



Clinical trial results:

A Phase 1/2, Randomized, Descriptive, Safety and Immunogenicity Study to Assess Pentavalent Meningococcal ABCYW Vaccine Formulations in Adults (18 to 25 years of age) and Adolescents (10 to 17 years of age)

Summary

EudraCT number	2023-000924-13
Trial protocol	Outside EU/EEA
Global end of trial date	27 August 2025

Results information

Result version number	v1 (current)
This version publication date	25 September 2026
First version publication date	25 September 2026

Trial information

Trial identification

Sponsor protocol code	VAN00010
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT06128733
WHO universal trial number (UTN)	U1111-1272-6824

Notes:

Sponsors

Sponsor organisation name	Sanofi Pasteur Inc
Sponsor organisation address	Discovery Drive, Swiftwater, Pennsylvania, United States, 18370-0187
Public contact	Trial Transparency Team, Sanofi Pasteur, Contact-US@sanofi.com
Scientific contact	Trial Transparency Team, Sanofi Pasteur, Contact-US@sanofi.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMA-003379-PIP01-22
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	30 March 2026
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	27 August 2025
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To describe the safety profile of the MenPenta vaccine formulations and the comparator vaccines in healthy adults and adolescents.

To describe the immune response to the MenPenta vaccine formulations and the comparator vaccines after the second vaccination when administered to healthy adolescents as measured by serum bactericidal assay using human complement (hSBA) in the A, C, W-135, Y, and the reference MenB strains.

Protection of trial subjects:

Vaccinations were performed by qualified and trained study personnel. Participants with allergy to any of the vaccine components were not vaccinated. After vaccination, participants were also kept under clinical observation for 30 minutes to ensure their safety. Appropriate medical equipment were also available on site in case of any immediate allergic reactions.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	31 October 2023
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Puerto Rico: 32
Country: Number of subjects enrolled	United States: 1183
Worldwide total number of subjects	1215
EEA total number of subjects	0

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	381
Adolescents (12-17 years)	713

Adults (18-64 years)	121
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study was conducted at 42 centers in 2 countries from 31 October 2023 to 27 August 2025.

Pre-assignment

Screening details:

A total of 1215 participants were randomized in the study (participants treated in 'Adolescents - Group 7: PENBRAYA' were open-label and enrolled). Adult participants (18 to 25 years of age) were randomized in a 1:1:1:1:1:1 ratio to 6 groups and adolescent participants (10 to 17 years of age) were randomized in a 3:3:1:1:1:1:1 ratio to 7 groups.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Carer, Data analyst, Assessor

Blinding implementation details:

Completed milestone= End of active phase.

Arms

Are arms mutually exclusive?	Yes
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Arm title	Adults - Group 1: MenPenta Formulation 1
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Arm description:

Participants aged 18 to 25 years received MenPenta formulation 1 (pentavalent meningococcal ABCYW standard dose) vaccine via intramuscular (IM) injection on Days 1, 31 and 181. Additionally, participants received a placebo IM injection on Day 1.

Arm type	Experimental
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Placebo IM injection on Day 1.

Investigational medicinal product name	MenPenta Formulation 1
Investigational medicinal product code	
Other name	MenPenta SD
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

MenPenta formulation 1 vaccine via IM injection on Days 1, 31 and 181.

Arm title	Adults - Group 2: MenPenta Formulation 2
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Arm description:

Participants aged 18 to 25 years received MenPenta formulation 2 (pentavalent meningococcal ABCYW high dose) vaccine via IM injection on Days 1, 31 and 181. Additionally, participants received a placebo IM injection on Day 1.

Arm type	Experimental
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Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use
Dosage and administration details: Placebo IM injection on Day 1.	
Investigational medicinal product name	MenPenta Formulation 2
Investigational medicinal product code	
Other name	MenPenta fHD
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use
Dosage and administration details: MenPenta formulation 2 vaccine via IM injection on Days 1, 31 and 181.	
Arm title	Adults - Group 3: Bexsero + Menveo
Arm description: Participants aged 18 to 25 years received Bexsero (meningococcal group B) + Menveo (meningococcal ACYW conjugate) vaccine via IM injection on Day 1 and only Bexsero vaccine via IM injection on Day 31. Additionally, participants received a placebo IM injection on Day 181.	
Arm type	Active comparator
Investigational medicinal product name	Bexsero
Investigational medicinal product code	J07AH09
Other name	
Pharmaceutical forms	Suspension for injection in pre-filled syringe
Routes of administration	Intramuscular use
Dosage and administration details: Bexsero vaccine via IM injection on Days 1 and 31.	
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use
Dosage and administration details: Placebo IM injection on Day 181.	
Investigational medicinal product name	Menveo
Investigational medicinal product code	J07AH08
Other name	
Pharmaceutical forms	Powder and solvent for solution for injection
Routes of administration	Intramuscular use
Dosage and administration details: Menveo vaccine via IM injection on Day 1.	
Arm title	Adults - Group 4: Trumenba + Menveo
Arm description: Participants aged 18 to 25 years received Trumenba (meningococcal group B) + Menveo (meningococcal ACYW conjugate) vaccine via IM injection on Day 1 and only Trumenba vaccine via IM injection on Days 31 and 181.	
Arm type	Active comparator
Investigational medicinal product name	Menveo
Investigational medicinal product code	J07AH08
Other name	
Pharmaceutical forms	Powder and solvent for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:	
Menveo vaccine via IM injection on Day 1.	
Investigational medicinal product name	Trumenba
Investigational medicinal product code	J07AH09
Other name	
Pharmaceutical forms	Suspension for injection in pre-filled syringe
Routes of administration	Intramuscular use
Dosage and administration details:	
Trumenba vaccine via IM injection on Days 1, 31 and 181.	
Arm title	Adults - Group 5: MenQuadfi
Arm description:	
Participants aged 18 to 25 years received MenQuadfi (meningococcal ACYW conjugate) vaccine via IM injection on Days 1 and 181. Additionally, participants received a placebo IM injection on Days 1 and 31.	
Arm type	Active comparator
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use
Dosage and administration details:	
Placebo IM injection on Days 1 and 31.	
Investigational medicinal product name	MenQuadfi
Investigational medicinal product code	J07AH08
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use
Dosage and administration details:	
MenQuadfi vaccine via IM injection on Days 1 and 181.	
Arm title	Adults - Group 6: Sanofi MenB
Arm description:	
Participants aged 18 to 25 years received Sanofi MenB (meningococcal B antigens standard dose) vaccine via IM injection on Days 1, 31 and 181. Additionally, participants received a placebo IM injection on Day 1.	
Arm type	Active comparator
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use
Dosage and administration details:	
Placebo IM injection on Day 1.	
Investigational medicinal product name	Sanofi MenB
Investigational medicinal product code	J07AH09
Other name	Sanofi MenB SD
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use
Dosage and administration details:	
Sanofi MenB vaccine via IM injection on Days 1, 31 and 181.	
Arm title	Adolescents - Group 1: MenPenta Formulation 1
Arm description:	
Participants aged 10 to 17 years received MenPenta formulation 1 (pentavalent meningococcal ABCYW standard dose) vaccine via IM injection on Days 1 and 181. Additionally, participants received a placebo	

IM injection on Day 1.

Arm type	Experimental
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Placebo IM injection on Day 1.

Investigational medicinal product name	MenPenta Formulation 1
Investigational medicinal product code	
Other name	MenPenta SD
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

MenPenta formulation 1 vaccine via IM injection on Days 1 and 181.

Arm title	Adolescents - Group 2: MenPenta Formulation 2
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Arm description:

Participants aged 10 to 17 years received MenPenta formulation 2 (pentavalent meningococcal ABCYW high dose) vaccine via IM injection on Days 1 and 181. Additionally, participants received a placebo IM injection on Day 1.

Arm type	Experimental
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Placebo IM injection on Day 1.

Investigational medicinal product name	MenPenta Formulation 2
Investigational medicinal product code	
Other name	MenPenta fHD
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

MenPenta formulation 2 vaccine via IM injection on Days 1 and 181.

Arm title	Adolescents - Group 3: Bexsero + Menveo
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Arm description:

Participants aged 10 to 17 years received Bexsero (meningococcal group B) + Menveo (meningococcal ACYW conjugate) vaccine via IM injection on Day 1 and only Bexsero vaccine via IM injection on Day 181.

Arm type	Active comparator
Investigational medicinal product name	Menveo
Investigational medicinal product code	J07AH08
Other name	
Pharmaceutical forms	Powder and solvent for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Menveo vaccine via IM injection on Day 1.

Investigational medicinal product name	Bexsero
Investigational medicinal product code	J07AH09
Other name	

Pharmaceutical forms	Suspension for injection in pre-filled syringe
Routes of administration	Intramuscular use

Dosage and administration details:

Bexsero vaccine via IM injection on Days 1 and 181.

Arm title	Adolescents - Group 4: Trumenba + Menveo
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Arm description:

Participants aged 10 to 17 years received Trumenba (meningococcal group B) + Menveo (meningococcal ACYW conjugate) vaccine via IM injection on Day 1 and only Trumenba vaccine via IM injection on Day 181.

Arm type	Active comparator
Investigational medicinal product name	Menveo
Investigational medicinal product code	J07AH08
Other name	
Pharmaceutical forms	Powder and solvent for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Menveo vaccine via IM injection on Day 1.

Investigational medicinal product name	Trumenba
Investigational medicinal product code	J07AH09
Other name	
Pharmaceutical forms	Suspension for injection in pre-filled syringe
Routes of administration	Intramuscular use

Dosage and administration details:

Trumenba vaccine via IM injection on Days 1 and 181.

Arm title	Adolescents - Group 5: MenQuadfi
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Arm description:

Participants aged 10 to 17 years received MenQuadfi (meningococcal ACYW conjugate) vaccine via IM injection on Days 1 and 181. Additionally, participants received a placebo IM injection on Day 1.

Arm type	Active comparator
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Placebo IM injection on Day 1.

Investigational medicinal product name	MenQuadfi
Investigational medicinal product code	J07AH08
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

MenQuadfi vaccine via IM injection on Days 1 and 181.

Arm title	Adolescents - Group 6: Sanofi MenB
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Arm description:

Participants aged 10 to 17 years received Sanofi MenB (meningococcal B antigens standard dose) vaccine via IM injection on Days 1 and 181. Additionally, participants received a placebo IM injection on Day 1.

Arm type	Active comparator
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Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use
Dosage and administration details: Placebo IM injection on Day 1.	
Investigational medicinal product name	Sanofi MenB
Investigational medicinal product code	J07AH09
Other name	Sanofi MenB SD
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use
Dosage and administration details: Sanofi MenB vaccine via IM injection on Days 1 and 181.	
Arm title	Adolescents - Group 7: PENBRAYA
Arm description: Participants aged 10 to 17 years received PENBRAYA (meningococcal ABCYW conjugate) vaccine via IM injection on Days 1 and 181.	
Arm type	Active comparator
Investigational medicinal product name	PENBRAYA
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use
Dosage and administration details: PENBRAYA vaccine via IM injection on Days 1 and 181.	

Number of subjects in period 1	Adults - Group 1: MenPenta Formulation 1	Adults - Group 2: MenPenta Formulation 2	Adults - Group 3: Bexsero + Menveo
Started	20	21	20
Completed	17	17	17
Not completed	3	4	3
Consent withdrawn by subject	1	1	-
Adverse event, non-fatal	1	-	-
Protocol deviation	1	2	2
Lost to follow-up	-	1	1
Withdrawal by parent/guardian	-	-	-

Number of subjects in period 1	Adults - Group 4: Trumenba + Menveo	Adults - Group 5: MenQuadfi	Adults - Group 6: Sanofi MenB
Started	20	20	20
Completed	15	19	16
Not completed	5	1	4
Consent withdrawn by subject	-	-	-
Adverse event, non-fatal	-	-	-
Protocol deviation	3	-	2

Lost to follow-up	2	1	2
Withdrawal by parent/guardian	-	-	-

Number of subjects in period 1	Adolescents - Group 1: MenPenta Formulation 1	Adolescents - Group 2: MenPenta Formulation 2	Adolescents - Group 3: Bexsero + Menveo
Started	298	300	100
Completed	266	270	91
Not completed	32	30	9
Consent withdrawn by subject	4	3	-
Adverse event, non-fatal	-	1	-
Protocol deviation	7	5	3
Lost to follow-up	12	11	4
Withdrawal by parent/guardian	9	10	2

Number of subjects in period 1	Adolescents - Group 4: Trumenba + Menveo	Adolescents - Group 5: MenQuadfi	Adolescents - Group 6: Sanofi MenB
Started	97	100	99
Completed	87	92	94
Not completed	10	8	5
Consent withdrawn by subject	2	-	3
Adverse event, non-fatal	1	-	-
Protocol deviation	3	2	1
Lost to follow-up	2	1	1
Withdrawal by parent/guardian	2	5	-

Number of subjects in period 1	Adolescents - Group 7: PENBRAYA
Started	100
Completed	95
Not completed	5
Consent withdrawn by subject	-
Adverse event, non-fatal	-
Protocol deviation	-
Lost to follow-up	3
Withdrawal by parent/guardian	2

Baseline characteristics

Reporting groups

Reporting group title	Adults - Group 1: MenPenta Formulation 1
Reporting group description:	
Participants aged 18 to 25 years received MenPenta formulation 1 (pentavalent meningococcal ABCYW standard dose) vaccine via intramuscular (IM) injection on Days 1, 31 and 181. Additionally, participants received a placebo IM injection on Day 1.	
Reporting group title	Adults - Group 2: MenPenta Formulation 2
Reporting group description:	
Participants aged 18 to 25 years received MenPenta formulation 2 (pentavalent meningococcal ABCYW high dose) vaccine via IM injection on Days 1, 31 and 181. Additionally, participants received a placebo IM injection on Day 1.	
Reporting group title	Adults - Group 3: Bexsero + Menveo
Reporting group description:	
Participants aged 18 to 25 years received Bexsero (meningococcal group B) + Menveo (meningococcal ACYW conjugate) vaccine via IM injection on Day 1 and only Bexsero vaccine via IM injection on Day 31. Additionally, participants received a placebo IM injection on Day 181.	
Reporting group title	Adults - Group 4: Trumenba + Menveo
Reporting group description:	
Participants aged 18 to 25 years received Trumenba (meningococcal group B) + Menveo (meningococcal ACYW conjugate) vaccine via IM injection on Day 1 and only Trumenba vaccine via IM injection on Days 31 and 181.	
Reporting group title	Adults - Group 5: MenQuadfi
Reporting group description:	
Participants aged 18 to 25 years received MenQuadfi (meningococcal ACYW conjugate) vaccine via IM injection on Days 1 and 181. Additionally, participants received a placebo IM injection on Days 1 and 31.	
Reporting group title	Adults - Group 6: Sanofi MenB
Reporting group description:	
Participants aged 18 to 25 years received Sanofi MenB (meningococcal B antigens standard dose) vaccine via IM injection on Days 1, 31 and 181. Additionally, participants received a placebo IM injection on Day 1.	
Reporting group title	Adolescents - Group 1: MenPenta Formulation 1
Reporting group description:	
Participants aged 10 to 17 years received MenPenta formulation 1 (pentavalent meningococcal ABCYW standard dose) vaccine via IM injection on Days 1 and 181. Additionally, participants received a placebo IM injection on Day 1.	
Reporting group title	Adolescents - Group 2: MenPenta Formulation 2
Reporting group description:	
Participants aged 10 to 17 years received MenPenta formulation 2 (pentavalent meningococcal ABCYW high dose) vaccine via IM injection on Days 1 and 181. Additionally, participants received a placebo IM injection on Day 1.	
Reporting group title	Adolescents - Group 3: Bexsero + Menveo
Reporting group description:	
Participants aged 10 to 17 years received Bexsero (meningococcal group B) + Menveo (meningococcal ACYW conjugate) vaccine via IM injection on Day 1 and only Bexsero vaccine via IM injection on Day 181.	
Reporting group title	Adolescents - Group 4: Trumenba + Menveo
Reporting group description:	
Participants aged 10 to 17 years received Trumenba (meningococcal group B) + Menveo (meningococcal ACYW conjugate) vaccine via IM injection on Day 1 and only Trumenba vaccine via IM injection on Day 181.	
Reporting group title	Adolescents - Group 5: MenQuadfi
Reporting group description:	
Participants aged 10 to 17 years received MenQuadfi (meningococcal ACYW conjugate) vaccine via IM injection on Days 1 and 181. Additionally, participants received a placebo IM injection on Day 1.	
Reporting group title	Adolescents - Group 6: Sanofi MenB

Reporting group description:

Participants aged 10 to 17 years received Sanofi MenB (meningococcal B antigens standard dose) vaccine via IM injection on Days 1 and 181. Additionally, participants received a placebo IM injection on Day 1.

