY hSBA titers  $\geq 1:8$  after 2 doses of MenABCWY vaccine

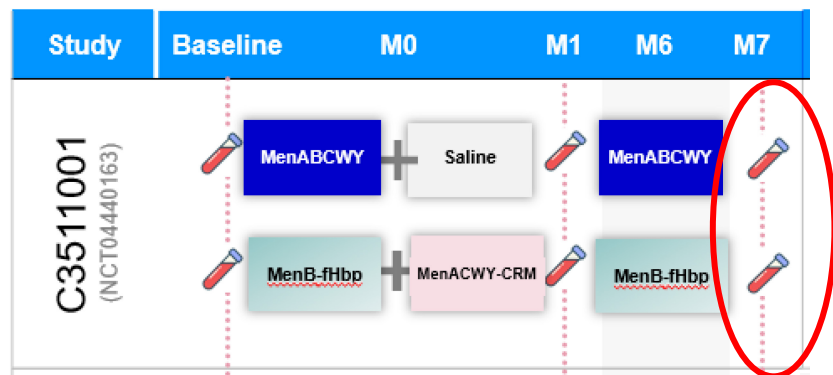
Abbreviations: hSBA=serum bactericidal assay using human complement.

\*For participants with a baseline hSBA titer  $< 1:4$ , seroresponse is defined as a titer  $\geq 1:16$ . For those with a baseline hSBA titer  $\geq 1:4$  and  $< 1:8$ , seroresponse is a titer  $\geq 4$  times the 1:8. For those with a baseline hSBA titer  $\geq 1:8$ , seroresponse is a titer  $\geq 4$  times the baseline titer.

N=439-451 or MenABCWY group; N=244-254 for MenB-fHbp + MenACWY-CRM group.

Data on File, Study C3511001 (NCT04440163) Aug 2022, Pfizer Inc.

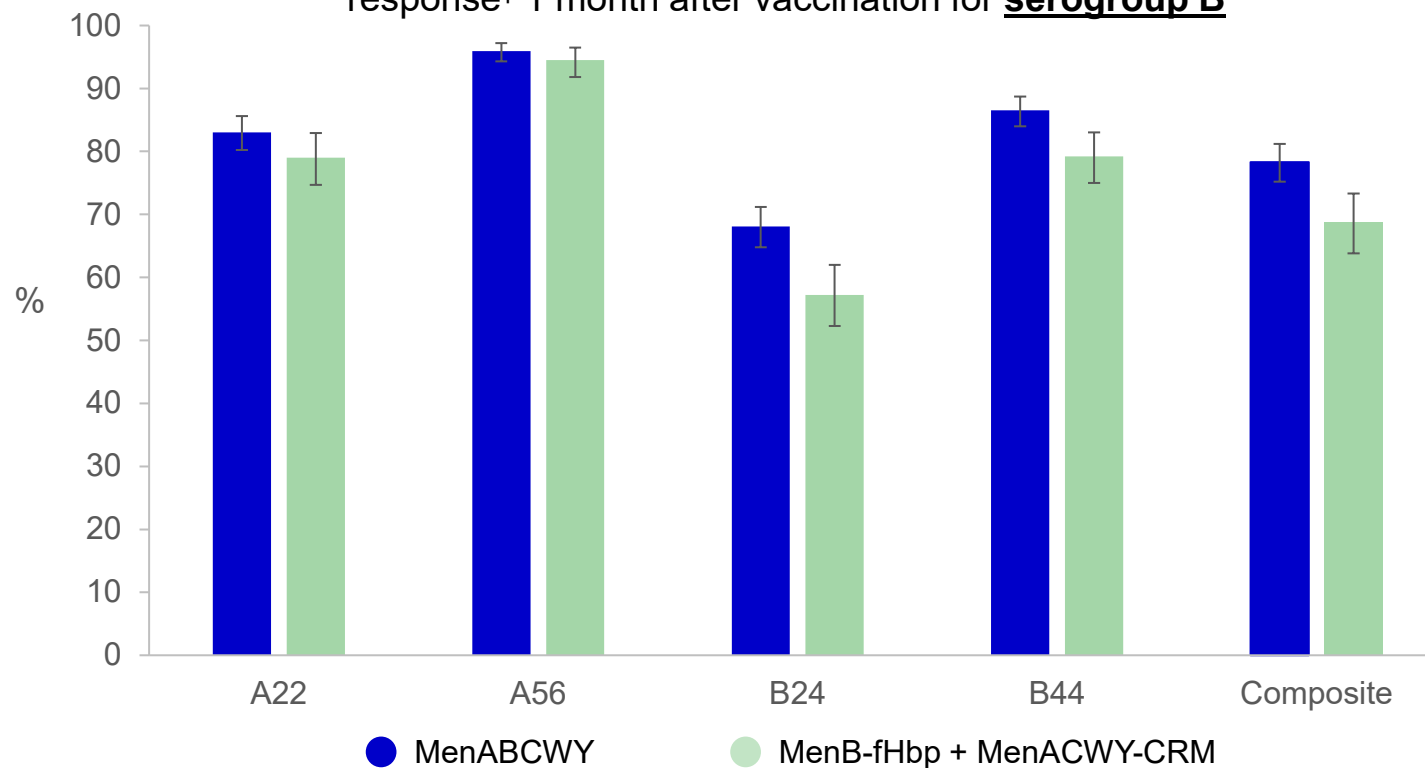
# 2 doses of MenABCWY vaccine elicit higher responses versus 2 doses of MenB-fHbp in B-naïve participants



Comparisons (B-naïve participants):

- MenABCWY vaccine 1 month after second dose
- MenB-fHbp 1 month after second dose

Percentage of participants achieving hSBA seroresponse\* and composite response† 1 month after vaccination for **serogroup B**



- 2 doses of MenABCWY vaccine were **noninferior** to 2 doses of MenB-fHbp
- 83.4-98.7% of participants had serogroup B hSBA titers  $\geq 1:8^{\wedge}$  after 2 doses of MenABCWY vaccine

Abbreviations: hSBA=serum bactericidal assay using human complement.

\*For participants with a baseline hSBA titer  $< 1:4$ , seroresponse is defined as a titer  $\geq 1:16$ . For those with a baseline hSBA titer  $\geq 1:4$  and  $< 1:8$  ( $< 1:16$  for A22), seroresponse is a titer  $\geq 4$  times the 1:8 (1:16 for A22).

†For those with a baseline hSBA titer  $\geq 1:8$  ( $\geq 1:16$  for A22), seroresponse is a titer  $\geq 4$  times the baseline titer.  $^{\wedge}$ hSBA titer  $\geq 1:8$  ( $\geq 1:16$  for A22) for all 4 MenB strains 1 month after Dose 2.  $^{\wedge}$  $\geq 1:16$  for A22 strain

N=755-845 for MenABCWY group; N=383-419 for MenB-fHbp + MenACWY-CRM group.

Data on File, Study C3511001 (NCT04440163) Aug 2022, Pfizer Inc.