Reporting group title	Adolescents - Group 7: PENBRAYA
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Reporting group description:

Participants aged 10 to 17 years received PENBRAYA (meningococcal ABCYW conjugate) vaccine via IM injection on Days 1 and 181.

Reporting group values	Adults - Group 1: MenPenta Formulation 1	Adults - Group 2: MenPenta Formulation 2	Adults - Group 3: Bexsero + Menveo
Number of subjects	20	21	20
Age categorical Units: Subjects			

Age Continuous Units: years arithmetic mean standard deviation	22.2 ± 2.41	22.1 ± 2.21	21.7 ± 2.36
Sex: Female, Male Units: participants			
Female	11	15	9
Male	9	6	11
Race Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Black or African American	8	5	7
Native Hawaiian or Other Pacific Islander	0	0	0
White	12	13	11
Mixed Origin	0	3	2
Not Reported	0	0	0
Unknown	0	0	0

Reporting group values	Adults - Group 4: Trumenba + Menveo	Adults - Group 5: MenQuadfi	Adults - Group 6: Sanofi MenB
Number of subjects	20	20	20
Age categorical Units: Subjects			

Age Continuous Units: years arithmetic mean standard deviation	22.9 ± 1.73	22.1 ± 2.00	22.0 ± 2.27
Sex: Female, Male Units: participants			
Female	13	9	16
Male	7	11	4

Race			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	1	1	0
Black or African American	4	6	2
Native Hawaiian or Other Pacific Islander	0	0	0
White	15	13	16
Mixed Origin	0	0	1
Not Reported	0	0	0
Unknown	0	0	1

Reporting group values	Adolescents - Group 1: MenPenta Formulation 1	Adolescents - Group 2: MenPenta Formulation 2	Adolescents - Group 3: Bexsero + Menveo
Number of subjects	298	300	100
Age categorical			
Units: Subjects			

Age Continuous			
Units: years			
arithmetic mean	13.6	13.6	13.6
standard deviation	± 2.59	± 2.70	± 2.60
Sex: Female, Male			
Units: participants			
Female	150	139	44
Male	148	161	56
Race			
Units: Subjects			
American Indian or Alaska Native	2	2	0
Asian	3	1	1
Black or African American	77	66	17
Native Hawaiian or Other Pacific Islander	1	0	0
White	207	214	75
Mixed Origin	6	14	6
Not Reported	2	2	1
Unknown	0	1	0

Reporting group values	Adolescents - Group 4: Trumenba + Menveo	Adolescents - Group 5: MenQuadfi	Adolescents - Group 6: Sanofi MenB
Number of subjects	97	100	99
Age categorical			
Units: Subjects			

Age Continuous			
Units: years			
arithmetic mean	13.6	13.7	13.8
standard deviation	± 2.64	± 2.72	± 2.57
Sex: Female, Male			
Units: participants			
Female	50	39	47

Male	47	61	52
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Race			
Units: Subjects			
American Indian or Alaska Native	0	1	0
Asian	0	1	1
Black or African American	25	24	26
Native Hawaiian or Other Pacific Islander	0	0	0
White	71	68	69
Mixed Origin	1	6	2
Not Reported	0	0	1
Unknown	0	0	0

Reporting group values	Adolescents - Group 7: PENBRAYA	Total	
Number of subjects	100	1215	
Age categorical			
Units: Subjects			

Age Continuous			
Units: years			
arithmetic mean	13.5		
standard deviation	± 2.54	-	
Sex: Female, Male			
Units: participants			
Female	44	586	
Male	56	629	
Race			
Units: Subjects			
American Indian or Alaska Native	0	5	
Asian	2	11	
Black or African American	25	292	
Native Hawaiian or Other Pacific Islander	0	1	
White	70	854	
Mixed Origin	3	44	
Not Reported	0	6	
Unknown	0	2	

End points

End points reporting groups

Reporting group title	Adults - Group 1: MenPenta Formulation 1
Reporting group description: Participants aged 18 to 25 years received MenPenta formulation 1 (pentavalent meningococcal ABCYW standard dose) vaccine via intramuscular (IM) injection on Days 1, 31 and 181. Additionally, participants received a placebo IM injection on Day 1.	
Reporting group title	Adults - Group 2: MenPenta Formulation 2
Reporting group description: Participants aged 18 to 25 years received MenPenta formulation 2 (pentavalent meningococcal ABCYW high dose) vaccine via IM injection on Days 1, 31 and 181. Additionally, participants received a placebo IM injection on Day 1.	
Reporting group title	Adults - Group 3: Bexsero + Menveo
Reporting group description: Participants aged 18 to 25 years received Bexsero (meningococcal group B) + Menveo (meningococcal ACYW conjugate) vaccine via IM injection on Day 1 and only Bexsero vaccine via IM injection on Day 31. Additionally, participants received a placebo IM injection on Day 181.	
Reporting group title	Adults - Group 4: Trumenba + Menveo
Reporting group description: Participants aged 18 to 25 years received Trumenba (meningococcal group B) + Menveo (meningococcal ACYW conjugate) vaccine via IM injection on Day 1 and only Trumenba vaccine via IM injection on Days 31 and 181.	
Reporting group title	Adults - Group 5: MenQuadfi
Reporting group description: Participants aged 18 to 25 years received MenQuadfi (meningococcal ACYW conjugate) vaccine via IM injection on Days 1 and 181. Additionally, participants received a placebo IM injection on Days 1 and 31.	
Reporting group title	Adults - Group 6: Sanofi MenB
Reporting group description: Participants aged 18 to 25 years received Sanofi MenB (meningococcal B antigens standard dose) vaccine via IM injection on Days 1, 31 and 181. Additionally, participants received a placebo IM injection on Day 1.	
Reporting group title	Adolescents - Group 1: MenPenta Formulation 1
Reporting group description: Participants aged 10 to 17 years received MenPenta formulation 1 (pentavalent meningococcal ABCYW standard dose) vaccine via IM injection on Days 1 and 181. Additionally, participants received a placebo IM injection on Day 1.	
Reporting group title	Adolescents - Group 2: MenPenta Formulation 2
Reporting group description: Participants aged 10 to 17 years received MenPenta formulation 2 (pentavalent meningococcal ABCYW high dose) vaccine via IM injection on Days 1 and 181. Additionally, participants received a placebo IM injection on Day 1.	
Reporting group title	Adolescents - Group 3: Bexsero + Menveo
Reporting group description: Participants aged 10 to 17 years received Bexsero (meningococcal group B) + Menveo (meningococcal ACYW conjugate) vaccine via IM injection on Day 1 and only Bexsero vaccine via IM injection on Day 181.	
Reporting group title	Adolescents - Group 4: Trumenba + Menveo
Reporting group description: Participants aged 10 to 17 years received Trumenba (meningococcal group B) + Menveo (meningococcal ACYW conjugate) vaccine via IM injection on Day 1 and only Trumenba vaccine via IM injection on Day 181.	
Reporting group title	Adolescents - Group 5: MenQuadfi
Reporting group description: Participants aged 10 to 17 years received MenQuadfi (meningococcal ACYW conjugate) vaccine via IM injection on Days 1 and 181. Additionally, participants received a placebo IM injection on Day 1.	

Reporting group title	Adolescents - Group 6: Sanofi MenB
Reporting group description:	
Participants aged 10 to 17 years received Sanofi MenB (meningococcal B antigens standard dose) vaccine via IM injection on Days 1 and 181. Additionally, participants received a placebo IM injection on Day 1.	
Reporting group title	Adolescents - Group 7: PENBRAYA
Reporting group description:	
Participants aged 10 to 17 years received PENBRAYA (meningococcal ABCYW conjugate) vaccine via IM injection on Days 1 and 181.	

Primary: Number of Participants With Unsolicited Systemic Adverse Events (AEs) After Each Vaccine Administration

End point title	Number of Participants With Unsolicited Systemic Adverse Events (AEs) After Each Vaccine Administration ^[1]
End point description:	
An AE is any untoward medical occurrence in a clinical study participant, temporally associated with the use of study vaccine, whether or not considered related to the study vaccine. An unsolicited AE is an observed AE that does not fulfill the conditions of solicited reactions, that is, pre-listed in the case report form in terms of diagnosis and onset window post-vaccination. Systemic AEs are all AEs that were not injection or administration site reactions. Immediate events are recorded to capture medically relevant unsolicited systemic AEs which occur within the first 30 minutes after vaccination. The Safety analysis set (SafAS) included all randomized and enrolled (PENBRAYA only) participants who had received protocol-defined study vaccines at Day 1, or received 1 protocol-defined study vaccine at Day 31 or Day 181.	
End point type	Primary
End point timeframe:	
Adults: Within 30 minutes after vaccine administration on Days 1, 31 and 181 Adolescents: Within 30 minutes after vaccine administration on Days 1 and 181	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: As the endpoint is descriptive in nature, no statistical analysis is provided.

End point values	Adults - Group 1: MenPenta Formulation 1	Adults - Group 2: MenPenta Formulation 2	Adults - Group 3: Bexsero + Menveo	Adults - Group 4: Trumenba + Menveo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	21	19	20
Units: participants	0	0	0	0

End point values	Adults - Group 5: MenQuadfi	Adults - Group 6: Sanofi MenB	Adolescents - Group 1: MenPenta Formulation 1	Adolescents - Group 2: MenPenta Formulation 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	20	296	300
Units: participants	0	0	0	0

End point values	Adolescents - Group 3: Bexsero +	Adolescents - Group 4: Trumenba +	Adolescents - Group 5: MenQuadfi	Adolescents - Group 6: Sanofi MenB
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	Menveo	Menveo		
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	100	97	99	97
Units: participants	0	0	0	1

End point values	Adolescents - Group 7: PENBRAYA			
Subject group type	Reporting group			
Number of subjects analysed	100			
Units: participants	0			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Solicited Injection Site Reactions After Each Vaccine Administration

End point title	Number of Participants With Solicited Injection Site Reactions After Each Vaccine Administration ^[2]
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End point description:

An adverse reaction (AR) is any noxious and unintended response to a study vaccine related to any dose. Solicited injection site reactions are reactions at and around the injection site of the vaccine observed and reported under the conditions (nature and onset) pre-listed in the protocol and case report form. The SafAS included all randomized and enrolled (PENBRAYA only) participants who had received protocol-defined study vaccines at Day 1, or received 1 protocol-defined study vaccine at Day 31 or Day 181.

End point type	Primary
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End point timeframe:

Adults: Within 7 days after vaccine administration on Days 1, 31 and 181 Adolescents: Within 7 days after vaccine administration on Days 1 and 181

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: As the endpoint is descriptive in nature, no statistical analysis is provided.

End point values	Adults - Group 1: MenPenta Formulation 1	Adults - Group 2: MenPenta Formulation 2	Adults - Group 3: Bexsero + Menveo	Adults - Group 4: Trumenba + Menveo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	21	18	20
Units: participants	14	16	15	14

End point values	Adults - Group 5: MenQuadfi	Adults - Group 6: Sanofi MenB	Adolescents - Group 1: MenPenta Formulation 1	Adolescents - Group 2: MenPenta Formulation 2
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Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	19	20	295	299
Units: participants	10	19	219	219

End point values	Adolescents - Group 3: Bexsero + Menveo	Adolescents - Group 4: Trumenba + Menveo	Adolescents - Group 5: MenQuadfi	Adolescents - Group 6: Sanofi MenB
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	100	96	99	97
Units: participants	89	75	31	73

End point values	Adolescents - Group 7: PENBRAYA			
Subject group type	Reporting group			
Number of subjects analysed	100			
Units: participants	80			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Solicited Systemic Reactions After Each Vaccine Administration

End point title	Number of Participants With Solicited Systemic Reactions After Each Vaccine Administration ^[3]
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End point description:

An AR is any noxious and unintended response to a study vaccine related to any dose. Solicited systemic reactions are systemic AEs observed and reported under the conditions (nature and onset) pre-listed in the protocol and case report form. The SafAS included all randomized and enrolled (PENBRAYA only) participants who had received protocol-defined study vaccines at Day 1, or received 1 protocol-defined study vaccine at Day 31 or Day 181.

End point type	Primary
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End point timeframe:

Adults: Within 7 days after vaccine administration on Days 1, 31 and 181 Adolescents: Within 7 days after vaccine administration on Days 1 and 181

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: As the endpoint is descriptive in nature, no statistical analysis is provided.

End point values	Adults - Group 1: MenPenta Formulation 1	Adults - Group 2: MenPenta Formulation 2	Adults - Group 3: Bexsero + Menveo	Adults - Group 4: Trumenba + Menveo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	21	18	20
Units: participants	10	16	11	14

End point values	Adults - Group 5: MenQuadfi	Adults - Group 6: Sanofi MenB	Adolescents - Group 1: MenPenta Formulation 1	Adolescents - Group 2: MenPenta Formulation 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	19	20	295	299
Units: participants	13	15	192	183

End point values	Adolescents - Group 3: Bexsero + Menveo	Adolescents - Group 4: Trumenba + Menveo	Adolescents - Group 5: MenQuadfi	Adolescents - Group 6: Sanofi MenB
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	100	96	99	97
Units: participants	75	68	51	58

End point values	Adolescents - Group 7: PENBRAYA			
Subject group type	Reporting group			
Number of subjects analysed	100			
Units: participants	72			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Unsolicited Adverse Events After Each Vaccine Administration

End point title	Number of Participants With Unsolicited Adverse Events After Each Vaccine Administration ^[4]
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End point description:

An AE is any untoward medical occurrence in a clinical study participant, temporally associated with the use of study vaccine, whether or not considered related to the study vaccine. An unsolicited AE is an observed AE that does not fulfill the conditions of solicited reactions, that is, pre-listed in the case report form in terms of diagnosis and onset window post-vaccination. The SafAS included all randomized and enrolled (PENBRAYA only) participants who had received protocol-defined study vaccines at Day 1, or received 1 protocol-defined study vaccine at Day 31 or Day 181.

End point type	Primary
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End point timeframe:

Adults: Within 30 days after vaccine administration on Days 1, 31 and 181 Adolescents: Within 30 days after vaccine administration on Days 1 and 181

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: As the endpoint is descriptive in nature, no statistical analysis is provided.

End point values	Adults - Group 1: MenPenta Formulation 1	Adults - Group 2: MenPenta Formulation 2	Adults - Group 3: Bexsero + Menveo	Adults - Group 4: Trumenba + Menveo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	21	19	20
Units: participants	3	6	4	6

End point values	Adults - Group 5: MenQuadfi	Adults - Group 6: Sanofi MenB	Adolescents - Group 1: MenPenta Formulation 1	Adolescents - Group 2: MenPenta Formulation 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	20	296	300
Units: participants	7	5	65	58

End point values	Adolescents - Group 3: Bexsero + Menveo	Adolescents - Group 4: Trumenba + Menveo	Adolescents - Group 5: MenQuadfi	Adolescents - Group 6: Sanofi MenB
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	100	97	99	97
Units: participants	27	24	24	32

End point values	Adolescents - Group 7: PENBRAYA			
Subject group type	Reporting group			
Number of subjects analysed	100			
Units: participants	14			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Serious Adverse Events (SAEs) and Adverse Event of Special Interest (AESIs)

End point title	Number of Participants With Serious Adverse Events (SAEs)
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End point description:

An SAE is any untoward medical occurrence that at any dose results in death or is life-threatening or requires inpatient hospitalization or prolongation of existing hospitalization or results in persistent or significant disability/incapacity or is a congenital anomaly/birth defect or is an important medical event. An AESI (serious or non-serious) is 1 of scientific and medical concern specific to the Sponsor's study vaccine or program, for which ongoing monitoring and rapid communication by the investigator to the Sponsor can be appropriate. The SafAS included all randomized and enrolled (PENBRAYA only) participants who had received protocol-defined study vaccines at Day 1, or received 1 protocol-defined study vaccine at Day 31 or Day 181.

End point type	Primary
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End point timeframe:

From the first vaccine administration (Day 1) until 180 days after last vaccine administration, approximately 361 days

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: As the endpoint is descriptive in nature, no statistical analysis is provided.

End point values	Adults - Group 1: MenPenta Formulation 1	Adults - Group 2: MenPenta Formulation 2	Adults - Group 3: Bexsero + Menveo	Adults - Group 4: Trumenba + Menveo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	21	19	20
Units: participants				
Any SAEs	0	0	1	1
Any AESIs	0	0	0	0

End point values	Adults - Group 5: MenQuadfi	Adults - Group 6: Sanofi MenB	Adolescents - Group 1: MenPenta Formulation 1	Adolescents - Group 2: MenPenta Formulation 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	20	296	300
Units: participants				
Any SAEs	0	0	2	3
Any AESIs	0	0	0	0

End point values	Adolescents - Group 3: Bexsero + Menveo	Adolescents - Group 4: Trumenba + Menveo	Adolescents - Group 5: MenQuadfi	Adolescents - Group 6: Sanofi MenB
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	100	97	99	97
Units: participants				
Any SAEs	1	1	0	0
Any AESIs	0	1	0	0

End point values	Adolescents - Group 7: PENBRAYA			
Subject group type	Reporting group			
Number of subjects analysed	100			
Units: participants				
Any SAEs	0			
Any AESIs	0			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Medically Attended Adverse Events (MAAEs)

End point title	Number of Participants With Medically Attended Adverse Events (MAAEs) ^[6]
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End point description:

An MAAE is a new onset or a worsening of a condition that prompts the participant or participant's parent/legally acceptable representative to seek unplanned medical advice at a physician's office or emergency department. The SafAS included all randomized and enrolled (PENBRAYA only) participants who had received protocol-defined study vaccines at Day 1, or received 1 protocol-defined study vaccine at Day 31 or Day 181.

End point type	Primary
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End point timeframe:

From the first vaccine administration (Day 1) until 180 days after last vaccine administration, approximately 361 days

Notes:

[6] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: As the endpoint is descriptive in nature, no statistical analysis is provided.

End point values	Adults - Group 1: MenPenta Formulation 1	Adults - Group 2: MenPenta Formulation 2	Adults - Group 3: Bexsero + Menveo	Adults - Group 4: Trumenba + Menveo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	21	19	20
Units: participants	1	2	2	6

End point values	Adults - Group 5: MenQuadfi	Adults - Group 6: Sanofi MenB	Adolescents - Group 1: MenPenta Formulation 1	Adolescents - Group 2: MenPenta Formulation 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	20	296	300
Units: participants	3	2	41	37

End point values	Adolescents - Group 3: Bexsero +	Adolescents - Group 4: Trumenba +	Adolescents - Group 5: MenQuadfi	Adolescents - Group 6: Sanofi MenB
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	Menveo	Menveo		
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	100	97	99	97
Units: participants	20	20	18	16

End point values	Adolescents - Group 7: PENBRAYA			
Subject group type	Reporting group			
Number of subjects analysed	100			
Units: participants	13			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Abnormal Biological Test Results

End point title	Number of Participants With Abnormal Biological Test Results ^[7]
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End point description:

Blood samples were collected for assessment of abnormal hematology and clinical chemistry parameters. Only participants with outside normal range hematology and clinical chemistry parameters are reported. SafAS-Day01S was a subset of SafAS-Day01 included participants from sentinel cohort. SafAS-Day31S was a subset of SafAS-Day31 included participants from sentinel cohort. SafAS-Day181S was a subset of SafAS-Day181 included participants from sentinel cohort. Hemoglobin(Hb);White Blood Cell(WBC);Lymphocytes(LYM);Neutrophils(NEU);Eosinophils(EOS);Platelets(PLT);Prothrombin time(PT);Active partial thromboplastin time(aPTT);Creatinine(Cr);C-reactive protein(CRP);Alanine aminotransferase(ALT);Aspartate transaminase(AST);Alkaline phosphatase(ALP);Bilirubin(BR);Liver function test(LFT);BR increase-LFT increase(BR-LFT inc);BR increase-LFT normal(BR-LFT normal). Here, n=Number of participants analyzed at specific timepoints; and 99999=No participants analyzed at specific timepoints.

End point type	Primary
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End point timeframe:

Adults: Within 8 days after vaccine administration on Days 1, 31 and 181 Adolescents: Within 8 days after vaccine administration on Days 1 and 181

Notes:

[7] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: As the endpoint is descriptive in nature, no statistical analysis is provided.

End point values	Adults - Group 1: MenPenta Formulation 1	Adults - Group 2: MenPenta Formulation 2	Adults - Group 3: Bexsero + Menveo	Adults - Group 4: Trumenba + Menveo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	6	4	5
Units: participants				
Day 9: Hb decrease (n=5,6,4,5,5,10,11,2,1,3,3,0)	1	0	2	0
Day 9: WBC increase(n=5,6,4,5,5,10,11,2,1,3,3,0)	0	0	0	0
Day 9:WBC decrease(n=5,6,4,5,5,10,11,2,1,3,3,0)	0	0	0	1

Day 9: LYM decrease(n=5,6,4,5,5,10,11,2,1,3,3,0)	0	0	0	0
Day 9: NEU decrease(n=5,6,4,5,5,10,11,2,1,3,3,0)	0	0	0	0
Day 9: EOS increase(n=5,6,4,5,5,10,11,2,1,3,3,0)	1	1	0	0
Day 9: PLT decrease(n=5,6,4,5,5,10,11,2,1,3,3,0)	0	0	0	1
Day 9: PT increase (n=5,6,4,5,5,10,11,2,1,3,3,0)	0	0	0	2
Day 9: aPTT increase(n=5,6,4,5,5,10,11,2,1,3,3,0)	0	0	0	0
Day 9: Cr increase (n=5,6,4,5,5,10,11,2,1,3,3,0)	0	0	0	0
Day 9: CRP increase(n=5,6,4,5,5,10,11,2,1,3,3,0)	1	0	0	0
Day 9: ALT increase(n=5,6,4,5,5,10,11,2,1,3,3,0)	0	1	0	0
Day 9: AST increase(n=5,6,4,5,5,10,11,2,1,3,3,0)	0	0	0	0
Day 9: ALP increase(n=5,6,4,5,5,10,11,2,1,3,3,0)	0	0	0	0
Day 9: BR-LFT inc (n=5,6,4,5,5,10,11,2,1,3,3,0)	0	0	0	0
Day 9: BR-LFT normal(n=5,6,4,5,5,10,11,2,1,3,3,0)	0	0	0	0
Day 39: Hb decrease (n=4,4,4,4,5,4,0,0,0,0,0,0,0)	1	0	2	0
Day 39: WBC increase(n=4,4,4,4,5,4,0,0,0,0,0,0,0)	0	0	1	0
Day 39: WBC decrease(n=4,4,4,4,5,4,0,0,0,0,0,0,0)	0	0	0	0
Day 39: LYM decrease(n=4,4,4,4,5,4,0,0,0,0,0,0,0)	0	0	0	0
Day 39: NEU decrease(n=4,4,4,4,5,4,0,0,0,0,0,0,0)	0	0	0	0
Day 39: EOS increase(n=4,4,4,4,5,4,0,0,0,0,0,0,0)	1	0	0	1
Day 39: PLT decrease(n=4,4,4,4,5,4,0,0,0,0,0,0,0)	0	0	0	0
Day 39: PT increase (n=4,4,4,4,5,4,0,0,0,0,0,0,0)	0	1	0	0
Day 39: aPTT increase(n=4,4,4,4,5,4,0,0,0,0,0,0,0)	0	0	0	0
Day 39: Cr increase (n=4,4,4,4,5,4,0,0,0,0,0,0,0)	0	0	0	0
Day 39: CRP increase(n=4,4,4,4,5,4,0,0,0,0,0,0,0)	0	0	1	0
Day 39: ALT increase(n=4,4,4,4,5,4,0,0,0,0,0,0,0)	0	1	1	0
Day 39: AST increase(n=4,4,4,4,5,4,0,0,0,0,0,0,0)	0	1	1	0
Day 39: ALP increase(n=4,4,4,4,5,4,0,0,0,0,0,0,0)	0	0	0	0
Day 39: BR-LFT inc (n=4,4,4,4,5,4,0,0,0,0,0,0,0)	0	0	0	0
Day 39: BR-LFT normal(n=4,4,4,4,5,4,0,0,0,0,0,0,0)	0	0	0	0
Day 189: Hb decrease(n=3,4,3,4,5,3,6,9,2,0,3,2,0)	1	0	2	0
Day 189: WBC increase(n=3,4,3,4,5,3,5,9,2,0,3,2,0)	0	0	0	0

Day189:WBC decrease(n=3,4,3,4,5,3,5,9,2,0,3,2,0)	0	0	0	0
Day189:LYM decrease(n=3,4,3,4,5,3,5,9,2,0,3,2,0)	0	0	0	0
Day189:NEU decrease(n=3,4,3,4,5,3,5,9,2,0,3,2,0)	0	0	1	0
Day189:EOS increase(n=3,4,3,4,5,3,5,9,2,0,3,2,0)	1	1	0	1
Day189:PLT decrease(n=3,4,3,4,5,3,5,9,2,0,3,2,0)	0	0	0	0
Day 189:PT increase(n=2,4,3,4,5,3,5,10,2,0,3,2,0)	0	0	0	0
Day189:aPTTincrease(n=2,4,3,4,5,3,5,10,2,0,3,2,0)	0	0	0	0
Day 189:Cr increase(n=3,4,3,4,5,3,6,10,2,0,3,2,0)	0	0	0	0
Day189:CRP increase(n=3,4,3,4,5,3,6,10,2,0,3,2,0)	0	0	1	0
Day189:ALT increase(n=3,4,3,4,5,3,6,10,2,0,3,2,0)	0	1	0	0
Day189:AST increase(n=3,4,3,4,5,3,6,10,2,0,3,2,0)	0	0	0	0
Day189:ALP increase(n=3,4,3,4,5,3,5,10,2,0,3,2,0)	0	0	0	0
Day 189:BR-LFT inc (n=3,4,3,4,5,3,6,10,2,0,3,2,0)	0	0	0	0
Day189:BR-LFTnormal(n=3,4,3,4,5,3,6,10,2,0,3,2,0)	1	0	0	0

End point values	Adults - Group 5: MenQuadfi	Adults - Group 6: Sanofi MenB	Adolescents - Group 1: MenPenta Formulation 1	Adolescents - Group 2: MenPenta Formulation 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	5	10	11
Units: participants				
Day 9: Hb decrease (n=5,6,4,5,5,5,10,11,2,1,3,3,0)	1	0	4	4
Day 9: WBC increase(n=5,6,4,5,5,5,10,11,2,1,3,3,0)	0	1	0	0
Day 9:WBC decrease(n=5,6,4,5,5,5,10,11,2,1,3,3,0)	0	0	2	2
Day 9: LYM decrease(n=5,6,4,5,5,5,10,11,2,1,3,3,0)	0	0	2	2
Day 9:NEU decrease(n=5,6,4,5,5,5,10,11,2,1,3,3,0)	0	0	1	1
Day 9: EOS increase(n=5,6,4,5,5,5,10,11,2,1,3,3,0)	0	0	0	1
Day 9: PLT decrease(n=5,6,4,5,5,5,10,11,2,1,3,3,0)	0	0	0	0
Day 9: PT increase (n=5,6,4,5,5,5,10,11,2,1,3,3,0)	1	0	4	0
Day 9:aPTT increase(n=5,6,4,5,5,5,10,11,2,1,3,3,0)	0	1	4	4
Day 9: Cr increase (n=5,6,4,5,5,5,10,11,2,1,3,3,0)	0	0	0	0
Day 9: CRP increase(n=5,6,4,5,5,5,10,11,2,1,3,3,0)	2	1	0	1

Day 9: ALT increase(n=5,6,4,5,5,5,10,11,2,1,3,3,0)	0	0	1	0
Day 9: AST increase(n=5,6,4,5,5,5,10,11,2,1,3,3,0)	0	0	0	0
Day 9: ALP increase(n=5,6,4,5,5,5,10,11,2,1,3,3,0)	0	0	0	0
Day 9:BR-LFT inc (n=5,6,4,5,5,5,10,11,2,1,3,3,0)	0	0	0	0
Day9:BR-LFT normal(n=5,6,4,5,5,5,10,11,2,1,3,3,0)	1	0	0	0
Day 39: Hb decrease (n=4,4,4,4,5,4,0,0,0,0,0,0,0)	0	0	99999	99999
Day 39: WBC increase(n=4,4,4,4,5,4,0,0,0,0,0,0,0)	0	0	99999	99999
Day 39:WBC decrease(n=4,4,4,4,5,4,0,0,0,0,0,0,0)	0	0	99999	99999
Day 39: LYM decrease(n=4,4,4,4,5,4,0,0,0,0,0,0,0)	0	0	99999	99999
Day 39:NEU decrease(n=4,4,4,4,5,4,0,0,0,0,0,0,0)	0	0	99999	99999
Day 39: EOS increase(n=4,4,4,4,5,4,0,0,0,0,0,0,0)	0	0	99999	99999
Day 39: PLT decrease(n=4,4,4,4,5,4,0,0,0,0,0,0,0)	0	0	99999	99999
Day 39: PT increase (n=4,4,4,4,5,4,0,0,0,0,0,0,0)	0	1	99999	99999
Day 39:aPTT increase(n=4,4,4,4,5,4,0,0,0,0,0,0,0)	0	1	99999	99999
Day 39: Cr increase (n=4,4,4,4,5,4,0,0,0,0,0,0,0)	0	0	99999	99999
Day 39: CRP increase(n=4,4,4,4,5,4,0,0,0,0,0,0,0)	0	1	99999	99999
Day 39: ALT increase(n=4,4,4,4,5,4,0,0,0,0,0,0,0)	0	1	99999	99999
Day 39: AST increase(n=4,4,4,4,5,4,0,0,0,0,0,0,0)	0	1	99999	99999
Day 39: ALP increase(n=4,4,4,4,5,4,0,0,0,0,0,0,0)	0	1	99999	99999
Day 39:BR-LFT inc (n=4,4,4,4,5,4,0,0,0,0,0,0,0)	0	0	99999	99999
Day39:BR-LFT normal(n=4,4,4,4,5,4,0,0,0,0,0,0,0)	1	0	99999	99999
Day 189:Hb decrease(n=3,4,3,4,5,3,6,9,2,0,3,2,0)	0	1	2	3
Day189:WBC increase(n=3,4,3,4,5,3,5,9,2,0,3,2,0)	0	1	0	1
Day189:WBC decrease(n=3,4,3,4,5,3,5,9,2,0,3,2,0)	0	0	1	0
Day189:LYM decrease(n=3,4,3,4,5,3,5,9,2,0,3,2,0)	0	0	1	0
Day189:NEU decrease(n=3,4,3,4,5,3,5,9,2,0,3,2,0)	0	0	1	1
Day189:EOS increase(n=3,4,3,4,5,3,5,9,2,0,3,2,0)	0	0	0	3
Day189:PLT decrease(n=3,4,3,4,5,3,5,9,2,0,3,2,0)	1	0	0	0
Day 189:PT increase(n=2,4,3,4,5,3,5,10,2,0,3,2,0)	1	1	2	2
Day189:aPTTincrease(n=2,4,3,4,5,3,5,10,2,0,3,2,0)	1	1	1	2
Day 189:Cr increase(n=3,4,3,4,5,3,6,10,2,0,3,2,0)	0	0	0	0

Day189:CRP increase(n=3,4,3,4,5,3,6,10,2,0,3,2,0)	1	1	0	1
Day189:ALT increase(n=3,4,3,4,5,3,6,10,2,0,3,2,0)	0	0	0	0
Day189:AST increase(n=3,4,3,4,5,3,6,10,2,0,3,2,0)	0	0	0	1
Day189:ALP increase(n=3,4,3,4,5,3,5,10,2,0,3,2,0)	0	0	0	2
Day 189:BR-LFT inc (n=3,4,3,4,5,3,6,10,2,0,3,2,0)	0	0	0	0
Day189:BR- LFTnormal(n=3,4,3,4,5,3,6,10,2,0,3,2,0)	1	0	0	0