# MenABCWY vaccine protects against all 5 serogroups with 2 doses given 6 to 12 months apart

Seroresponse* 1m PD2		MenABCWY 0, 6m (Study 1001)			MenABCWY 0, 12m (Study 1004)		
Serogroups	N <sup>^</sup>	%	95% CI	N <sup>^</sup>	%	95% CI	
A	447	<b>97.8</b>	95.9, 98.9	116	<b>99.1</b>	95.3, 100	
C	451	<b>93.3</b>	90.6, 95.5	115	<b>99.1</b>	95.3, 100	
W	439	<b>97.3</b>	95.3, 98.6	113	<b>99.1</b>	95.2, 100	
Y	446	<b>94.4</b>	91.8, 96.3	111	<b>98.2</b>	93.6, 99.8	
<b>MenB strain</b>							
A22	778	<b>83.0</b>	80.2, 85.6	111	<b>95.5</b>	89.8, 98.5	
A56	807	<b>95.9</b>	94.3, 97.2	115	<b>100</b>	96.8, 100	
B24	833	<b>68.1</b>	64.8, 71.2	113	<b>92.9</b>	86.5, 96.9	
B44	845	<b>86.5</b>	84.0, 88.7	116	<b>94.8</b>	89.1, 98.1	
<b>MenB composite hSBA response<sup>†</sup></b>							
Before Dose 1	812	<b>1.2</b>	0.6, 2.3	114	<b>0.9</b>	0.0, 4.8	
1 Month after Dose 2	755	<b>78.3</b>	75.2, 81.2	110	<b>96.4</b>	91.0, 99.0	

- 2 doses of MenABCWY vaccine given 12 months apart elicit higher serogroup B responses
- 98.3-100% of participants had serogroups ABCWY hSBA titers  $\geq 1:8$  following 2 doses of MenABCWY vaccine given 12 months apart

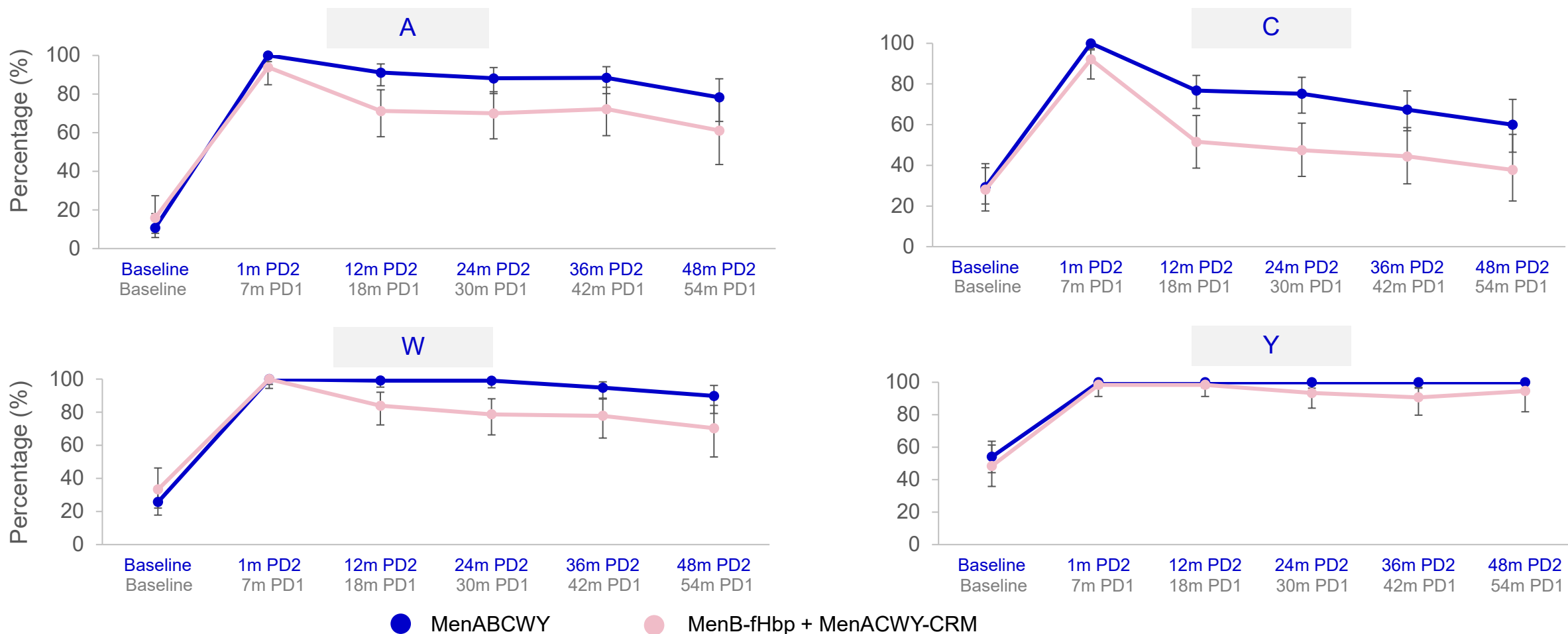
Abbreviations: hSBA=serum bactericidal assay using human complement; MenB=serogroup B.

\*For participants with a baseline hSBA titer  $< 1:4$ , seroresponse is defined as a titer  $\geq 1:16$ . For those with a baseline hSBA titer  $\geq 1:4$  and  $< 1:8$  ( $< 1:16$  for A22), seroresponse is a titer  $\geq 4$  times the 1:8 (1:16 for A22). For those with a baseline hSBA titer  $\geq 1:8$  ( $\geq 1:16$  for A22), seroresponse is a titer  $\geq 4$  times the baseline titer. <sup>^</sup>Number of subjects with valid and determinate hSBA titer for the given strain; for study 1001, population includes ACWY-naïve participants for serogroups ACWY. <sup>†</sup>hSBA titer  $\geq 1:8$  (1:16 for A22) for all 4 MenB strains 1 month after Dose 2.

Data on File, Study C3511001 (NCT04440163) and C3511004 (NCT04440176) Aug 2022, Pfizer Inc.

# MenACWY seroprotection persists up to 4 years in ACWY-naïve participants

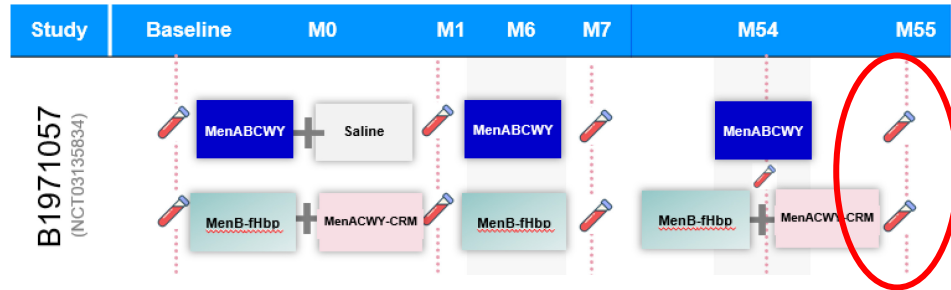
Percentage of individuals\* with hSBA titers  $\geq 1:8$  at all timepoints



Abbreviations: hSBA=serum bactericidal assay using human complement; PB=post booster; PD1=post dose 1; PD2=post dose 2.

\*Number of subjects with valid and determinate hSBA titer for the given strain ranged from 95-112 for MenABCWY and 54-64 for MenB-fHbp + MenACWY-CRM (Stage 2 mITT population [baseline through 36m PD2/42m PD1]), and 59-60 for MenABCWY and 36-37 for MenB-fHbp + MenACWY-CRM (Booster evaluable immunogenicity population [48m PD2 /54m PD1 Post Primary and Post Booster]).

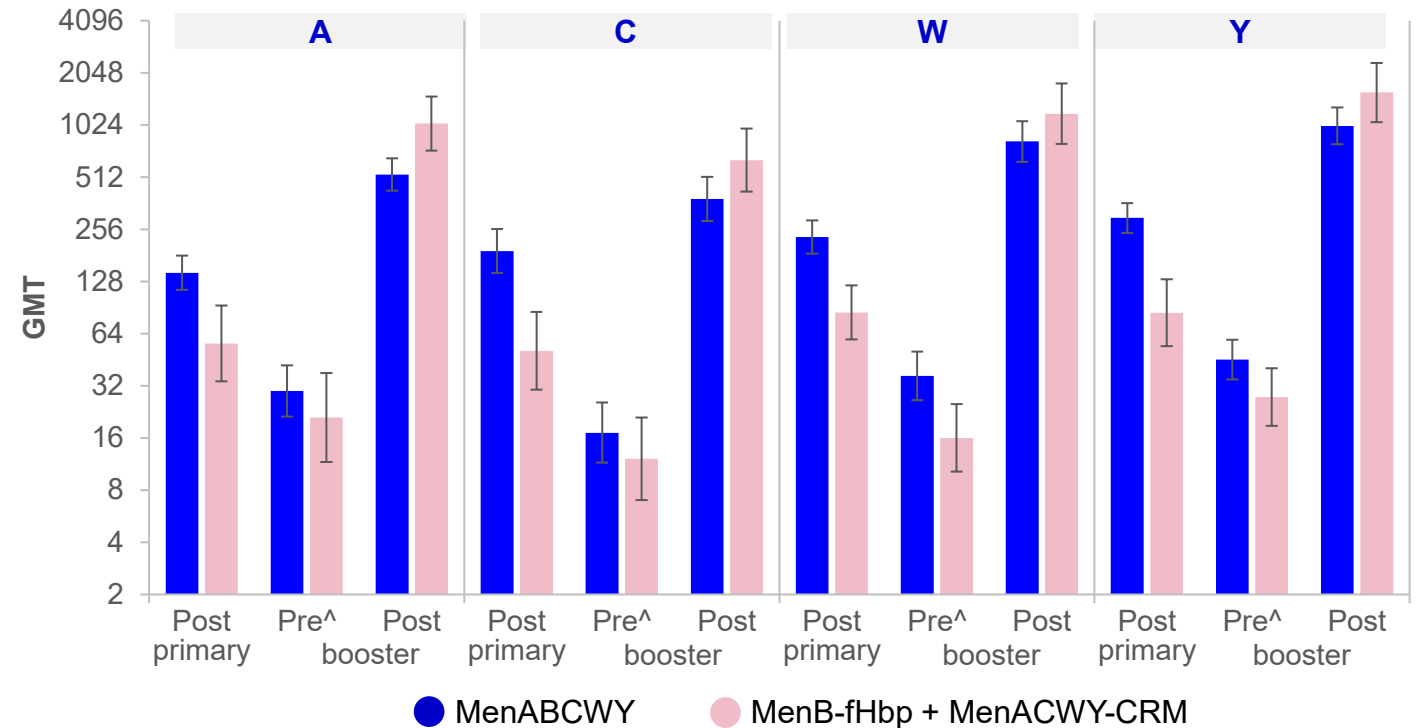
# Booster response observed following a dose of MenABCWY vaccine 4 years after a 2 dose primary series (0,6m) in ACWY-naïve participants



Comparisons (ACWY-naïve participants):

- MenABCWY vaccine 4 years<sup>^</sup> after second dose (pre booster) and 1 month after booster
- MenACWY-CRM 4.5 years<sup>^</sup> after single dose (pre booster) and 1 month after booster

GMTs\* 4 years after primary vaccination and 1 month after booster for **serogroups ACWY**



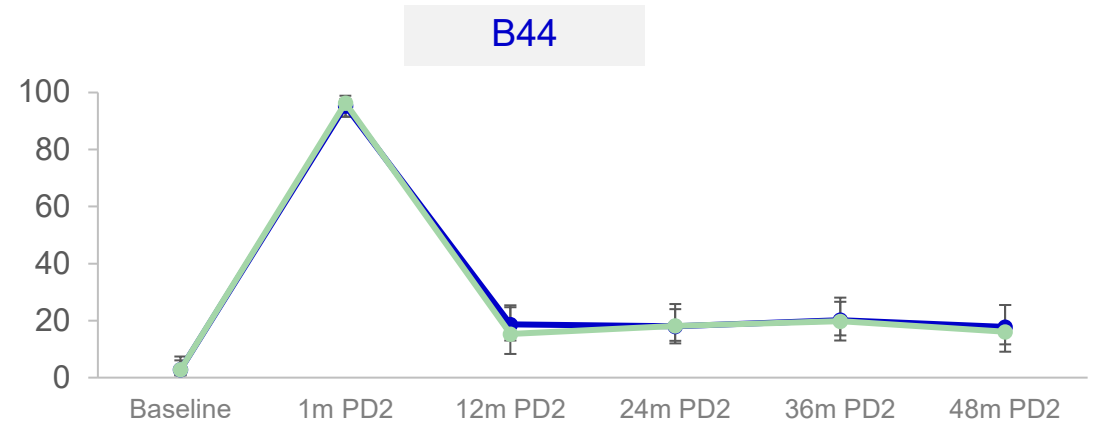
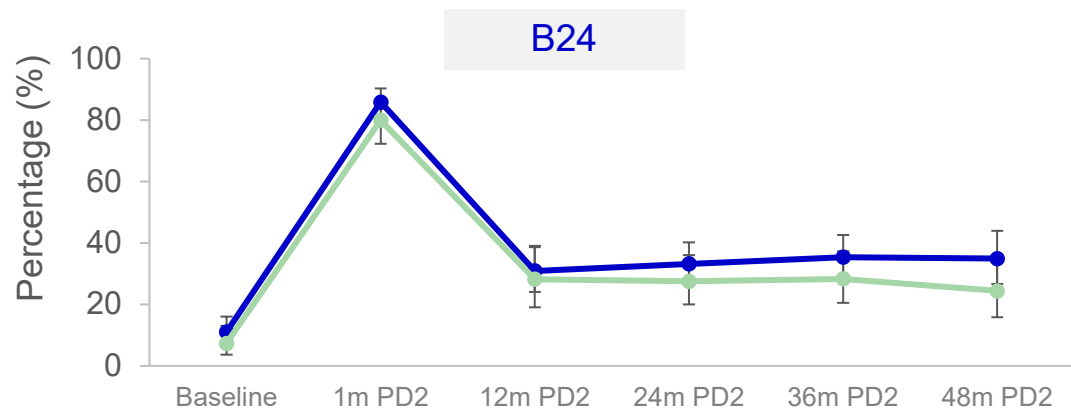
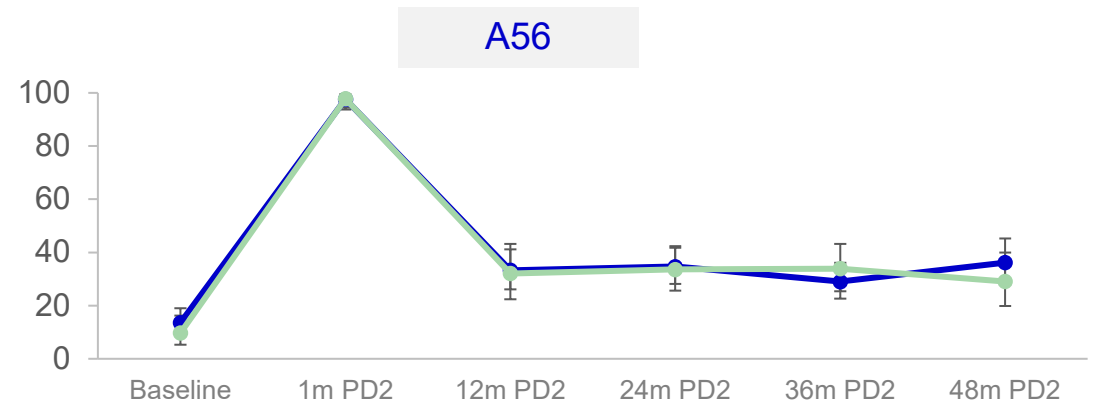
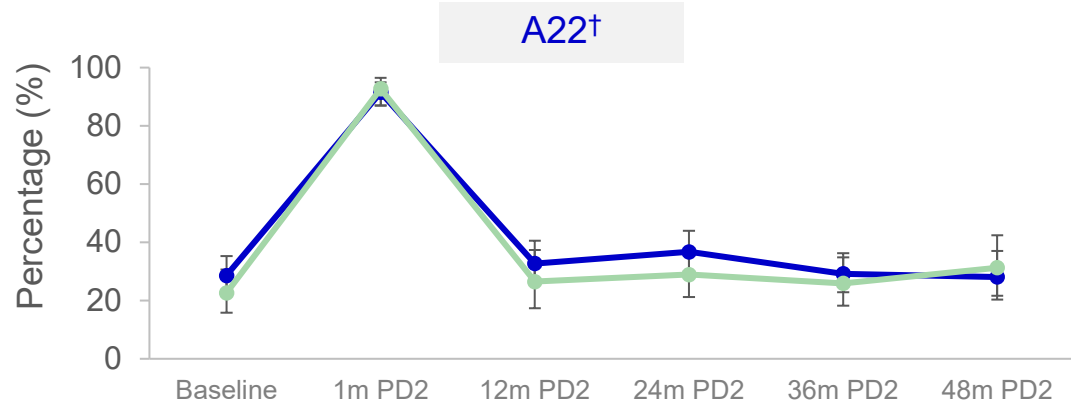
**100% of participants had ACWY hSBA titers  $\geq 1:8$  following a booster dose of MenABCWY vaccine at 4 years**