End point values	Adolescents - Group 3: Bexsero + Menveo	Adolescents - Group 4: Trumenba + Menveo	Adolescents - Group 5: MenQuadfi	Adolescents - Group 6: Sanofi MenB
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	1	3	3
Units: participants				
Day 9: Hb decrease (n=5,6,4,5,5,5,10,11,2,1,3,3,0)	0	1	2	2
Day 9: WBC increase(n=5,6,4,5,5,5,10,11,2,1,3,3,0)	0	0	0	0
Day 9:WBC decrease(n=5,6,4,5,5,5,10,11,2,1,3,3,0)	0	0	0	0
Day 9: LYM decrease(n=5,6,4,5,5,5,10,11,2,1,3,3,0)	0	0	0	1
Day 9:NEU decrease(n=5,6,4,5,5,5,10,11,2,1,3,3,0)	0	0	0	0
Day 9: EOS increase(n=5,6,4,5,5,5,10,11,2,1,3,3,0)	0	0	1	0
Day 9: PLT decrease(n=5,6,4,5,5,5,10,11,2,1,3,3,0)	0	0	0	0
Day 9: PT increase (n=5,6,4,5,5,5,10,11,2,1,3,3,0)	1	0	1	1
Day 9:aPTT increase(n=5,6,4,5,5,5,10,11,2,1,3,3,0)	0	1	0	1
Day 9: Cr increase (n=5,6,4,5,5,5,10,11,2,1,3,3,0)	0	0	0	0
Day 9: CRP increase(n=5,6,4,5,5,5,10,11,2,1,3,3,0)	0	0	0	0
Day 9: ALT increase(n=5,6,4,5,5,5,10,11,2,1,3,3,0)	0	0	0	0
Day 9: AST increase(n=5,6,4,5,5,5,10,11,2,1,3,3,0)	0	0	0	0
Day 9: ALP increase(n=5,6,4,5,5,5,10,11,2,1,3,3,0)	0	0	0	0
Day 9:BR-LFT inc (n=5,6,4,5,5,5,10,11,2,1,3,3,0)	0	0	0	0
Day9:BR-LFT normal(n=5,6,4,5,5,5,10,11,2,1,3,3,0)	0	0	0	0
Day 39: Hb decrease (n=4,4,4,4,5,4,0,0,0,0,0,0,0)	99999	99999	99999	99999
Day 39: WBC increase(n=4,4,4,4,5,4,0,0,0,0,0,0,0)	99999	99999	99999	99999
Day 39:WBC decrease(n=4,4,4,4,5,4,0,0,0,0,0,0,0)	99999	99999	99999	99999

Day 39: LYM decrease(n=4,4,4,4,5,4,0,0,0,0,0,0)	99999	99999	99999	99999
Day 39: NEU decrease(n=4,4,4,4,5,4,0,0,0,0,0,0)	99999	99999	99999	99999
Day 39: EOS increase(n=4,4,4,4,5,4,0,0,0,0,0,0)	99999	99999	99999	99999
Day 39: PLT decrease(n=4,4,4,4,5,4,0,0,0,0,0,0)	99999	99999	99999	99999
Day 39: PT increase (n=4,4,4,4,5,4,0,0,0,0,0,0)	99999	99999	99999	99999
Day 39: aPTT increase(n=4,4,4,4,5,4,0,0,0,0,0,0)	99999	99999	99999	99999
Day 39: Cr increase (n=4,4,4,4,5,4,0,0,0,0,0,0)	99999	99999	99999	99999
Day 39: CRP increase(n=4,4,4,4,5,4,0,0,0,0,0,0)	99999	99999	99999	99999
Day 39: ALT increase(n=4,4,4,4,5,4,0,0,0,0,0,0)	99999	99999	99999	99999
Day 39: AST increase(n=4,4,4,4,5,4,0,0,0,0,0,0)	99999	99999	99999	99999
Day 39: ALP increase(n=4,4,4,4,5,4,0,0,0,0,0,0)	99999	99999	99999	99999
Day 39: BR-LFT inc (n=4,4,4,4,5,4,0,0,0,0,0,0)	99999	99999	99999	99999
Day39: BR-LFT normal(n=4,4,4,4,5,4,0,0,0,0,0,0)	99999	99999	99999	99999
Day 189: Hb decrease(n=3,4,3,4,5,3,6,9,2,0,3,2,0)	0	99999	2	0
Day189: WBC increase(n=3,4,3,4,5,3,5,9,2,0,3,2,0)	0	99999	0	0
Day189: WBC decrease(n=3,4,3,4,5,3,5,9,2,0,3,2,0)	0	99999	0	0
Day189: LYM decrease(n=3,4,3,4,5,3,5,9,2,0,3,2,0)	0	99999	0	0
Day189: NEU decrease(n=3,4,3,4,5,3,5,9,2,0,3,2,0)	0	99999	1	1
Day189: EOS increase(n=3,4,3,4,5,3,5,9,2,0,3,2,0)	0	99999	1	0
Day189: PLT decrease(n=3,4,3,4,5,3,5,9,2,0,3,2,0)	0	99999	0	0
Day 189: PT increase(n=2,4,3,4,5,3,5,10,2,0,3,2,0)	1	99999	0	0
Day189: aPTT increase(n=2,4,3,4,5,3,5,10,2,0,3,2,0)	1	99999	0	0
Day 189: Cr increase(n=3,4,3,4,5,3,6,10,2,0,3,2,0)	0	99999	0	0
Day189: CRP increase(n=3,4,3,4,5,3,6,10,2,0,3,2,0)	0	99999	0	0
Day189: ALT increase(n=3,4,3,4,5,3,6,10,2,0,3,2,0)	0	99999	0	0
Day189: AST increase(n=3,4,3,4,5,3,6,10,2,0,3,2,0)	0	99999	0	0
Day189: ALP increase(n=3,4,3,4,5,3,5,10,2,0,3,2,0)	0	99999	0	0
Day 189: BR-LFT inc (n=3,4,3,4,5,3,6,10,2,0,3,2,0)	0	99999	0	0
Day189: BR-LFT normal(n=3,4,3,4,5,3,6,10,2,0,3,2,0)	0	99999	1	0

End point values	Adolescents - Group 7: PENBRAYA			
Subject group type	Reporting group			
Number of subjects analysed	0 ^[8]			
Units: participants				
Day 9: Hb decrease (n=5,6,4,5,5,5,10,11,2,1,3,3,0) Day 9: WBC increase(n=5,6,4,5,5,5,10,11,2,1,3,3,0) Day 9:WBC decrease(n=5,6,4,5,5,5,10,11,2,1,3,3,0) Day 9: LYM decrease(n=5,6,4,5,5,5,10,11,2,1,3,3,0) Day 9:NEU decrease(n=5,6,4,5,5,5,10,11,2,1,3,3,0) Day 9: EOS increase(n=5,6,4,5,5,5,10,11,2,1,3,3,0) Day 9: PLT decrease(n=5,6,4,5,5,5,10,11,2,1,3,3,0) Day 9: PT increase (n=5,6,4,5,5,5,10,11,2,1,3,3,0) Day 9:aPTT increase(n=5,6,4,5,5,5,10,11,2,1,3,3,0) Day 9: Cr increase (n=5,6,4,5,5,5,10,11,2,1,3,3,0) Day 9: CRP increase(n=5,6,4,5,5,5,10,11,2,1,3,3,0) Day 9: ALT increase(n=5,6,4,5,5,5,10,11,2,1,3,3,0) Day 9: AST increase(n=5,6,4,5,5,5,10,11,2,1,3,3,0) Day 9: ALP increase(n=5,6,4,5,5,5,10,11,2,1,3,3,0) Day 9:BR-LFT inc (n=5,6,4,5,5,5,10,11,2,1,3,3,0) Day9:BR-LFT normal(n=5,6,4,5,5,5,10,11,2,1,3,3,0) Day 39: Hb decrease (n=4,4,4,4,5,4,0,0,0,0,0,0,0) Day 39: WBC increase(n=4,4,4,4,5,4,0,0,0,0,0,0,0) Day 39:WBC decrease(n=4,4,4,4,5,4,0,0,0,0,0,0,0) Day 39: LYM decrease(n=4,4,4,4,5,4,0,0,0,0,0,0,0) Day 39:NEU decrease(n=4,4,4,4,5,4,0,0,0,0,0,0,0) Day 39: EOS increase(n=4,4,4,4,5,4,0,0,0,0,0,0,0) Day 39: PLT decrease(n=4,4,4,4,5,4,0,0,0,0,0,0,0) Day 39: PT increase (n=4,4,4,4,5,4,0,0,0,0,0,0,0) Day 39:aPTT increase(n=4,4,4,4,5,4,0,0,0,0,0,0,0) Day 39: Cr increase (n=4,4,4,4,5,4,0,0,0,0,0,0,0) Day 39: CRP increase(n=4,4,4,4,5,4,0,0,0,0,0,0,0) Day 39: ALT increase(n=4,4,4,4,5,4,0,0,0,0,0,0,0)				

Day 39: AST increase(n=4,4,4,4,5,4,0,0,0,0,0)				
Day 39: ALP increase(n=4,4,4,4,5,4,0,0,0,0,0)				
Day 39:BR-LFT inc (n=4,4,4,4,5,4,0,0,0,0,0)				
Day39:BR-LFT normal(n=4,4,4,4,5,4,0,0,0,0,0)				
Day 189:Hb decrease(n=3,4,3,4,5,3,6,9,2,0,3,2,0)				
Day189:WBC increase(n=3,4,3,4,5,3,5,9,2,0,3,2,0)				
Day189:WBC decrease(n=3,4,3,4,5,3,5,9,2,0,3,2,0)				
Day189:LYM decrease(n=3,4,3,4,5,3,5,9,2,0,3,2,0)				
Day189:NEU decrease(n=3,4,3,4,5,3,5,9,2,0,3,2,0)				
Day189:EOS increase(n=3,4,3,4,5,3,5,9,2,0,3,2,0)				
Day189:PLT decrease(n=3,4,3,4,5,3,5,9,2,0,3,2,0)				
Day 189:PT increase(n=2,4,3,4,5,3,5,10,2,0,3,2,0)				
Day189:aPTTincrease(n=2,4,3,4,5,3,5,10,2,0,3,2,0)				
Day 189:Cr increase(n=3,4,3,4,5,3,6,10,2,0,3,2,0)				
Day189:CRP increase(n=3,4,3,4,5,3,6,10,2,0,3,2,0)				
Day189:ALT increase(n=3,4,3,4,5,3,6,10,2,0,3,2,0)				
Day189:AST increase(n=3,4,3,4,5,3,6,10,2,0,3,2,0)				
Day189:ALP increase(n=3,4,3,4,5,3,5,10,2,0,3,2,0)				
Day 189:BR-LFT inc (n=3,4,3,4,5,3,6,10,2,0,3,2,0)				
Day189:BR-LFTnormal(n=3,4,3,4,5,3,6,10,2,0,3,2,0)				

Notes:

[8] - No participants analyzed; abnormal biological test results were analyzed for sentinel cohort only.

Statistical analyses

No statistical analyses for this end point

Primary: Adolescents Only: Percentage of Participants With Seroresponse Against Meningococcal Serogroups A, C, W and Y Strains at Days 1 and 211

End point title	Adolescents Only: Percentage of Participants With Seroresponse Against Meningococcal Serogroups A, C, W and Y Strains at Days 1 and 211 ^{[9][10]}
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End point description:

The seroresponse was defined as post-second vaccination titers $\geq 1:16$ for participants with pre-vaccination human complement serum bactericidal assay (hSBA) titers $< 1:4$, or post-second vaccination titers ≥ 4 times the pre-vaccination titer for participants with a pre-vaccination titer $\geq$ the lower limit of quantification (LLOQ). The LLOQ was a titer of $1:4$, and it is the same as the limit of detection (LOD) for the meningococcal serogroups A, C, W and Y hSBA assay. The Full analysis set (FAS) 2 – adolescents included participants who were vaccinated per protocol at Day 181 and had 1 valid post-vaccination blood sample at Day 211. The percentages are rounded off to the tenth decimal place. Here, n= Number

of participants analyzed for specific serogroup.

End point type	Primary
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End point timeframe:

Pre-vaccination on Day 1 and 1 month after the second vaccination (Day 211)

Notes:

[9] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: As the endpoint is descriptive in nature, no statistical analysis is provided.

[10] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As specified in the endpoint title, only adolescent participants were included in the analysis for this endpoint.

End point values	Adolescents - Group 1: MenPenta Formulation 1	Adolescents - Group 2: MenPenta Formulation 2	Adolescents - Group 3: Bexsero + Menveo	Adolescents - Group 4: Trumenba + Menveo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	245	254	81	81
Units: percentage of participants				
number (confidence interval 95%)				
Serogroup A (n=227,240,77,78,82,78,88)	97.8 (94.9 to 99.3)	96.3 (93.0 to 98.3)	98.7 (93.0 to 100)	55.1 (43.4 to 66.4)
Serogroup C (n=237,244,81,81,78,81,88)	97.0 (94.0 to 98.8)	98.0 (95.3 to 99.3)	95.1 (87.8 to 98.6)	75.3 (64.5 to 84.2)
Serogroup W (n=245,254,81,79,82,84,90)	96.7 (93.7 to 98.6)	95.3 (91.9 to 97.5)	71.6 (60.5 to 81.1)	74.7 (63.6 to 83.8)
Serogroup Y (n=224,232,75,76,74,81,85)	97.8 (94.9 to 99.3)	97.4 (94.5 to 99.0)	78.7 (67.7 to 87.3)	82.9 (72.5 to 90.6)

End point values	Adolescents - Group 5: MenQuadfi	Adolescents - Group 6: Sanofi MenB	Adolescents - Group 7: PENBRAYA	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	82	84	90	
Units: percentage of participants				
number (confidence interval 95%)				
Serogroup A (n=227,240,77,78,82,78,88)	86.6 (77.3 to 93.1)	96.2 (89.2 to 99.2)	90.9 (82.9 to 96.0)	
Serogroup C (n=237,244,81,81,78,81,88)	97.4 (91.0 to 99.7)	66.7 (55.3 to 76.8)	92.0 (84.3 to 96.7)	
Serogroup W (n=245,254,81,79,82,84,90)	98.8 (93.4 to 100)	14.3 (7.6 to 23.6)	96.7 (90.6 to 99.3)	
Serogroup Y (n=224,232,75,76,74,81,85)	100 (95.1 to 100)	11.1 (5.2 to 20.0)	94.1 (86.8 to 98.1)	

Statistical analyses

No statistical analyses for this end point

Primary: Adolescents Only: Percentage of Participants With Human Complement

Serum Bactericidal Assay Titer $\geq 1:8$ Against Meningococcal Serogroups A, C, W and Y Strains at Days 1 and 211

End point title	Adolescents Only: Percentage of Participants With Human Complement Serum Bactericidal Assay Titer $\geq 1:8$ Against Meningococcal Serogroups A, C, W and Y Strains at Days 1 and 211 ^[11] ^[12]
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End point description:

The percentage of participants with antibody titers $\geq 1:8$ against meningococcal serogroups A, C, W and Y was measured by hSBA. The 95% confidence interval (CI) for the single percentage was based on the Clopper-Pearson method. The FAS2 – adolescents included participants who were vaccinated per protocol at Day 181 and had 1 valid post-vaccination blood sample at Day 211. The percentages are rounded off to the tenth decimal place. Here, n= Number of participants analyzed for each serogroup at specific timepoints.

End point type	Primary
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End point timeframe:

Pre-vaccination on Day 1 and 1 month after the second vaccination (Day 211)

Notes:

[11] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: As the endpoint is descriptive in nature, no statistical analysis is provided.

[12] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As specified in the endpoint title, only adolescent participants were included in the analysis for this endpoint.