Abbreviations: hSBA=serum bactericidal assay using human complement; GMT= geometric mean titer; Post primary series =2 doses for MenABCWY and a single dose for MenACWY-CRM.  
 \*Number of subjects with valid and determinate hSBA titer for the given strain ranged from 59-60 for MenABCWY and 35-37 for MenB-fHbp + MenACWY-CRM. <sup>^</sup>Pre booster= 4 years after second dose of MenABCWY and 4.5 years after single dose of MenACWY-CRM.  
 Data on File, Study B1971057 (NCT03135834) Aug 2022, Pfizer Inc.

# MenB seroprotection up to 4 years after 2 doses of MenABCWY

Percentage of individuals\* with hSBA titers  $\geq 1:8^\dagger$  at all timepoints



● MenABCWY      ● MenB-fHbp + MenACWY-CRM

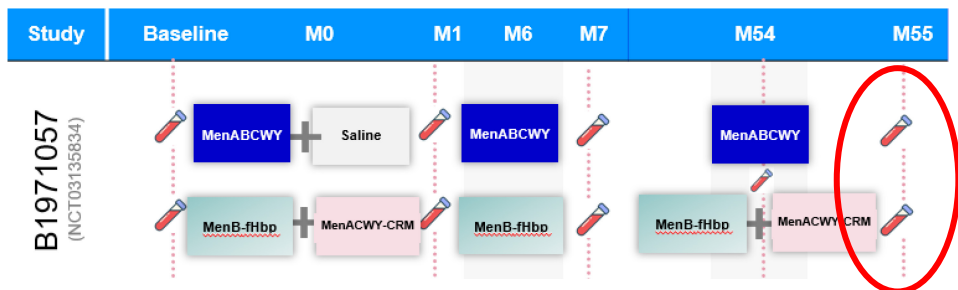
Abbreviations: hSBA=serum bactericidal assay using human complement; PD2=post dose 2.

\*Number of subjects with valid and determinate hSBA titer for the given strain ranged from 162-212 for MenABCWY and 83-137 for MenB-fHbp + MenACWY-CRM (Stage 2 mITT population [baseline through 36m PD2]), and 121-129 for MenABCWY and 81-87 for MenB-fHbp + MenACWY-CRM (Booster evaluable immunogenicity population [48m PD2 Post Primary and Post Booster]).<sup>†</sup>hSBA  $\geq 1:16$  for A22.

Data on File, Study B1971057 (NCT03135834) Aug 2022, Pfizer Inc.



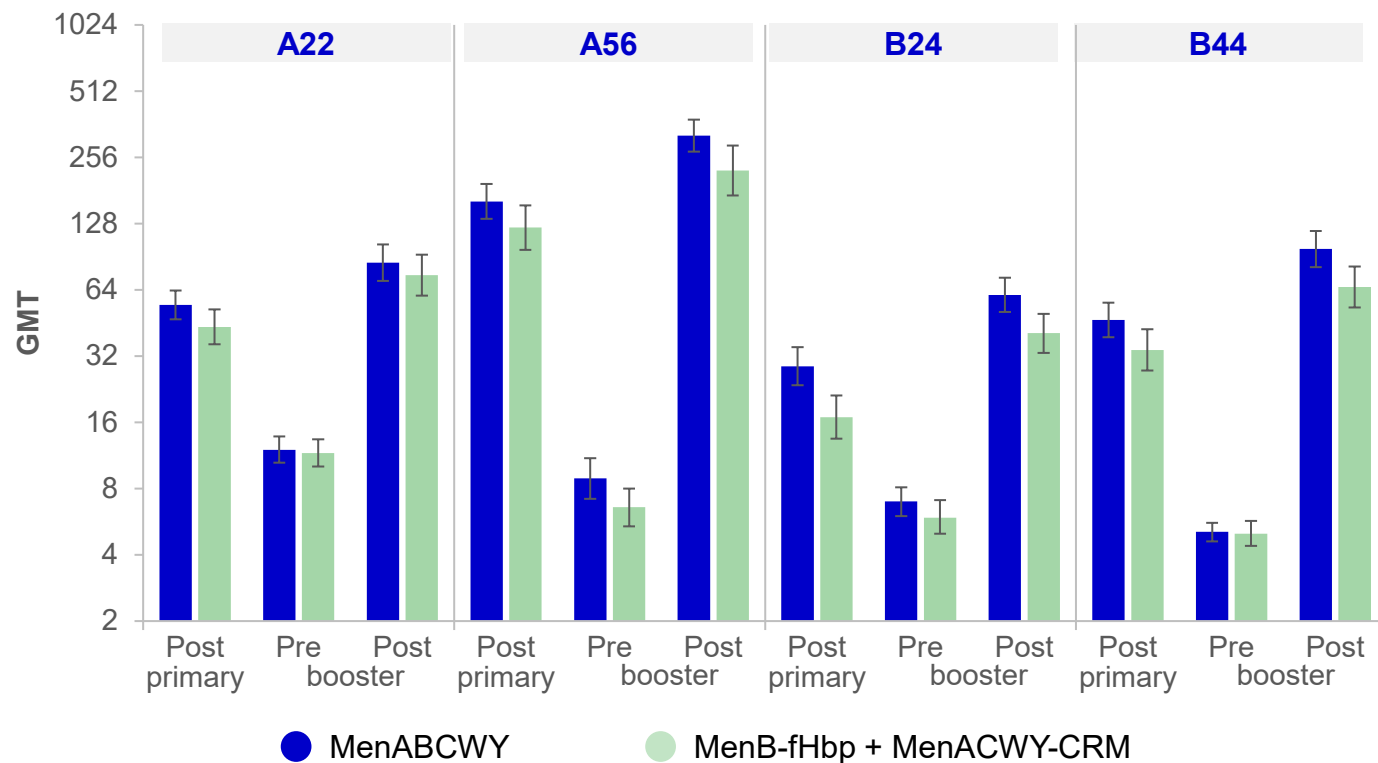
# Booster response observed following a dose of MenABCWY vaccine 4 years after a 2 dose primary series (0,6m) in B-naïve participants



Comparisons (B-naïve participants):

- MenABCWY vaccine 4 years after second dose (pre booster) and 1 month after booster
- MenB-fHbp 4 years after second dose (pre booster) and 1 month after booster

GMTs\* 4 years after primary vaccination and 1 month after booster for **serogroup B**



- 95.1-100% of participants had B hSBA titers  $\geq 1:8^{\wedge}$  following a booster dose of MenABCWY vaccine 4 years

Abbreviations: hSBA=serum bactericidal assay using human complement; GMT= geometric mean tier; Post primary series (2 doses for both MenABCWY and MenB-fHbp)

\*Number of subjects with valid and determinate hSBA titer for the given strain ranged from 121-130 for MenABCWY and 81-88 for MenB-fHbp + MenACWY-CRM.  $^{\wedge} \geq 1:16$  for A22 strain

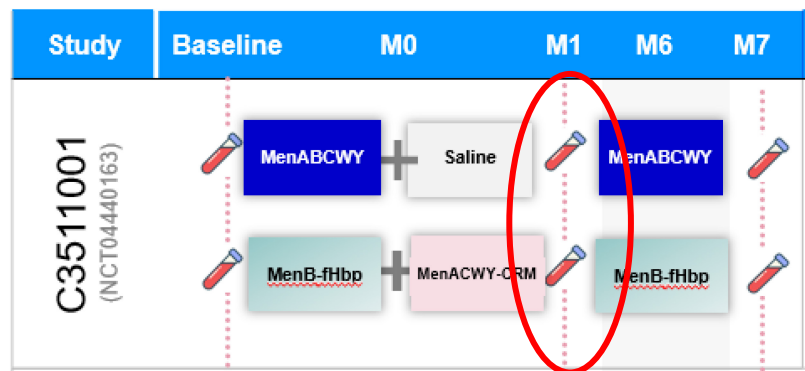
Data on File, Study B1971057 (NCT03135834) Aug 2022, Pfizer Inc.