End point values	Adolescents - Group 1: MenPenta Formulation 1	Adolescents - Group 2: MenPenta Formulation 2	Adolescents - Group 3: Bexsero + Menveo	Adolescents - Group 4: Trumenba + Menveo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	260	265	88	84
Units: percentage of participants				
number (confidence interval 95%)				
Serogroup A: Day 1 (n=245,256,83,79,85,83,92)	52.2 (45.8 to 58.6)	59.8 (53.5 to 65.8)	48.2 (37.1 to 59.4)	57.0 (45.3 to 68.1)
Serogroup A: Day 211 (n=243,252,84,84,88,84,90)	99.6 (97.7 to 100)	99.2 (97.2 to 99.9)	98.8 (93.5 to 100)	85.7 (76.4 to 92.4)
Serogroup C: Day 1 (n=253,256,83,83,85,86,89)	32.8 (27.1 to 39.0)	39.8 (33.8 to 46.1)	34.9 (24.8 to 46.2)	30.1 (20.5 to 41.2)
Serogroup C: Day 211 (n=247,256,88,83,84,84,93)	100 (98.5 to 100)	99.6 (97.8 to 100)	98.9 (93.8 to 100)	94.0 (86.5 to 98.0)
Serogroup W: Day 1 (n=248,256,85,80,84,87,92)	41.9 (35.7 to 48.3)	46.5 (40.3 to 52.8)	34.1 (24.2 to 45.2)	45.0 (33.8 to 56.5)
Serogroup W: Day 211 (n=260,265,86,84,89,86,92)	100 (98.6 to 100)	99.2 (97.3 to 99.9)	90.7 (82.5 to 95.9)	95.2 (88.3 to 98.7)
Serogroup Y: Day 1 (n=234,239,80,78,79,83,90)	29.5 (23.7 to 35.8)	22.2 (17.1 to 28.0)	21.3 (12.9 to 31.8)	21.8 (13.2 to 32.6)
Serogroup Y: Day 211 (n=249,261,84,82,85,86,89)	100 (98.5 to 100)	99.6 (97.9 to 100)	86.9 (77.8 to 93.3)	90.2 (81.7 to 95.7)

End point values	Adolescents - Group 5: MenQuadfi	Adolescents - Group 6: Sanofi MenB	Adolescents - Group 7: PENBRAYA	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	89	87	93	
Units: percentage of participants				

number (confidence interval 95%)				
Serogroup A: Day 1 (n=245,256,83,79,85,83,92)	56.5 (45.3 to 67.2)	56.6 (45.3 to 67.5)	53.3 (42.6 to 63.7)	
Serogroup A: Day 211 (n=243,252,84,84,88,84,90)	97.7 (92.0 to 99.7)	100 (95.7 to 100)	97.8 (92.2 to 99.7)	
Serogroup C: Day 1 (n=253,256,83,83,85,86,89)	30.6 (21.0 to 41.5)	31.4 (21.8 to 42.3)	37.1 (27.1 to 48.0)	
Serogroup C: Day 211 (n=247,256,88,83,84,84,93)	100 (95.7 to 100)	85.7 (76.4 to 92.4)	98.9 (94.2 to 100)	
Serogroup W: Day 1 (n=248,256,85,80,84,87,92)	47.6 (36.6 to 58.8)	50.6 (39.6 to 61.5)	38.0 (28.1 to 48.8)	
Serogroup W: Day 211 (n=260,265,86,84,89,86,92)	100 (95.9 to 100)	57.0 (45.8 to 67.6)	100 (96.1 to 100)	
Serogroup Y: Day 1 (n=234,239,80,78,79,83,90)	27.8 (18.3 to 39.1)	28.9 (19.5 to 39.9)	20.0 (12.3 to 29.8)	
Serogroup Y: Day 211 (n=249,261,84,82,85,86,89)	100 (95.8 to 100)	33.7 (23.9 to 44.7)	100 (95.9 to 100)	

Statistical analyses

No statistical analyses for this end point

Primary: Adolescents Only: Geometric Mean Titers (GMT) of Antibodies Against Meningococcal Serogroups A, C, W and Y Strains at Days 1 and 211

End point title	Adolescents Only: Geometric Mean Titers (GMT) of Antibodies Against Meningococcal Serogroups A, C, W and Y Strains at Days 1 and 211 ^{[13][14]}
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End point description:

The antibodies titer against meningococcal serogroups A, C, W and Y was measured by hSBA and the results were expressed as GMT. The 95% CI for the single percentage was based on the Clopper-Pearson method. The FAS2 – adolescents included participants who were vaccinated per protocol at Day 181 and had 1 valid post-vaccination blood sample at Day 211. Here, n= Number of participants analyzed for each serogroup at specific timepoints.

End point type	Primary
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End point timeframe:

Pre-vaccination on Day 1 and 1 month after the second vaccination (Day 211)

Notes:

[13] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: As the endpoint is descriptive in nature, no statistical analysis is provided.

[14] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As specified in the endpoint title, only adolescent participants were included in the analysis for this endpoint.

End point values	Adolescents - Group 1: MenPenta Formulation 1	Adolescents - Group 2: MenPenta Formulation 2	Adolescents - Group 3: Bexsero + Menveo	Adolescents - Group 4: Trumenba + Menveo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	260	265	88	84
Units: titer				
geometric mean (confidence interval 95%)				
Serogroup A: Day 1 (n=245,256,83,79,85,83,92)	7.00 (6.13 to 8.00)	8.58 (7.41 to 9.94)	6.33 (5.31 to 7.55)	8.89 (6.52 to 12.1)

Serogroup A: Day 211 (n=243,252,84,84,88,84,90)	638 (531 to 767)	640 (536 to 763)	967 (720 to 1298)	43.8 (29.5 to 65.0)
Serogroup C: Day 1 (n=253,256,83,83,85,86,89)	5.15 (4.32 to 6.13)	6.64 (5.45 to 8.08)	5.54 (4.11 to 7.47)	5.36 (3.97 to 7.23)
Serogroup C: Day 211 (n=247,256,88,83,84,84,93)	823 (716 to 945)	970 (833 to 1130)	250 (188 to 332)	69.0 (46.7 to 102)
Serogroup W: Day 1 (n=248,256,85,80,84,87,92)	6.15 (5.18 to 7.31)	6.86 (5.80 to 8.10)	5.45 (4.17 to 7.13)	7.40 (5.33 to 10.3)
Serogroup W: Day 211 (n=260,265,86,84,89,86,92)	402 (349 to 462)	410 (350 to 481)	71.1 (48.2 to 105)	89.8 (63.0 to 128)
Serogroup Y: Day 1 (n=234,239,80,78,79,83,90)	4.40 (3.73 to 5.18)	3.89 (3.31 to 4.56)	3.48 (2.73 to 4.44)	3.63 (2.82 to 4.66)
Serogroup Y: Day 211 (n=249,261,84,82,85,86,89)	466 (405 to 536)	482 (417 to 556)	60.9 (41.0 to 90.6)	81.1 (54.6 to 120)

End point values	Adolescents - Group 5: MenQuadfi	Adolescents - Group 6: Sanofi MenB	Adolescents - Group 7: PENBRAYA	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	89	87	93	
Units: titer				
geometric mean (confidence interval 95%)				
Serogroup A: Day 1 (n=245,256,83,79,85,83,92)	8.27 (6.54 to 10.4)	8.00 (6.10 to 10.5)	7.42 (5.78 to 9.53)	
Serogroup A: Day 211 (n=243,252,84,84,88,84,90)	217 (157 to 299)	678 (485 to 947)	272 (202 to 366)	
Serogroup C: Day 1 (n=253,256,83,83,85,86,89)	4.99 (3.76 to 6.61)	5.84 (4.18 to 8.17)	5.81 (4.20 to 8.05)	
Serogroup C: Day 211 (n=247,256,88,83,84,84,93)	604 (456 to 799)	53.4 (35.6 to 80.1)	297 (226 to 390)	
Serogroup W: Day 1 (n=248,256,85,80,84,87,92)	5.94 (4.60 to 7.68)	8.06 (5.82 to 11.2)	5.53 (4.20 to 7.28)	
Serogroup W: Day 211 (n=260,265,86,84,89,86,92)	456 (342 to 607)	10.3 (7.12 to 14.8)	291 (243 to 348)	
Serogroup Y: Day 1 (n=234,239,80,78,79,83,90)	3.70 (2.95 to 4.64)	4.50 (3.32 to 6.09)	3.97 (2.98 to 5.30)	
Serogroup Y: Day 211 (n=249,261,84,82,85,86,89)	435 (340 to 556)	6.08 (4.18 to 8.84)	283 (232 to 346)	

Statistical analyses

No statistical analyses for this end point

Primary: Adolescents Only: Percentage of Participants With Human Complement Serum Bactericidal Assay Titer $\geq$ Lower Limit of Quantification Against Meningococcal Serogroups A, C, W and Y Strains at Days 1 and 211

End point title	Adolescents Only: Percentage of Participants With Human Complement Serum Bactericidal Assay Titer $\geq$ Lower Limit of Quantification Against Meningococcal Serogroups A, C, W and Y Strains at Days 1 and 211 ^{[15][16]}
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End point description:

The percentage of participants with antibody titers $\geq$ LLOQ against meningococcal serogroups A, C, W and Y was measured by hSBA. The LLOQ was a titer of 1:4, and it is the same as the LOD for the

meningococcal serogroups A, C, W and Y hSBA assay. The 95% CI for the single percentage was based on the Clopper-Pearson method. The FAS2 – adolescents included participants who were vaccinated per protocol at Day 181 and had 1 valid post-vaccination blood sample at Day 211. The percentages are rounded off to the tenth decimal place. Here, n= Number of participants analyzed for each serogroup at specific timepoints.

End point type	Primary
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End point timeframe:

Pre-vaccination on Day 1 and 1 month after the second vaccination (Day 211)

Notes:

[15] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: As the endpoint is descriptive in nature, no statistical analysis is provided.

[16] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As specified in the endpoint title, only adolescent participants were included in the analysis for this endpoint.

End point values	Adolescents - Group 1: MenPenta Formulation 1	Adolescents - Group 2: MenPenta Formulation 2	Adolescents - Group 3: Bexsero + Menveo	Adolescents - Group 4: Trumenba + Menveo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	260	265	88	84
Units: percentage of participants				
number (confidence interval 95%)				
Serogroup A: Day 1 (n=245,256,83,79,85,83,92)	82.0 (76.7 to 86.6)	84.0 (78.9 to 88.3)	85.5 (76.1 to 92.3)	79.7 (69.2 to 88.0)
Serogroup A: Day 211 (n=243,252,84,84,88,84,90)	100 (98.5 to 100)	100 (98.5 to 100)	100 (95.7 to 100)	92.9 (85.1 to 97.3)
Serogroup C: Day 1 (n=253,256,83,83,85,86,89)	50.2 (43.9 to 56.5)	56.3 (49.9 to 62.4)	56.6 (45.3 to 67.5)	54.2 (42.9 to 65.2)
Serogroup C: Day 211 (n=247,256,88,83,84,84,93)	100 (98.5 to 100)	99.6 (97.8 to 100)	98.9 (93.8 to 100)	96.4 (89.8 to 99.2)
Serogroup W: Day 1 (n=248,256,85,80,84,87,92)	53.6 (47.2 to 60.0)	63.3 (57.1 to 69.2)	57.6 (46.4 to 68.3)	61.3 (49.7 to 71.9)
Serogroup W: Day 211 (n=260,265,86,84,89,86,92)	100 (98.6 to 100)	99.6 (97.9 to 100)	96.5 (90.1 to 99.3)	97.6 (91.7 to 99.7)
Serogroup Y: Day 1 (n=234,239,80,78,79,83,90)	36.3 (30.2 to 42.8)	31.8 (25.9 to 38.1)	30.0 (20.3 to 41.3)	30.8 (20.8 to 42.2)
Serogroup Y: Day 211 (n=249,261,84,82,85,86,89)	100 (98.5 to 100)	99.6 (97.9 to 100)	91.7 (83.6 to 96.6)	93.9 (86.3 to 98.0)

End point values	Adolescents - Group 5: MenQuadfi	Adolescents - Group 6: Sanofi MenB	Adolescents - Group 7: PENBRAYA	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	89	87	93	
Units: percentage of participants				
number (confidence interval 95%)				
Serogroup A: Day 1 (n=245,256,83,79,85,83,92)	81.2 (71.2 to 88.8)	79.5 (69.2 to 87.6)	77.2 (67.2 to 85.3)	
Serogroup A: Day 211 (n=243,252,84,84,88,84,90)	100 (95.9 to 100)	100 (95.7 to 100)	97.8 (92.2 to 99.7)	
Serogroup C: Day 1 (n=253,256,83,83,85,86,89)	54.1 (43.0 to 65.0)	53.5 (42.4 to 64.3)	55.1 (44.1 to 65.6)	

Serogroup C: Day 211 (n=247,256,88,83,84,84,93)	100 (95.7 to 100)	91.7 (83.6 to 96.6)	100 (96.1 to 100)	
Serogroup W: Day 1 (n=248,256,85,80,84,87,92)	54.8 (43.5 to 65.7)	65.5 (54.6 to 75.4)	51.1 (40.4 to 61.7)	
Serogroup W: Day 211 (n=260,265,86,84,89,86,92)	100 (95.9 to 100)	67.4 (56.5 to 77.2)	100 (96.1 to 100)	
Serogroup Y: Day 1 (n=234,239,80,78,79,83,90)	32.9 (22.7 to 44.4)	34.9 (24.8 to 46.2)	31.1 (21.8 to 41.7)	
Serogroup Y: Day 211 (n=249,261,84,82,85,86,89)	100 (95.8 to 100)	41.9 (31.3 to 53.0)	100 (95.9 to 100)	

Statistical analyses

No statistical analyses for this end point

Primary: Adolescents Only: Percentage of Participants With Seroresponse Against Reference Strains of Meningococcal Serogroup B at Days 1 and 211

End point title	Adolescents Only: Percentage of Participants With Seroresponse Against Reference Strains of Meningococcal Serogroup B at Days 1 and 211 ^{[17][18]}
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End point description:

The seroresponse was defined as a 4-fold increase in hSBA titers from pre-vaccination to post-second vaccination. The FAS2 – adolescents included participants who were vaccinated per protocol at Day 181 and had 1 valid post-vaccination blood sample at Day 211. The percentages are rounded off to the tenth decimal place. Here, n= Number of participants analyzed for specific serogroup.

End point type	Primary
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End point timeframe:

Pre-vaccination on Day 1 and 1 month after the second vaccination (Day 211)

Notes:

[17] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: As the endpoint is descriptive in nature, no statistical analysis is provided.

[18] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As specified in the endpoint title, only adolescent participants were included in the analysis for this endpoint.

End point values	Adolescents - Group 1: MenPenta Formulation 1	Adolescents - Group 2: MenPenta Formulation 2	Adolescents - Group 3: Bexsero + Menveo	Adolescents - Group 4: Trumenba + Menveo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	256	263	87	84
Units: percentage of participants				
number (confidence interval 95%)				
Strain (A56) (n=256,263,86,83,90,87,94)	33.2 (27.5 to 39.3)	45.2 (39.1 to 51.5)	10.5 (4.9 to 18.9)	85.5 (76.1 to 92.3)
Strain (B44) (n=255,262,86,82,88,86,91)	55.3 (49.0 to 61.5)	65.6 (59.6 to 71.4)	62.8 (51.7 to 73.0)	80.5 (70.3 to 88.4)
Strain (A10) (n=255,260,83,84,89,85,91)	40.4 (34.3 to 46.7)	43.1 (37.0 to 49.3)	12.0 (5.9 to 21.0)	0 (0 to 4.3)
Strain (B79) (n=255,259,87,75,88,88,82)	86.3 (81.4 to 90.2)	89.2 (84.8 to 92.7)	96.6 (90.3 to 99.3)	14.7 (7.6 to 24.7)

End point values	Adolescents - Group 5: MenQuadfi	Adolescents - Group 6: Sanofi MenB	Adolescents - Group 7: PENBRAYA	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	90	88	94	
Units: percentage of participants				
number (confidence interval 95%)				
Strain (A56) (n=256,263,86,83,90,87,94)	1.1 (0 to 6.0)	35.6 (25.6 to 46.6)	85.1 (76.3 to 91.6)	
Strain (B44) (n=255,262,86,82,88,86,91)	5.7 (1.9 to 12.8)	65.1 (54.1 to 75.1)	72.5 (62.2 to 81.4)	
Strain (A10) (n=255,260,83,84,89,85,91)	1.1 (0 to 6.1)	55.3 (44.1 to 66.1)	0 (0 to 4.0)	
Strain (B79) (n=255,259,87,75,88,88,82)	2.3 (0.3 to 8.0)	96.6 (90.4 to 99.3)	15.9 (8.7 to 25.6)	

Statistical analyses

No statistical analyses for this end point

Primary: Adolescents Only: Percentage of Participants With Human Complement Serum Bactericidal Assay Titer $\geq 1:4$ and $\geq 1:8$ Against Reference Strains of Meningococcal Serogroup B at Days 1 and 211

End point title	Adolescents Only: Percentage of Participants With Human Complement Serum Bactericidal Assay Titer $\geq 1:4$ and $\geq 1:8$ Against Reference Strains of Meningococcal Serogroup B at Days 1 and 211 ^{[19][20]}
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End point description:

The percentage of participants with antibody titers $\geq 1:4$ and $\geq 1:8$ against the reference strains of the meningococcal serogroup B was measured by hSBA. The 95% CI for the single percentage was based on the Clopper-Pearson method. The FAS2 – adolescents included participants who were vaccinated per protocol at Day 181 and had 1 valid post-vaccination blood sample at Day 211. The percentages are rounded off to the tenth decimal place. S-A56= Strain (A56); S-B44= Strain (B44); S-A10= Strain (A10); S-B79= Strain (B79). Here, n= Number of participants analyzed for each serogroup at specific timepoints.

End point type	Primary
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End point timeframe:

Pre-vaccination on Day 1 and 1 month after the second vaccination (Day 211)

Notes:

[19] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: As the endpoint is descriptive in nature, no statistical analysis is provided.

[20] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As specified in the endpoint title, only adolescent participants were included in the analysis for this endpoint.

End point values	Adolescents - Group 1: MenPenta Formulation 1	Adolescents - Group 2: MenPenta Formulation 2	Adolescents - Group 3: Bexsero + Menveo	Adolescents - Group 4: Trumenba + Menveo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	263	267	89	85
Units: percentage of participants				
number (confidence interval 95%)				
S- A56:Day1,>=1:4(n=258,266,89,83,90,	100 (98.6 to 100)	100 (98.6 to 100)	100 (95.9 to 100)	100 (95.7 to 100)
S- A56:Day1,>=1:8(n=258,266,89,83,90,	5.0 (2.7 to 8.5)	6.0 (3.5 to 9.6)	3.4 (0.7 to 9.5)	4.8 (1.3 to 11.9)
S- A56:Day211,>=1:4(n=262,266,87,85,9	100 (98.6 to 100)	100 (98.6 to 100)	100 (95.8 to 100)	100 (95.8 to 100)
S- A56:Day211,>=1:8(n=262,266,87,85,9	57.6 (51.4 to 63.7)	66.2 (60.1 to 71.8)	41.4 (30.9 to 52.4)	96.5 (90.0 to 99.3)
S- B44:Day1,>=1:4(n=259,264,89,83,90,	73.7 (67.9 to 79.0)	73.1 (67.3 to 78.4)	68.5 (57.8 to 78.0)	73.5 (62.7 to 82.6)
S- B44:Day1,>=1:8(n=259,264,89,83,90,	53.3 (47.0 to 59.5)	48.1 (41.9 to 54.3)	48.3 (37.6 to 59.2)	49.4 (38.2 to 60.6)
S- B44:Day211,>=1:4(n=260,267,87,84,8	97.3 (94.5 to 98.9)	99.6 (97.9 to 100)	100 (95.8 to 100)	100 (95.7 to 100)
S- B44:Day211,>=1:8(n=260,267,87,84,8	92.3 (88.4 to 95.2)	97.4 (94.7 to 98.9)	98.9 (93.8 to 100)	98.8 (93.5 to 100)
S- A10:Day1,>=1:4(n=257,266,88,84,90,	1.9 (0.6 to 4.5)	4.5 (2.4 to 7.7)	3.4 (0.7 to 9.6)	2.4 (0.3 to 8.3)
S- A10:Day1,>=1:8(n=257,266,88,84,90,	1.6 (0.4 to 3.9)	3.4 (1.6 to 6.3)	2.3 (0.3 to 8.0)	2.4 (0.3 to 8.3)
S- A10:Day211,>=1:4(n=262,263,85,85,9	72.5 (66.7 to 77.8)	80.6 (75.3 to 85.2)	24.7 (16.0 to 35.3)	4.7 (1.3 to 11.6)
S- A10:Day211,>=1:8(n=262,263,85,85,9	63.0 (56.8 to 68.8)	69.6 (63.6 to 75.1)	22.4 (14.0 to 32.7)	2.4 (0.3 to 8.2)
S- B79:Day1,>=1:4(n=256,261,89,83,88,	4.3 (2.2 to 7.6)	5.7 (3.3 to 9.3)	4.5 (1.2 to 11.1)	7.2 (2.7 to 15.1)
S- B79:Day1,>=1:8(n=256,261,89,83,88,	4.3 (2.2 to 7.6)	5.4 (3.0 to 8.8)	4.5 (1.2 to 11.1)	7.2 (2.7 to 15.1)
S- B79:Day211,>=1:4(n=263,267,88,76,9	93.5 (89.9 to 96.2)	97.8 (95.2 to 99.2)	97.7 (92.0 to 99.7)	34.2 (23.7 to 46.0)
S- B79:Day211,>=1:8(n=263,267,88,76,9	93.2 (89.4 to 95.9)	97.8 (95.2 to 99.2)	97.7 (92.0 to 99.7)	34.2 (23.7 to 46.0)

End point values	Adolescents - Group 5: MenQuadfi	Adolescents - Group 6: Sanofi MenB	Adolescents - Group 7: PENBRAYA	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	91	89	94	
Units: percentage of participants				
number (confidence interval 95%)				
S- A56:Day1,>=1:4(n=258,266,89,83,90,	100 (96.0 to 100)	100 (95.9 to 100)	100 (96.2 to 100)	
S- A56:Day1,>=1:8(n=258,266,89,83,90,	6.7 (2.5 to 13.9)	6.7 (2.5 to 14.1)	3.2 (0.7 to 9.0)	
S- A56:Day211,>=1:4(n=262,266,87,85,9	100 (96.0 to 100)	100 (95.8 to 100)	100 (96.2 to 100)	
S- A56:Day211,>=1:8(n=262,266,87,85,9	7.7 (3.1 to 15.2)	54.0 (43.0 to 64.8)	98.9 (94.2 to 100)	

S- B44:Day1,>=1:4(n=259,264,89,83,90,	73.3 (63.0 to 82.1)	75.9 (65.5 to 84.4)	71.4 (61.0 to 80.4)	
S- B44:Day1,>=1:8(n=259,264,89,83,90,	52.2 (41.4 to 62.9)	49.4 (38.5 to 60.4)	60.4 (49.6 to 70.5)	
S- B44:Day211,>=1:4(n=260,267,87,84,8	73.0 (62.6 to 81.9)	98.9 (93.8 to 100)	100 (96.2 to 100)	
S- B44:Day211,>=1:8(n=260,267,87,84,8	55.1 (44.1 to 65.6)	96.6 (90.4 to 99.3)	100 (96.2 to 100)	
S- A10:Day1,>=1:4(n=257,266,88,84,90,	5.6 (1.8 to 12.5)	4.5 (1.3 to 11.2)	4.3 (1.2 to 10.8)	
S- A10:Day1,>=1:8(n=257,266,88,84,90,	3.3 (0.7 to 9.4)	3.4 (0.7 to 9.6)	3.3 (0.7 to 9.2)	
S- A10:Day211,>=1:4(n=262,263,85,85,9	5.6 (1.8 to 12.5)	86.0 (76.9 to 92.6)	2.2 (0.3 to 7.6)	
S- A10:Day211,>=1:8(n=262,263,85,85,9	4.4 (1.2 to 11.0)	79.1 (69.0 to 87.1)	1.1 (0 to 5.8)	
S- B79:Day1,>=1:4(n=256,261,89,83,88,	6.8 (2.5 to 14.3)	6.7 (2.5 to 14.1)	8.8 (3.9 to 16.6)	
S- B79:Day1,>=1:8(n=256,261,89,83,88,	6.8 (2.5 to 14.3)	5.6 (1.8 to 12.6)	8.8 (3.9 to 16.6)	
S- B79:Day211,>=1:4(n=263,267,88,76,9	10.0 (4.7 to 18.1)	98.9 (93.8 to 100)	29.8 (20.3 to 40.7)	
S- B79:Day211,>=1:8(n=263,267,88,76,9	10.0 (4.7 to 18.1)	98.9 (93.8 to 100)	27.4 (18.2 to 38.2)	

Statistical analyses

No statistical analyses for this end point

Primary: Adolescents Only: Geometric Mean Titers of Antibodies Against Reference Strains of Meningococcal Serogroup B at Days 1 and 211

End point title	Adolescents Only: Geometric Mean Titers of Antibodies Against Reference Strains of Meningococcal Serogroup B at Days 1 and 211 ^[21] ^[22]
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End point description:

The antibodies titer against the reference strains of the meningococcal serogroup B was measured by hSBA and the results were expressed as GMT. The 95% CI for the single percentage was based on the Clopper-Pearson method. The FAS2 – adolescents included participants who were vaccinated per protocol at Day 181 and had 1 valid post-vaccination blood sample at Day 211. Here, n= Number of participants analyzed for each serogroup at specific timepoints.

End point type	Primary
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End point timeframe:

Pre-vaccination on Day 1 and 1 month after the second vaccination (Day 211)

Notes:

[21] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: As the endpoint is descriptive in nature, no statistical analysis is provided.

[22] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As specified in the endpoint title, only adolescent participants were included in the analysis for this endpoint.

End point values	Adolescents - Group 1: MenPenta Formulation 1	Adolescents - Group 2: MenPenta Formulation 2	Adolescents - Group 3: Bexsero + Menveo	Adolescents - Group 4: Trumenba + Menveo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	263	267	89	85
Units: titer				
geometric mean (confidence interval 95%)				
Strain (A56): Day 1 (n=258,266,89,83,90,89,94)	4.98 (4.70 to 5.27)	5.01 (4.73 to 5.31)	4.76 (4.45 to 5.10)	4.82 (4.49 to 5.18)
Strain (A56):Day211(n=262,266,87,85,91,87,	21.2 (17.3 to 25.9)	33.1 (26.6 to 41.0)	9.00 (7.35 to 11.0)	107 (84.2 to 137)
Strain (B44): Day 1 (n=259,264,89,83,90,87,91)	9.24 (7.86 to 10.9)	8.80 (7.53 to 10.3)	8.20 (6.26 to 10.7)	7.61 (6.01 to 9.64)
Strain (B44): Day 211 (n=260,267,87,84,89,88,94)	57.1 (48.0 to 67.9)	79.4 (67.9 to 93.0)	52.8 (43.4 to 64.3)	111 (88.0 to 140)
Strain (A10): Day 1 (n=257,266,88,84,90,88,92)	2.65 (2.50 to 2.80)	2.73 (2.59 to 2.88)	2.78 (2.41 to 3.20)	2.69 (2.42 to 2.99)
Strain (A10):Day211(n=262,263,85,85,90,86,	13.9 (11.6 to 16.6)	17.5 (14.7 to 20.9)	4.57 (3.51 to 5.94)	2.65 (2.49 to 2.81)
Strain (B79):Day 1 (n=256,261,89,83,88,89,91)	3.87 (3.61 to 4.14)	3.87 (3.66 to 4.09)	3.82 (3.49 to 4.17)	4.16 (3.47 to 4.99)
Strain (B79):Day211(n=263,267,88,76,90,88,	209 (168 to 260)	267 (222 to 322)	584 (444 to 769)	7.79 (5.78 to 10.5)

End point values	Adolescents - Group 5: MenQuadfi	Adolescents - Group 6: Sanofi MenB	Adolescents - Group 7: PENBRAYA	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	91	89	94	
Units: titer				
geometric mean (confidence interval 95%)				
Strain (A56): Day 1 (n=258,266,89,83,90,89,94)	4.95 (4.57 to 5.36)	4.99 (4.54 to 5.48)	4.67 (4.46 to 4.89)	
Strain (A56):Day211(n=262,266,87,85,91,87,	5.18 (4.64 to 5.78)	19.6 (13.9 to 27.6)	119 (94.8 to 149)	
Strain (B44): Day 1 (n=259,264,89,83,90,87,91)	9.50 (7.20 to 12.6)	8.54 (6.69 to 10.9)	10.7 (8.03 to 14.2)	
Strain (B44): Day 211 (n=260,267,87,84,89,88,94)	9.90 (7.44 to 13.2)	78.0 (58.6 to 104)	111 (93.7 to 132)	
Strain (A10): Day 1 (n=257,266,88,84,90,88,92)	2.88 (2.49 to 3.35)	2.77 (2.47 to 3.10)	2.68 (2.49 to 2.89)	
Strain (A10):Day211(n=262,263,85,85,90,86,	2.87 (2.51 to 3.29)	25.5 (18.6 to 34.9)	2.56 (2.48 to 2.64)	
Strain (B79):Day 1 (n=256,261,89,83,88,89,91)	3.94 (3.55 to 4.38)	3.98 (3.55 to 4.45)	4.27 (3.67 to 4.97)	
Strain (B79):Day211(n=263,267,88,76,90,88,	4.30 (3.73 to 4.95)	516 (371 to 717)	6.84 (5.29 to 8.83)	

Statistical analyses

Primary: Adolescents Only: Percentage of Participants With Human Complement Serum Bactericidal Assay Titer $\geq$ Lower Limit of Quantification Against Reference Strains of Meningococcal Serogroup B at Days 1 and 211

End point title	Adolescents Only: Percentage of Participants With Human Complement Serum Bactericidal Assay Titer $\geq$ Lower Limit of Quantification Against Reference Strains of Meningococcal Serogroup B at Days 1 and 211 ^[23] ^[24]
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End point description:

The percentage of participants with antibody titers $\geq$ LLOQ against the reference strains of the meningococcal serogroup B was measured by hSBA. The 95% CI for the single percentage was based on the Clopper-Pearson method. The FAS2 – adolescents included participants who were vaccinated per protocol at Day 181 and had 1 valid post-vaccination blood sample at Day 211. The percentages are rounded off to the tenth decimal place. Here, n = Number of participants analyzed for each serogroup at specific timepoints.

End point type	Primary
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End point timeframe:

Pre-vaccination on Day 1 and 1 month after the second vaccination (Day 211)

Notes:

[23] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: As the endpoint is descriptive in nature, no statistical analysis is provided.

[24] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As specified in the endpoint title, only adolescent participants were included in the analysis for this endpoint.

End point values	Adolescents - Group 1: MenPenta Formulation 1	Adolescents - Group 2: MenPenta Formulation 2	Adolescents - Group 3: Bexsero + Menveo	Adolescents - Group 4: Trumenba + Menveo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	263	267	89	85
Units: percentage of participants				
number (confidence interval 95%)				
Strain (A56): Day 1 (n=258,266,89,83,90,89,94)	5.0 (2.7 to 8.5)	6.0 (3.5 to 9.6)	3.4 (0.7 to 9.5)	4.8 (1.3 to 11.9)
Strain (A56):Day211(n=262,266,87,85,91,87,	57.6 (51.4 to 63.7)	66.2 (60.1 to 71.8)	41.4 (30.9 to 52.4)	96.5 (90.0 to 99.3)
Strain (B44): Day 1 (n=259,264,89,83,90,87,91)	73.7 (67.9 to 79.0)	73.1 (67.3 to 78.4)	68.5 (57.8 to 78.0)	73.5 (62.7 to 82.6)
Strain (B44): Day 211 (n=260,267,87,84,89,88,94)	97.3 (94.5 to 98.9)	99.6 (97.9 to 100)	100 (95.8 to 100)	100 (95.7 to 100)
Strain (A10): Day 1 (n=257,266,88,84,90,88,92)	1.9 (0.6 to 4.5)	4.5 (2.4 to 7.7)	3.4 (0.7 to 9.6)	2.4 (0.3 to 8.3)
Strain (A10):Day211(n=262,263,85,85,90,86,	72.5 (66.7 to 77.8)	80.6 (75.3 to 85.2)	24.7 (16.0 to 35.3)	4.7 (1.3 to 11.6)
Strain (B79): Day 1 (n=256,261,89,83,88,89,91)	4.3 (2.2 to 7.6)	5.7 (3.3 to 9.3)	4.5 (1.2 to 11.1)	7.2 (2.7 to 15.1)
Strain (B79):Day211(n=263,267,88,76,90,88,	93.5 (89.9 to 96.2)	97.8 (95.2 to 99.2)	97.7 (92.0 to 99.7)	34.2 (23.7 to 46.0)

End point values	Adolescents - Group 5: MenQuadfi	Adolescents - Group 6: Sanofi MenB	Adolescents - Group 7: PENBRAYA	
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Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	91	89	94	
Units: percentage of participants				
number (confidence interval 95%)				
Strain (A56): Day 1 (n=258,266,89,83,90,89,94)	6.7 (2.5 to 13.9)	6.7 (2.5 to 14.1)	3.2 (0.7 to 9.0)	
Strain (A56):Day211(n=262,266,87,85,91,87,	7.7 (3.1 to 15.2)	54.0 (43.0 to 64.8)	98.9 (94.2 to 100)	
Strain (B44): Day 1 (n=259,264,89,83,90,87,91)	73.3 (63.0 to 82.1)	75.9 (65.5 to 84.4)	71.4 (61.0 to 80.4)	
Strain (B44): Day 211 (n=260,267,87,84,89,88,94)	73.0 (62.6 to 81.9)	98.9 (93.8 to 100)	100 (96.2 to 100)	
Strain (A10): Day 1 (n=257,266,88,84,90,88,92)	5.6 (1.8 to 12.5)	4.5 (1.3 to 11.2)	4.3 (1.2 to 10.8)	
Strain (A10):Day211(n=262,263,85,85,90,86,	5.6 (1.8 to 12.5)	86.0 (76.9 to 92.6)	2.2 (0.3 to 7.6)	
Strain (B79): Day 1 (n=256,261,89,83,88,89,91)	6.8 (2.5 to 14.3)	6.7 (2.5 to 14.1)	8.8 (3.9 to 16.6)	
Strain (B79):Day211(n=263,267,88,76,90,88,	10.0 (4.7 to 18.1)	98.9 (93.8 to 100)	29.8 (20.3 to 40.7)	

Statistical analyses

No statistical analyses for this end point

Secondary: Adolescents Only: Percentage of Participants With Seroresponse Against Meningococcal Serogroups A, C, W and Y Strains at Days 31 and 181

End point title	Adolescents Only: Percentage of Participants With Seroresponse Against Meningococcal Serogroups A, C, W and Y Strains at Days 31 and 181 ^[25]
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End point description:

The seroresponse was defined as post-vaccination titers $\geq 1:16$ for participants with pre-vaccination hSBA titers $< 1:4$, or post-vaccination titers ≥ 4 times the pre-vaccination titer for participants with a pre-vaccination titer $\geq$ the LLOQ. The LLOQ was a titer of 1:4, and it is the same as the LOD for the meningococcal serogroups A, C, W and Y hSBA assay. Day 31: FAS1 – adolescents included participants who were vaccinated per protocol at Day 1 and had 1 valid post-vaccination blood sample at Day 31. Day 181: FAS2 – adolescents included participants who were vaccinated per protocol at Day 181 and had 1 valid post-vaccination blood sample at Day 211. The percentages are rounded off to the tenth decimal place. Here, n= Number of participants analyzed for each serogroup at specific timepoints; and -99999 and 99999= No participants analyzed at specific timepoints.