An abstract 3D graphic composed of several overlapping, curved, blue and purple planes that create a sense of depth and movement, resembling a stylized wave or a series of connected segments. The colors transition from a light blue on the left to a deep purple on the right.

# Immunogenicity ACWY-primed



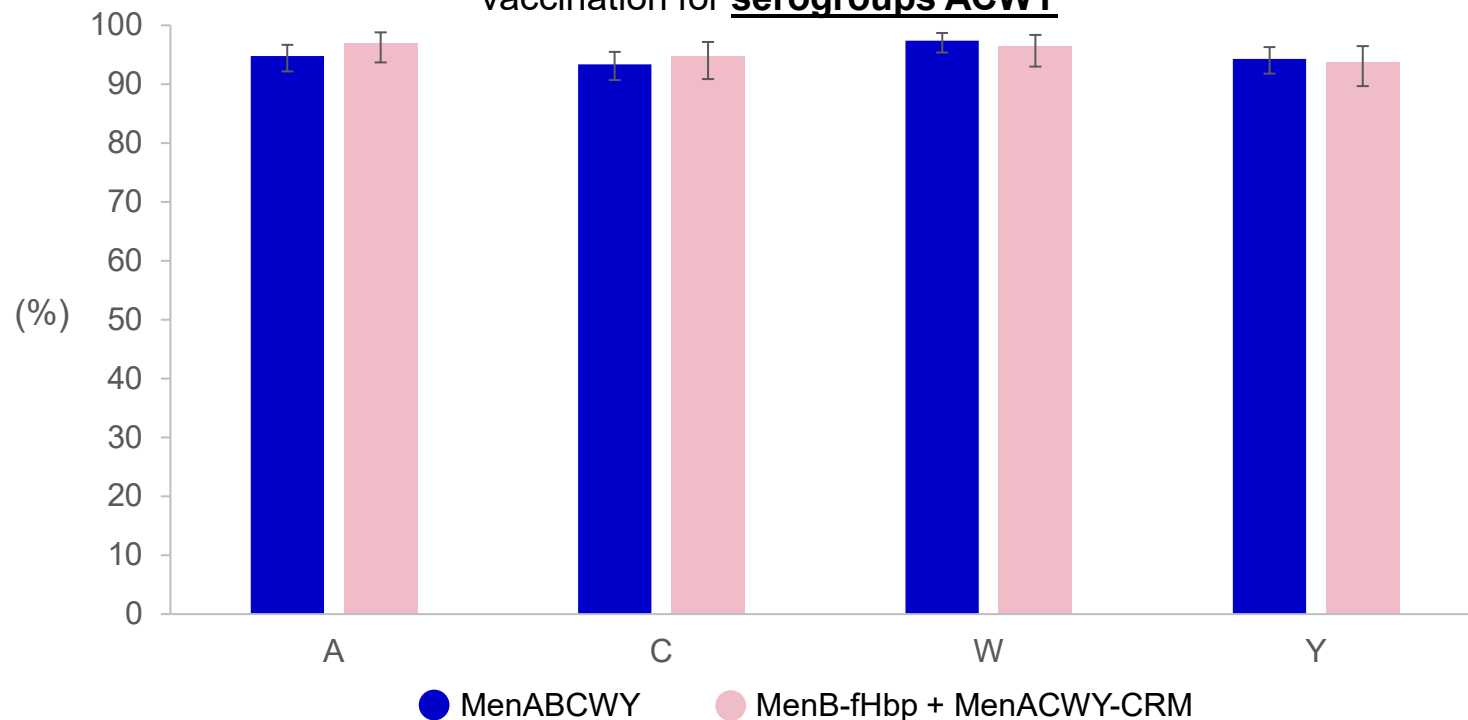
# A single dose of MenABCWY vaccine can be used as an alternative to ACWY vaccines in ACWY-primed adolescents



Comparisons (ACWY-primed participants):

- MenABCWY vaccine 1 month after first dose
- MenACWY-CRM 1 month after single dose

Percentage of participants achieving hSBA seroresponse\* 1 month after vaccination for **serogroups ACWY**



- 1 dose of MenABCWY vaccine was **noninferior** to 1 dose of MenACWY-CRM in ACWY-primed participants
- 99.5-100% of participants had serogroups ACWY hSBA titers  $\geq 1:8$  after 1 dose of MenABCWY vaccine

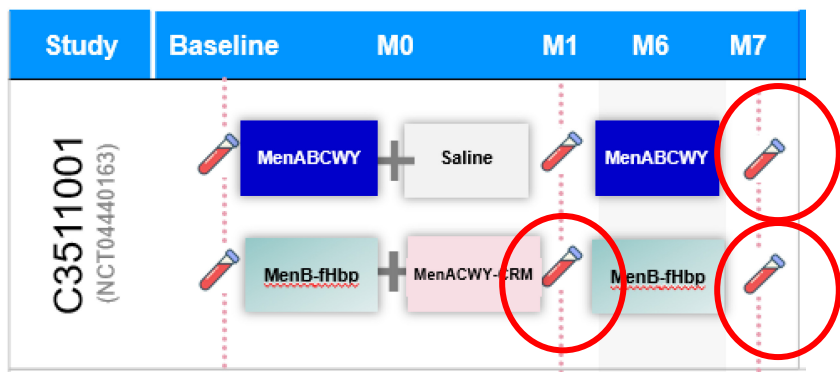
Abbreviations: hSBA=serum bactericidal assay using human complement.

\*For participants with a baseline hSBA titer  $< 1:4$ , seroresponse is defined as a titer  $\geq 1:16$ . For those with a baseline hSBA titer  $\geq 1:4$  and  $< 1:8$ , seroresponse is a titer  $\geq 4$  times the baseline titer.

N=428-442 for MenABCWY group; N=222-227 for MenB-fHbp + MenACWY-CRM group.

Data on File, Study C3511001 (NCT04440163) Aug 2022, Pfizer Inc.

# 2 doses of MenABCWY vaccine can be used as an alternative to 1 dose MenACWY-CRM and 2 doses MenB-fHbp in ACWY-primed adolescents



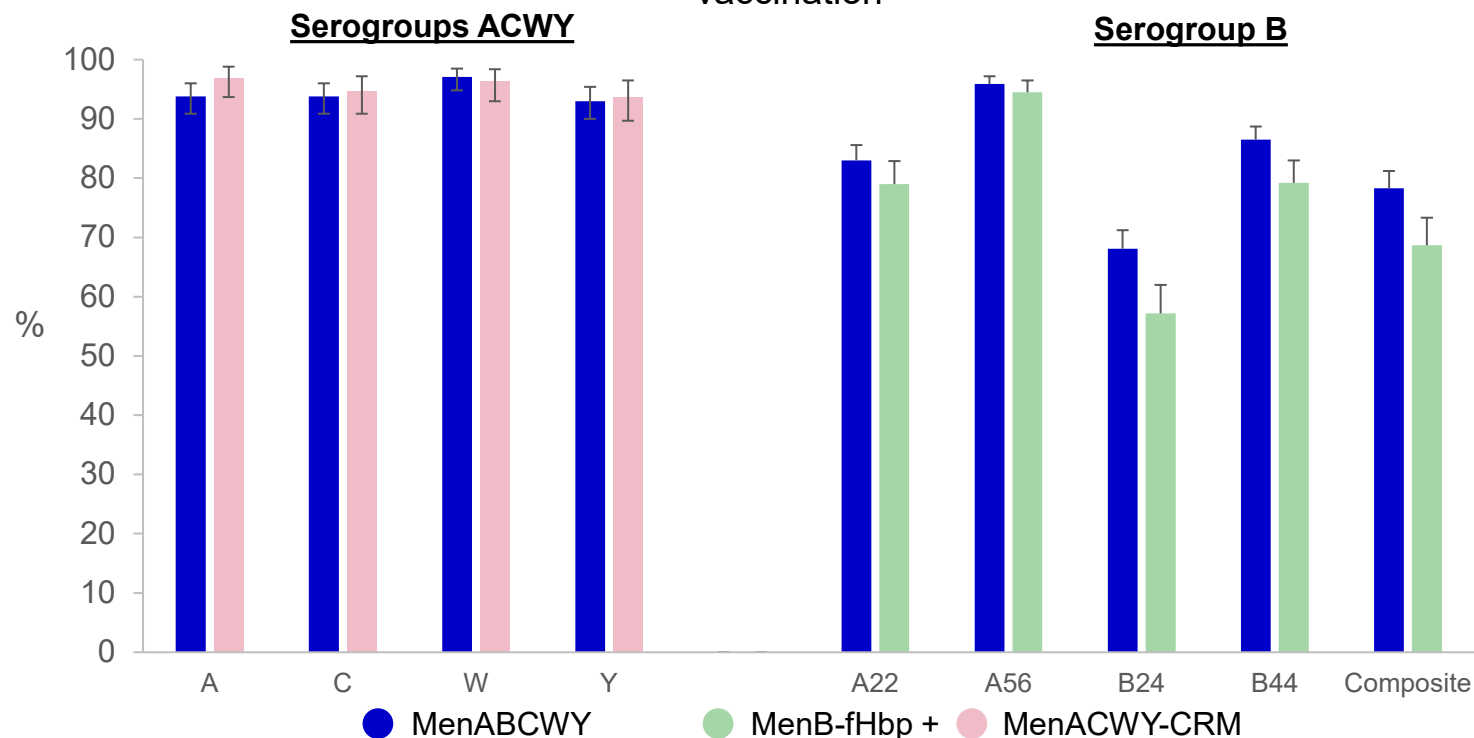
Comparisons (ACWY-primed participants):

- MenABCWY vaccine 1 month after second dose
- MenACWY-CRM 1 month after single dose

Comparisons (All participants group B vaccine naive):

- MenABCWY vaccine 1 month after second dose
- MenB-fHbp 1 month after second dose

Percentage of participants achieving hSBA seroresponse\* 1 month after vaccination



- 2 doses of MenABCWY vaccine were **noninferior** to 1 dose of MenACWY-CRM in ACWY-primed participants
  - 99-100% had serogroups ACWY hSBA titers  $\geq 1:8$  after 2 doses of MenABCWY vaccine
- 100% of ACWY-primed participants have protective titers four years after 2 doses of MenABCWY vaccine (Study B1971057)



Abbreviations: hSBA=serum bactericidal assay using human complement.

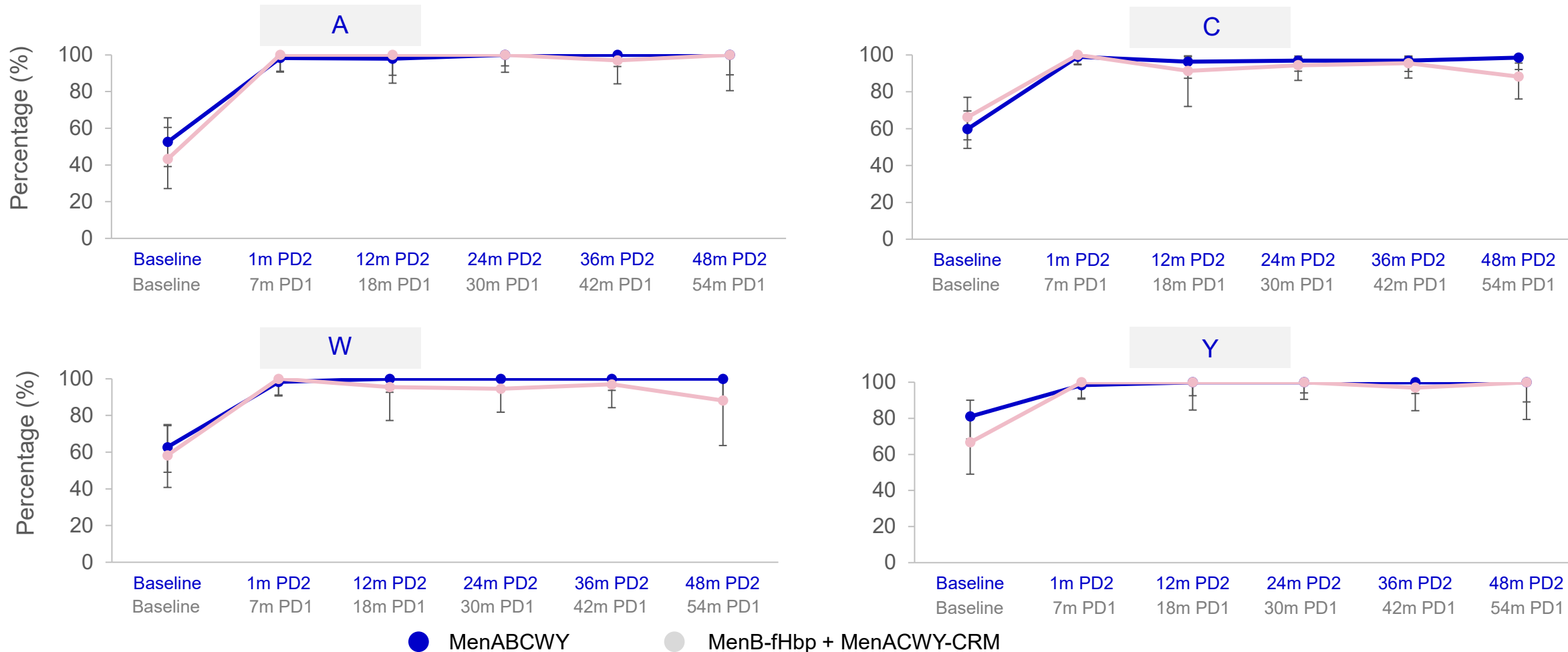
\*For participants with a baseline hSBA titer  $< 1:4$ , seroresponse is defined as a titer  $\geq 1:16$ . For those with a baseline hSBA titer  $\geq 1:4$  and  $< 1:8$ , seroresponse is a titer  $\geq 4$  times the 1:8. For those with a baseline hSBA titer  $\geq 1:8$ , seroresponse is a titer  $\geq 4$  times the baseline titer.

N=376-387 for MenABCWY group; N=22-227 for MenB-fHbp + MenACWY-CRM group.

Data on File, Study C3511001 (NCT04440163) and Study B1971057 (NCT03135834) Aug 2022, Pfizer Inc

# MenACWY seroprotection persists up to 4 years in ACWY-primed population

Percentage of participants\* (95% CI) with hSBA titers  $\geq 1:8$



Abbreviations: hSBA=serum bactericidal assay using human complement; PB=post booster; PD1=post dose 1; PD2=post dose 2.

\*Number of subjects with valid and determinate hSBA titer for the given strain. Lower N for groups A, W, Y compared to C due to receipt of monovalent C vaccine prior to study entry.

For groups A, W, and Y, N=48-61 for MenABCWY and 22-38 for MenB-fHbp + MenACWY-CRM (Stage 2 mITT population [baseline through 36m PD2/42m PD1]), and 32-33 for MenABCWY and 16-17 for MenB-fHbp + MenACWY-CRM (Booster evaluable immunogenicity population [48m PD2 /54m PD1 Post Primary and Post Booster]). For group C, N=54-100 for MenABCWY and 23-72 for MenB-fHbp + MenACWY-CRM (Stage 2 mITT population), and 68-70 for MenABCWY and 51 for MenB-fHbp + MenACWY-CRM (Booster evaluable immunogenicity population).