End point type	Secondary
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End point timeframe:

One month after the first vaccination (Day 31) and pre-vaccination on Day 181

Notes:

[25] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As specified in the endpoint title, only adolescent participants were included in the analysis for this endpoint.

End point values	Adolescents - Group 1: MenPenta Formulation 1	Adolescents - Group 2: MenPenta Formulation 2	Adolescents - Group 3: Bexsero + Menveo	Adolescents - Group 4: Trumenba + Menveo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	91	81	40	32
Units: percentage of participants				
number (confidence interval 95%)				
Serogroup A: Day 31 (n=35,47,11,6,18,13,0)	100 (90.0 to 100)	93.6 (82.5 to 98.7)	72.7 (39.0 to 94.0)	66.7 (22.3 to 95.7)
Serogroup A: Day 181 (n=0,0,0,0,0,1,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Serogroup C: Day 31 (n=91,81,40,32,31,57,15)	91.2 (83.4 to 96.1)	95.1 (87.8 to 98.6)	85.0 (70.2 to 94.3)	68.8 (50.0 to 83.9)
Serogroup C: Day 181 (n=0,0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Serogroup W: Day 31 (n=34,42,13,5,13,15,0)	91.2 (76.3 to 98.1)	92.9 (80.5 to 98.5)	100 (75.3 to 100)	60.0 (14.7 to 94.7)
Serogroup W: Day 181 (n=0,0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Serogroup Y: Day 31 (n=43,45,21,14,12,22,0)	93.0 (80.9 to 98.5)	97.8 (88.2 to 99.9)	85.7 (63.7 to 97.0)	92.9 (66.1 to 99.8)
Serogroup Y: Day 181 (n=0,0,0,0,0,1,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)

End point values	Adolescents - Group 5: MenQuadfi	Adolescents - Group 6: Sanofi MenB	Adolescents - Group 7: PENBRAYA	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	31	57	15	
Units: percentage of participants				
number (confidence interval 95%)				
Serogroup A: Day 31 (n=35,47,11,6,18,13,0)	50.0 (26.0 to 74.0)	100 (75.3 to 100)	99999 (-99999 to 99999)	
Serogroup A: Day 181 (n=0,0,0,0,0,1,0)	99999 (-99999 to 99999)	100 (2.5 to 100)	99999 (-99999 to 99999)	
Serogroup C: Day 31 (n=91,81,40,32,31,57,15)	96.8 (83.3 to 99.9)	50.9 (37.3 to 64.4)	60.0 (32.3 to 83.7)	
Serogroup C: Day 181 (n=0,0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	
Serogroup W: Day 31 (n=34,42,13,5,13,15,0)	92.3 (64.0 to 99.8)	13.3 (1.7 to 40.5)	99999 (-99999 to 99999)	
Serogroup W: Day 181 (n=0,0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	
Serogroup Y: Day 31 (n=43,45,21,14,12,22,0)	91.7 (61.5 to 99.8)	9.1 (1.1 to 29.2)	99999 (-99999 to 99999)	
Serogroup Y: Day 181 (n=0,0,0,0,0,1,0)	99999 (-99999 to 99999)	0 (0 to 97.5)	99999 (-99999 to 99999)	

Statistical analyses

No statistical analyses for this end point

Secondary: Adolescents Only: Percentage of Participants With Human Complement Serum Bactericidal Assay Titer $\geq 1:8$ Against Meningococcal Serogroups A, C, W and Y Strains at Days 31 and 181

End point title	Adolescents Only: Percentage of Participants With Human Complement Serum Bactericidal Assay Titer $\geq 1:8$ Against Meningococcal Serogroups A, C, W and Y Strains at Days 31 and 181 ^[26]
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End point description:

The percentage of participants with antibody titers $\geq 1:8$ against meningococcal serogroups A, C, W and Y was measured by hSBA. The 95% CI for the single percentage was based on the Clopper-Pearson method. Day 31: FAS1 – adolescents included participants who were vaccinated per protocol at Day 1 and had 1 valid post-vaccination blood sample at Day 31. Day 181: FAS2 – adolescents included participants who were vaccinated per protocol at Day 181 and had 1 valid post-vaccination blood sample at Day 211. The percentages are rounded off to the tenth decimal place. Here, n= Number of participants analyzed for each serogroup at specific timepoints; and -99999 and 99999= No participants analyzed at specific timepoints.

End point type	Secondary
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End point timeframe:

One month after the first vaccination (Day 31) and pre-vaccination on Day 181

Notes:

[26] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As specified in the endpoint title, only adolescent participants were included in the analysis for this endpoint.

End point values	Adolescents - Group 1: MenPenta Formulation 1	Adolescents - Group 2: MenPenta Formulation 2	Adolescents - Group 3: Bexsero + Menveo	Adolescents - Group 4: Trumenba + Menveo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	93	81	42	33
Units: percentage of participants				
number (confidence interval 95%)				
Serogroup A: Day 31 (n=39,50,12,9,19,14,0)	100 (91.0 to 100)	100 (92.9 to 100)	75.0 (42.8 to 94.5)	88.9 (51.8 to 99.7)
Serogroup A: Day 181 (n=0,0,0,0,0,1,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Serogroup C: Day 31 (n=93,81,42,33,33,59,15)	97.8 (92.4 to 99.7)	97.5 (91.4 to 99.7)	90.5 (77.4 to 97.3)	81.8 (64.5 to 93.0)
Serogroup C: Day 181 (n=0,0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Serogroup W: Day 31 (n=40,50,15,5,16,16,0)	100 (91.2 to 100)	100 (92.9 to 100)	100 (78.2 to 100)	100 (47.8 to 100)
Serogroup W: Day 181 (n=0,0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Serogroup Y: Day 31 (n=50,52,23,15,17,25,0)	96.0 (86.3 to 99.5)	100 (93.2 to 100)	100 (85.2 to 100)	100 (78.2 to 100)
Serogroup Y: Day 181 (n=0,0,0,0,0,1,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)

End point values	Adolescents - Group 5: MenQuadfi	Adolescents - Group 6: Sanofi MenB	Adolescents - Group 7: PENBRAYA	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	33	59	15	
Units: percentage of participants				

number (confidence interval 95%)				
Serogroup A: Day 31 (n=39,50,12,9,19,14,0)	84.2 (60.4 to 96.6)	100 (76.8 to 100)	99999 (-99999 to 99999)	
Serogroup A: Day 181 (n=0,0,0,0,0,1,0)	99999 (-99999 to 99999)	100 (2.5 to 100)	99999 (-99999 to 99999)	
Serogroup C: Day 31 (n=93,81,42,33,33,59,15)	100 (89.4 to 100)	81.4 (69.1 to 90.3)	86.7 (59.5 to 98.3)	
Serogroup C: Day 181 (n=0,0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	
Serogroup W: Day 31 (n=40,50,15,5,16,16,0)	100 (79.4 to 100)	56.3 (29.9 to 80.2)	99999 (-99999 to 99999)	
Serogroup W: Day 181 (n=0,0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	
Serogroup Y: Day 31 (n=50,52,23,15,17,25,0)	94.1 (71.3 to 99.9)	32.0 (14.9 to 53.5)	99999 (-99999 to 99999)	
Serogroup Y: Day 181 (n=0,0,0,0,0,1,0)	99999 (-99999 to 99999)	0 (0 to 97.5)	99999 (-99999 to 99999)	

Statistical analyses

No statistical analyses for this end point

Secondary: Adolescents Only: Geometric Mean Titers of Antibodies Against Meningococcal Serogroups A, C, W and Y Strains at Days 31 and 181

End point title	Adolescents Only: Geometric Mean Titers of Antibodies Against Meningococcal Serogroups A, C, W and Y Strains at Days 31 and 181 ^[27]
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End point description:

The antibodies titer against meningococcal serogroups A, C, W and Y was measured by hSBA and the results were expressed as GMT. The 95% CI for the single percentage was based on the Clopper-Pearson method. Day 31: FAS1 – adolescents included participants who were vaccinated per protocol at Day 1 and had 1 valid post-vaccination blood sample at Day 31. Day 181: FAS2 – adolescents included participants who were vaccinated per protocol at Day 181 and had 1 valid post-vaccination blood sample at Day 211. Here, n= Number of participants analyzed for each serogroup at specific timepoints; -9999 and 9999= The 95% CI was not computed, if number analyzed was <=5 or standard deviation was 0; and -99999 and 99999= No participants analyzed at specific timepoints.

End point type	Secondary
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End point timeframe:

One month after the first vaccination (Day 31) and pre-vaccination on Day 181

Notes:

[27] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As specified in the endpoint title, only adolescent participants were included in the analysis for this endpoint.

End point values	Adolescents - Group 1: MenPenta Formulation 1	Adolescents - Group 2: MenPenta Formulation 2	Adolescents - Group 3: Bexsero + Menveo	Adolescents - Group 4: Trumenba + Menveo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	93	81	42	33
Units: titer				
geometric mean (confidence interval 95%)				
Serogroup A: Day 31 (n=39,50,12,9,19,14,0)	189 (134 to 268)	246 (170 to 354)	71.8 (16.6 to 311)	110 (18.8 to 639)

Serogroup A: Day 181 (n=0,0,0,0,0,1,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Serogroup C: Day 31 (n=93,81,42,33,33,59,15)	231 (174 to 306)	301 (227 to 400)	141 (77.8 to 257)	60.1 (29.2 to 124)
Serogroup C: Day 181 (n=0,0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Serogroup W: Day 31 (n=40,50,15,5,16,16,0)	122 (79.0 to 187)	143 (100 to 204)	70.2 (34.6 to 143)	73.5 (-9999 to 9999)
Serogroup W: Day 181 (n=0,0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Serogroup Y: Day 31 (n=50,52,23,15,17,25,0)	95.7 (63.4 to 144)	158 (111 to 225)	51.8 (26.9 to 99.7)	77.0 (30.9 to 192)
Serogroup Y: Day 181 (n=0,0,0,0,0,1,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)

End point values	Adolescents - Group 5: MenQuadfi	Adolescents - Group 6: Sanofi MenB	Adolescents - Group 7: PENBRAYA	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	33	59	15	
Units: titer				
geometric mean (confidence interval 95%)				
Serogroup A: Day 31 (n=39,50,12,9,19,14,0)	46.1 (17.8 to 120)	164 (93.9 to 286)	99999 (-99999 to 99999)	
Serogroup A: Day 181 (n=0,0,0,0,0,1,0)	99999 (-99999 to 99999)	32.0 (-9999 to 9999)	99999 (-99999 to 99999)	
Serogroup C: Day 31 (n=93,81,42,33,33,59,15)	273 (183 to 407)	30.9 (19.4 to 49.3)	92.6 (32.3 to 266)	
Serogroup C: Day 181 (n=0,0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	
Serogroup W: Day 31 (n=40,50,15,5,16,16,0)	76.1 (46.4 to 125)	7.03 (3.67 to 13.5)	99999 (-99999 to 99999)	
Serogroup W: Day 181 (n=0,0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	
Serogroup Y: Day 31 (n=50,52,23,15,17,25,0)	81.7 (36.5 to 183)	5.43 (2.83 to 10.4)	99999 (-99999 to 99999)	
Serogroup Y: Day 181 (n=0,0,0,0,0,1,0)	99999 (-99999 to 99999)	2.00 (-9999 to 9999)	99999 (-99999 to 99999)	

Statistical analyses

No statistical analyses for this end point

Secondary: Adolescents Only: Percentage of Participants With Human Complement Serum Bactericidal Assay Titer $\geq$ Lower Limit of Quantification Against Meningococcal Serogroups A, C, W and Y Strains at Days 31 and 181

End point title	Adolescents Only: Percentage of Participants With Human Complement Serum Bactericidal Assay Titer $\geq$ Lower Limit of Quantification Against Meningococcal Serogroups A, C, W and Y Strains at Days 31 and 181 ^[28]
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End point description:

The percentage of participants with antibody titers $\geq$ LLOQ against meningococcal serogroups A, C, W and Y was measured by hSBA. The LLOQ was a titer of 1:4, and it is the same as the LOD for the

meningococcal serogroups A, C, W and Y hSBA assay. The 95% CI for the single percentage was based on the Clopper-Pearson method. Day 31: FAS1 – adolescents included participants who were vaccinated per protocol at Day 1 and had 1 valid post-vaccination blood sample at Day 31. Day 181: FAS2 – adolescents included participants who were vaccinated per protocol at Day 181 and had 1 valid post-vaccination blood sample at Day 211. The percentages are rounded off to the tenth decimal place. Here, n= Number of participants analyzed for each serogroup at specific timepoints; and -99999 and 99999= No participants analyzed at specific timepoints.

End point type	Secondary
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End point timeframe:

One month after the first vaccination (Day 31) and pre-vaccination on Day 181

Notes:

[28] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As specified in the endpoint title, only adolescent participants were included in the analysis for this endpoint.

End point values	Adolescents - Group 1: MenPenta Formulation 1	Adolescents - Group 2: MenPenta Formulation 2	Adolescents - Group 3: Bexsero + Menveo	Adolescents - Group 4: Trumenba + Menveo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	93	81	42	33
Units: percentage of participants				
number (confidence interval 95%)				
Serogroup A: Day 31 (n=39,50,12,9,19,14,0)	100 (91.0 to 100)	100 (92.9 to 100)	83.3 (51.6 to 97.9)	88.9 (51.8 to 99.7)
Serogroup A: Day 181 (n=0,0,0,0,0,1,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Serogroup C: Day 31 (n=93,81,42,33,33,59,15)	98.9 (94.2 to 100)	98.8 (93.3 to 100)	92.9 (80.5 to 98.5)	93.9 (79.8 to 99.3)
Serogroup C: Day 181 (n=0,0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Serogroup W: Day 31 (n=40,50,15,5,16,16,0)	100 (91.2 to 100)	100 (92.9 to 100)	100 (78.2 to 100)	100 (47.8 to 100)
Serogroup W: Day 181 (n=0,0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Serogroup Y: Day 31 (n=50,52,23,15,17,25,0)	96.0 (86.3 to 99.5)	100 (93.2 to 100)	100 (85.2 to 100)	100 (78.2 to 100)
Serogroup Y: Day 181 (n=0,0,0,0,0,1,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)

End point values	Adolescents - Group 5: MenQuadfi	Adolescents - Group 6: Sanofi MenB	Adolescents - Group 7: PENBRAYA	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	33	59	15	
Units: percentage of participants				
number (confidence interval 95%)				
Serogroup A: Day 31 (n=39,50,12,9,19,14,0)	84.2 (60.4 to 96.6)	100 (76.8 to 100)	99999 (-99999 to 99999)	
Serogroup A: Day 181 (n=0,0,0,0,0,1,0)	99999 (-99999 to 99999)	100 (2.5 to 100)	99999 (-99999 to 99999)	
Serogroup C: Day 31 (n=93,81,42,33,33,59,15)	100 (89.4 to 100)	89.8 (79.2 to 96.2)	100 (78.2 to 100)	
Serogroup C: Day 181 (n=0,0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	

Serogroup W: Day 31 (n=40,50,15,5,16,16,0)	100 (79.4 to 100)	56.3 (29.9 to 80.2)	99999 (-99999 to 99999)	
Serogroup W: Day 181 (n=0,0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	
Serogroup Y: Day 31 (n=50,52,23,15,17,25,0)	100 (80.5 to 100)	36.0 (18.0 to 57.5)	99999 (-99999 to 99999)	
Serogroup Y: Day 181 (n=0,0,0,0,0,1,0)	99999 (-99999 to 99999)	0 (0 to 97.5)	99999 (-99999 to 99999)	

Statistical analyses

No statistical analyses for this end point

Secondary: Adolescents Only: Percentage of Participants With Seroresponse Against Reference Strains of Meningococcal Serogroup B at Days 31 and 181

End point title	Adolescents Only: Percentage of Participants With Seroresponse Against Reference Strains of Meningococcal Serogroup B at Days 31 and 181 ^[29]
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End point description:

The seroresponse was defined as a 4-fold increase in hSBA titers from pre-vaccination to post-vaccination. The seroresponse against reference strains of meningococcal serogroup B at Days 31 and 181 was not applicable. Therefore, no data collected and analyzed.