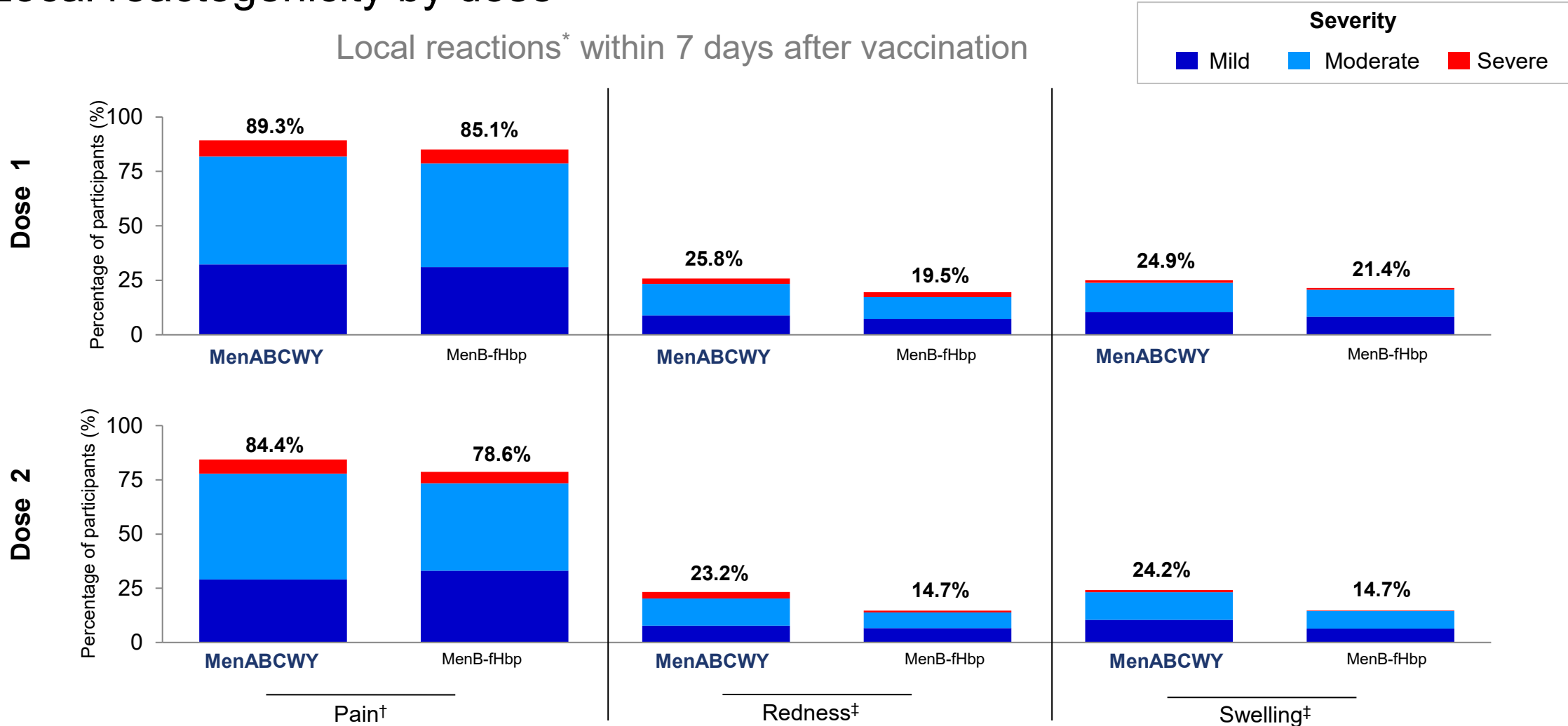
Data on File, Study B1971057 (NCT03135834) Aug 2022, Pfizer Inc.

An abstract 3D graphic composed of several overlapping, curved, blue and purple planes that create a sense of depth and movement, resembling a stylized wave or a series of connected segments. The planes are rendered with soft shadows and highlights, giving them a three-dimensional appearance.

# Safety

# Local reactogenicity by dose

Local reactions\* within 7 days after vaccination



No differences observed between: ACWY-Naïve and Primed participants or Primary and Booster vaccination

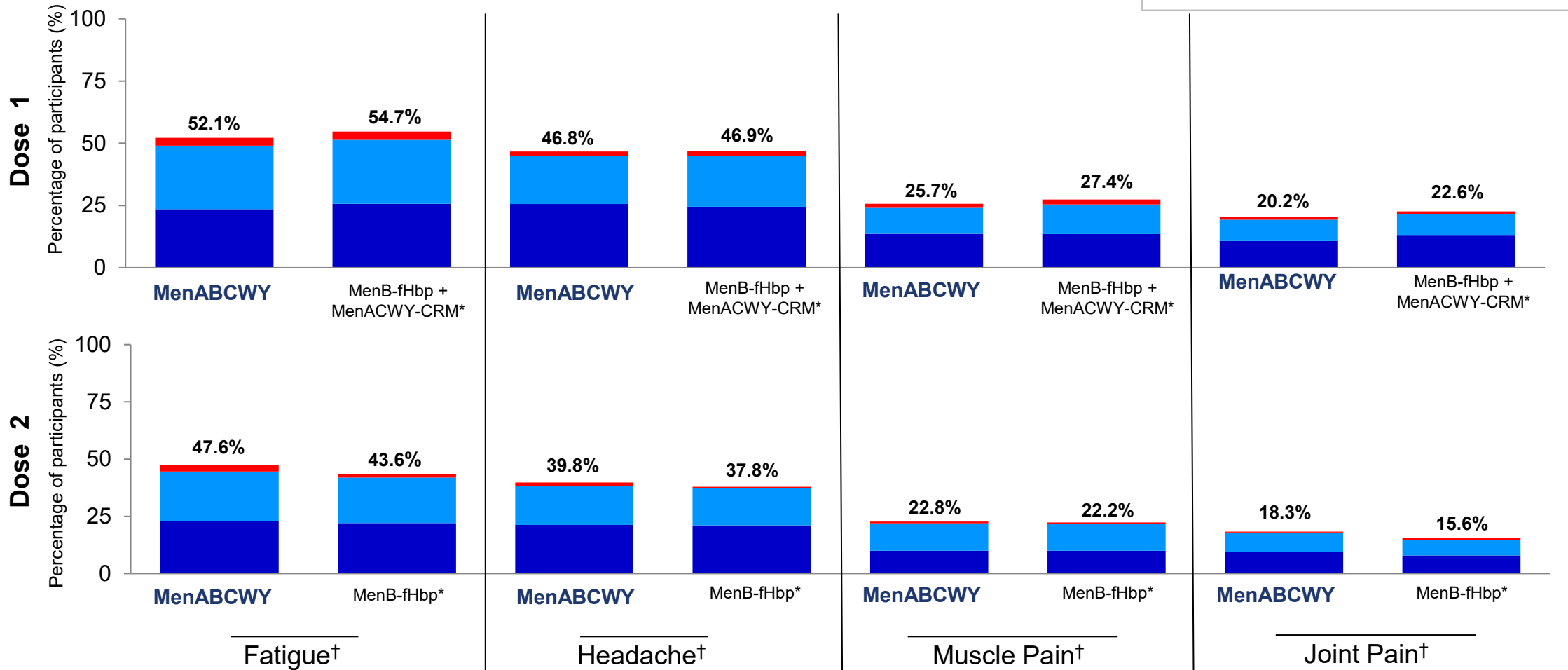
\*Local reactions are summarized only for the left arm, which is the MenABCWY vaccine or MenB+fHbp injection site; †Mild=does not interfere with activity, moderate=interferes with activity, severe=prevents daily activity.

‡Mild=>2.0 to 5.0 cm, moderate=>5.0 to 10.0 cm, and severe is >10.0 cm.

Data on File, Study C3511001 (NCT04440163) Aug 2022, Pfizer Inc.

# Systemic reactogenicity by dose

Systemic events within 7 days after vaccination



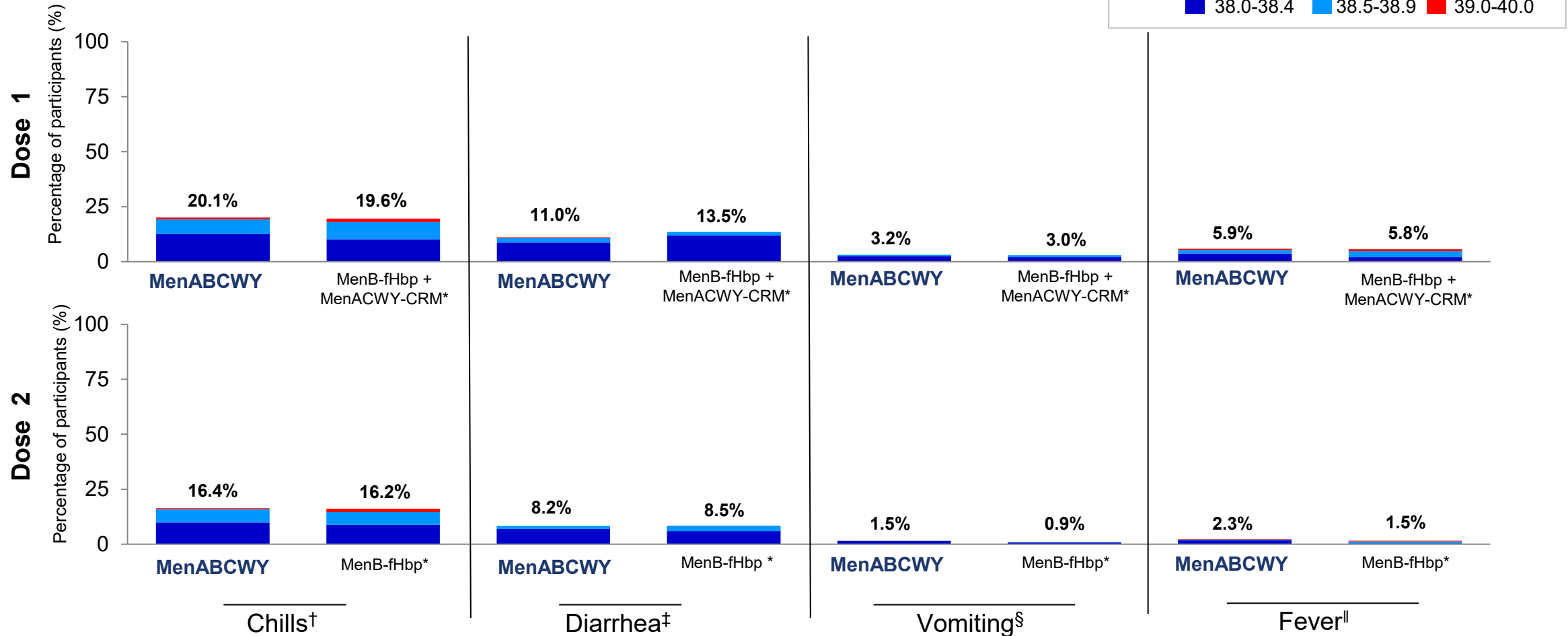
No differences observed between: ACWY-Naïve and Primed participants or Primary and Booster vaccination



\*MenB-fHbp + MenACWY-CRM group: MenB-fHbp and MenACWY-CRM given at dose 1 and 3, MenB-fHbp given at dose 2.  
 †Mild: does not interfere with activity; Moderate: some interference with activity; Severe: prevents daily routine activity.  
 Data on File, Study C3511001 (NCT04440163) Aug 2022, Pfizer Inc.

# Systemic reactogenicity by dose

Systemic events within 7 days after vaccination



No differences observed between: ACWY-Naïve and Primed participants or Primary and Booster vaccination



\*MenB-fHbp + MenACWY-CRM group: MenB-fHbp and MenACWY-CRM given at dose 1 and 3, MenB-fHbp given at dose 2. <sup>†</sup>Mild: does not interfere with activity; Moderate: some interference with activity; Severe: prevents daily routine activity. <sup>‡</sup>Mild: 2–3 loose stools in 24 hours; Moderate: 4–5 loose stools in 24 hours; Severe: 6 or more loose stools in 24 hours. <sup>§</sup>Mild: 1–2 times in 24 hours; Moderate: >2 times in 24 hours; Severe: requires intravenous hydration. <sup>||</sup>No fevers >40 °C were reported. Data on File, Study C3511001 (NCT04440163) Aug 2022, Pfizer Inc.

# Number (%) of participants reporting $\geq 1$ adverse event during the vaccination phase\*

Endpoint	MenABCWY + Saline N=1763				MenB-fHbp + MenACWY-CRM N=649			
	n	%	(95% CI)	Number of Events	n	%	(95% CI)	Number of Events
<b>All AEs</b>	368	<b>20.9</b>	(19.0, 22.8)	638	132	<b>20.3</b>	(17.3, 23.6)	202
<b>Related</b>	11	<b>0.6</b>	(0.3, 1.1)	19	4	<b>0.6</b>	(0.2, 1.6)	5
<b>Severe</b>	13	<b>0.7</b>	(0.4, 1.3)	17	4	<b>0.6</b>	(0.2, 1.6)	4
<b>All SAEs</b>	7	<b>0.4</b>	(0.2, 0.8)	9	0	<b>0</b>	(0.0, 0.6)	0
<b>Related</b>	0	<b>0</b>	(0.0, 0.2)	0	0	<b>0</b>	(0.0, 0.6)	0
<b>All MAEs</b>	263	<b>14.9</b>	(13.3, 16.7)	436	93	<b>14.3</b>	(11.7, 17.3)	141
<b>Related</b>	2	<b>0.1</b>	(0.0, 0.4)	2	1	<b>0.2</b>	(0.0, 0.9)	1
<b>Severe</b>	8	<b>0.5</b>	(0.2, 0.9)	9	3	<b>0.5</b>	(0.1, 1.3)	3
<b>All NDCMCs</b>	20	<b>1.1</b>	(0.7, 1.7)	23	2	<b>0.3</b>	(0.0, 1.1)	2
<b>Related</b>	0	<b>0</b>	(0.0, 0.2)	0	0	<b>0</b>	(0.0, 0.6)	0
<b>Severe</b>	1	<b>&lt;0.1</b>	(0.0, 0.3)	2	0	<b>0</b>	(0.0, 0.6)	0

Higher number of NDCMCs of ADHD in the MenABCWY group – most of them with ADHD-related symptoms before entering the study

Abbreviations: AE=adverse event; MAE=medically attended event (nonserious AE that results in an evaluation at a medical facility); NDCMC=newly diagnosed chronic medical condition (a disease or medical condition, not previously identified, that is expected to be persistent or is otherwise long-lasting in its effects); SAE=serious adverse event.  
\*Vaccination phase refers to the time from the first study vaccination (Visit 1) through 1 month after the second study vaccination (Visit 4).

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# Overall conclusion: Data support the use of MenABCWY vaccine in the US adolescent meningococcal vaccination platform

## Safety

- MenABCWY vaccine was safe and well tolerated in adolescents and young adults

## ACWY protection

- A single dose of MenABCWY vaccine can be used as an alternative to ACWY vaccines in ACWY-naïve or primed adolescents and young adults

## ABCWY protection

- MenABCWY vaccine protects against all 5 serogroups with 2 doses given 6 to 12 months apart
- Booster response was observed following a dose of MenABCWY vaccine 4 years after a 2 dose primary series (0,6m) for all 5 serogroups
- If 2 doses of MenABCWY vaccine are administered at 11-12 yrs of age, data support that a single (booster) dose from 16 years of age can provide protection against all 5 serogroups



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