End point type	Secondary
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End point timeframe:

One month after the first vaccination (Day 31) and pre-vaccination on Day 181

Notes:

[29] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As specified in the endpoint title, only adolescent participants were included in the analysis for this endpoint.

End point values	Adolescents - Group 1: MenPenta Formulation 1	Adolescents - Group 2: MenPenta Formulation 2	Adolescents - Group 3: Bexsero + Menveo	Adolescents - Group 4: Trumenba + Menveo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[30]	0 ^[31]	0 ^[32]	0 ^[33]
Units: percentage of participants				
number (confidence interval 95%)				
Strain (A56): Day 31	(to)	(to)	(to)	(to)
Strain (A56): Day 181	(to)	(to)	(to)	(to)
Strain (B44): Day 31	(to)	(to)	(to)	(to)
Strain (B44): Day 181	(to)	(to)	(to)	(to)
Strain (A10): Day 31	(to)	(to)	(to)	(to)
Strain (A10): Day 181	(to)	(to)	(to)	(to)
Strain (B79): Day 31	(to)	(to)	(to)	(to)
Strain (B79): Day 181	(to)	(to)	(to)	(to)

Notes:

[30] - No participants analyzed; seroresponse to strains of meningococcal serogroup B was not applicable.

[31] - No participants analyzed; seroresponse to strains of meningococcal serogroup B was not applicable.

[32] - No participants analyzed; seroresponse to strains of meningococcal serogroup B was not applicable.

applicable.

[33] - No participants analyzed; seroresponse to strains of meningococcal serogroup B was not applicable.

End point values	Adolescents - Group 5: MenQuadfi	Adolescents - Group 6: Sanofi MenB	Adolescents - Group 7: PENBRAYA	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0 ^[34]	0 ^[35]	0 ^[36]	
Units: percentage of participants				
number (confidence interval 95%)				
Strain (A56): Day 31	(to)	(to)	(to)	
Strain (A56): Day 181	(to)	(to)	(to)	
Strain (B44): Day 31	(to)	(to)	(to)	
Strain (B44): Day 181	(to)	(to)	(to)	
Strain (A10): Day 31	(to)	(to)	(to)	
Strain (A10): Day 181	(to)	(to)	(to)	
Strain (B79): Day 31	(to)	(to)	(to)	
Strain (B79): Day 181	(to)	(to)	(to)	

Notes:

[34] - No participants analyzed; seroresponse to strains of meningococcal serogroup B was not applicable.

[35] - No participants analyzed; seroresponse to strains of meningococcal serogroup B was not applicable.

[36] - No participants analyzed; seroresponse to strains of meningococcal serogroup B was not applicable.

Statistical analyses

No statistical analyses for this end point

Secondary: Adolescents Only: Percentage of Participants With Human Complement Serum Bactericidal Assay Titer $\geq 1:4$ and $\geq 1:8$ Against Reference Strains of Meningococcal Serogroup B at Days 31 and 181

End point title	Adolescents Only: Percentage of Participants With Human Complement Serum Bactericidal Assay Titer $\geq 1:4$ and $\geq 1:8$ Against Reference Strains of Meningococcal Serogroup B at Days 31 and 181 ^[37]
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End point description:

The percentage of participants with antibody titers $\geq 1:4$ and $\geq 1:8$ against the reference strains of the meningococcal serogroup B was measured by hSBA. The 95% CI for the single percentage was based on the Clopper-Pearson method. The antibodies titer against reference strains of meningococcal serogroup B at Days 31 and 181 was not applicable. Therefore, no data collected and analyzed.

End point type	Secondary
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End point timeframe:

One month after the first vaccination (Day 31) and pre-vaccination on Day 181

Notes:

[37] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As specified in the endpoint title, only adolescent participants were included in the analysis for this endpoint.

End point values	Adolescents - Group 1: MenPenta Formulation 1	Adolescents - Group 2: MenPenta Formulation 2	Adolescents - Group 3: Bexsero + Menveo	Adolescents - Group 4: Trumenba + Menveo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[38]	0 ^[39]	0 ^[40]	0 ^[41]
Units: percentage of participants				
number (confidence interval 95%)				
Strain (A56): Day 31, >= 1:4	(to)	(to)	(to)	(to)
Strain (A56): Day 31, >= 1:8	(to)	(to)	(to)	(to)
Strain (A56): Day 181, >= 1:4	(to)	(to)	(to)	(to)
Strain (A56): Day 181, >= 1:8	(to)	(to)	(to)	(to)
Strain (B44): Day 31, >= 1:4	(to)	(to)	(to)	(to)
Strain (B44): Day 31, >= 1:8	(to)	(to)	(to)	(to)
Strain (B44): Day 181, >= 1:4	(to)	(to)	(to)	(to)
Strain (B44): Day 181, >= 1:8	(to)	(to)	(to)	(to)
Strain (A10): Day 31, >= 1:4	(to)	(to)	(to)	(to)
Strain (A10): Day 31, >= 1:8	(to)	(to)	(to)	(to)
Strain (A10): Day 181, >= 1:4	(to)	(to)	(to)	(to)
Strain (A10): Day 181, >= 1:8	(to)	(to)	(to)	(to)
Strain (B79): Day 31, >= 1:4	(to)	(to)	(to)	(to)
Strain (B79): Day 31, >= 1:8	(to)	(to)	(to)	(to)
Strain (B79): Day 181, >= 1:4	(to)	(to)	(to)	(to)
Strain (B79): Day 181, >= 1:8	(to)	(to)	(to)	(to)

Notes:

[38] - No participants analyzed;antibodies titer to strains of meningococcal serogroupB was not applicable.

[39] - No participants analyzed;antibodies titer to strains of meningococcal serogroupB was not applicable.

[40] - No participants analyzed;antibodies titer to strains of meningococcal serogroupB was not applicable.

[41] - No participants analyzed;antibodies titer to strains of meningococcal serogroupB was not applicable.

End point values	Adolescents - Group 5: MenQuadfi	Adolescents - Group 6: Sanofi MenB	Adolescents - Group 7: PENBRAYA	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0 ^[42]	0 ^[43]	0 ^[44]	
Units: percentage of participants				
number (confidence interval 95%)				
Strain (A56): Day 31, >= 1:4	(to)	(to)	(to)	
Strain (A56): Day 31, >= 1:8	(to)	(to)	(to)	
Strain (A56): Day 181, >= 1:4	(to)	(to)	(to)	
Strain (A56): Day 181, >= 1:8	(to)	(to)	(to)	
Strain (B44): Day 31, >= 1:4	(to)	(to)	(to)	
Strain (B44): Day 31, >= 1:8	(to)	(to)	(to)	
Strain (B44): Day 181, >= 1:4	(to)	(to)	(to)	
Strain (B44): Day 181, >= 1:8	(to)	(to)	(to)	
Strain (A10): Day 31, >= 1:4	(to)	(to)	(to)	
Strain (A10): Day 31, >= 1:8	(to)	(to)	(to)	
Strain (A10): Day 181, >= 1:4	(to)	(to)	(to)	
Strain (A10): Day 181, >= 1:8	(to)	(to)	(to)	
Strain (B79): Day 31, >= 1:4	(to)	(to)	(to)	
Strain (B79): Day 31, >= 1:8	(to)	(to)	(to)	

Strain (B79): Day 181, >= 1:4	(to)	(to)	(to)	
Strain (B79): Day 181, >= 1:8	(to)	(to)	(to)	

Notes:

[42] - No participants analyzed;antibodies titer to strains of meningococcal serogroupB was not applicable.

[43] - No participants analyzed;antibodies titer to strains of meningococcal serogroupB was not applicable.

[44] - No participants analyzed;antibodies titer to strains of meningococcal serogroupB was not applicable.

Statistical analyses

No statistical analyses for this end point

Secondary: Adolescents Only: Geometric Mean Titers of Antibodies Against Reference Strains of Meningococcal Serogroup B at Days 31 and 181

End point title	Adolescents Only: Geometric Mean Titers of Antibodies Against Reference Strains of Meningococcal Serogroup B at Days 31 and 181 ^[45]
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End point description:

The antibodies titer against the reference strains of the meningococcal serogroup B was measured by hSBA and the results were expressed as GMT. The 95% CI for the single percentage was based on the Clopper-Pearson method. The antibodies titer against reference strains of meningococcal serogroup B at Days 31 and 181 was not applicable. Therefore, no data collected and analyzed.

End point type	Secondary
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End point timeframe:

One month after the first vaccination (Day 31) and pre-vaccination on Day 181

Notes:

[45] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As specified in the endpoint title, only adolescent participants were included in the analysis for this endpoint.

End point values	Adolescents - Group 1: MenPenta Formulation 1	Adolescents - Group 2: MenPenta Formulation 2	Adolescents - Group 3: Bexsero + Menveo	Adolescents - Group 4: Trumenba + Menveo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[46]	0 ^[47]	0 ^[48]	0 ^[49]
Units: titer				
geometric mean (confidence interval 95%)				
Strain (A56): Day 31	(to)	(to)	(to)	(to)
Strain (A56): Day 181	(to)	(to)	(to)	(to)
Strain (B44): Day 31	(to)	(to)	(to)	(to)
Strain (B44): Day 181	(to)	(to)	(to)	(to)
Strain (A10): Day 31	(to)	(to)	(to)	(to)
Strain (A10): Day 181	(to)	(to)	(to)	(to)
Strain (B79): Day 31	(to)	(to)	(to)	(to)
Strain (B79): Day 181	(to)	(to)	(to)	(to)

Notes:

[46] - No participants analyzed;antibodies titer to strains of meningococcal serogroupB was not applicable.

[47] - No participants analyzed;antibodies titer to strains of meningococcal serogroupB was not applicable.

[48] - No participants analyzed;antibodies titer to strains of meningococcal serogroupB was not applicable.

[49] - No participants analyzed;antibodies titer to strains of meningococcal serogroupB was not applicable.

End point values	Adolescents - Group 5: MenQuadfi	Adolescents - Group 6: Sanofi MenB	Adolescents - Group 7: PENBRAYA	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0 ^[50]	0 ^[51]	0 ^[52]	
Units: titer				
geometric mean (confidence interval 95%)				
Strain (A56): Day 31	(to)	(to)	(to)	
Strain (A56): Day 181	(to)	(to)	(to)	
Strain (B44): Day 31	(to)	(to)	(to)	
Strain (B44): Day 181	(to)	(to)	(to)	
Strain (A10): Day 31	(to)	(to)	(to)	
Strain (A10): Day 181	(to)	(to)	(to)	
Strain (B79): Day 31	(to)	(to)	(to)	
Strain (B79): Day 181	(to)	(to)	(to)	

Notes:

[50] - No participants analyzed;antibodies titer to strains of meningococcal serogroupB was not applicable.

[51] - No participants analyzed;antibodies titer to strains of meningococcal serogroupB was not applicable.

[52] - No participants analyzed;antibodies titer to strains of meningococcal serogroupB was not applicable.

Statistical analyses

No statistical analyses for this end point

Secondary: Adolescents Only: Percentage of Participants With Human Complement Serum Bactericidal Assay Titer $\geq$ Lower Limit of Quantification Against Reference Strains of Meningococcal Serogroup B at Days 31 and 181

End point title	Adolescents Only: Percentage of Participants With Human Complement Serum Bactericidal Assay Titer $\geq$ Lower Limit of Quantification Against Reference Strains of Meningococcal Serogroup B at Days 31 and 181 ^[53]
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End point description:

The percentage of participants with antibody titers $\geq$ LLOQ against the reference strains of the meningococcal serogroup B was measured by hSBA. The 95% CI for the single percentage was based on the Clopper-Pearson method. The antibodies titer against reference strains of meningococcal serogroup B at Days 31 and 181 was not applicable. Therefore, no data collected and analyzed.

End point type	Secondary
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End point timeframe:

One month after the first vaccination (Day 31) and pre-vaccination on Day 181

Notes:

[53] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As specified in the endpoint title, only adolescent participants were included in the analysis for this endpoint.

End point values	Adolescents - Group 1: MenPenta Formulation 1	Adolescents - Group 2: MenPenta Formulation 2	Adolescents - Group 3: Bexsero + Menveo	Adolescents - Group 4: Trumenba + Menveo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[54]	0 ^[55]	0 ^[56]	0 ^[57]
Units: percentage of participants				
number (confidence interval 95%)				
Strain (A56): Day 31	(to)	(to)	(to)	(to)
Strain (A56): Day 181	(to)	(to)	(to)	(to)
Strain (B44): Day 31	(to)	(to)	(to)	(to)
Strain (B44): Day 181	(to)	(to)	(to)	(to)
Strain (A10): Day 31	(to)	(to)	(to)	(to)
Strain (A10): Day 181	(to)	(to)	(to)	(to)
Strain (B79): Day 31	(to)	(to)	(to)	(to)
Strain (B79): Day 181	(to)	(to)	(to)	(to)

Notes:

[54] - No participants analyzed;antibodies titer to strains of meningococcal serogroupB was not applicable.

[55] - No participants analyzed;antibodies titer to strains of meningococcal serogroupB was not applicable.

[56] - No participants analyzed;antibodies titer to strains of meningococcal serogroupB was not applicable.

[57] - No participants analyzed;antibodies titer to strains of meningococcal serogroupB was not applicable.

End point values	Adolescents - Group 5: MenQuadfi	Adolescents - Group 6: Sanofi MenB	Adolescents - Group 7: PENBRAYA	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0 ^[58]	0 ^[59]	0 ^[60]	
Units: percentage of participants				
number (confidence interval 95%)				
Strain (A56): Day 31	(to)	(to)	(to)	
Strain (A56): Day 181	(to)	(to)	(to)	
Strain (B44): Day 31	(to)	(to)	(to)	
Strain (B44): Day 181	(to)	(to)	(to)	
Strain (A10): Day 31	(to)	(to)	(to)	
Strain (A10): Day 181	(to)	(to)	(to)	
Strain (B79): Day 31	(to)	(to)	(to)	
Strain (B79): Day 181	(to)	(to)	(to)	

Notes:

[58] - No participants analyzed;antibodies titer to strains of meningococcal serogroupB was not applicable.

[59] - No participants analyzed;antibodies titer to strains of meningococcal serogroupB was not applicable.

[60] - No participants analyzed;antibodies titer to strains of meningococcal serogroupB was not applicable.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Seroresponse Against Reference and Additional Strains of Meningococcal Serogroup B at Days 61 and 211

End point title	Percentage of Participants With Seroresponse Against Reference and Additional Strains of Meningococcal Serogroup B
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End point description:

The seroresponse was defined as a 4-fold increase in hSBA titers from pre-vaccination to post-vaccination. FAS3 – adolescents included participants who were vaccinated per protocol at Day 181 and had 1 valid post-vaccination blood sample at Day 211, producing at least 1 result for the 19 strains of serogroup B. The percentages are rounded off to the tenth decimal place. Here, n= Number of participants analyzed for each serogroup at specific timepoints for adolescent groups; and -99999 and 99999= No participants analyzed at specific timepoints.

End point type	Secondary
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End point timeframe:

Adults: 1 month after the second and third vaccination (Day 61 and Day 211, respectively);

Adolescents: 1 month after the second vaccination (Day 211)

End point values	Adults - Group 1: MenPenta Formulation 1	Adults - Group 2: MenPenta Formulation 2	Adults - Group 3: Bexsero + Menveo	Adults - Group 4: Trumenba + Menveo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[61]	0 ^[62]	0 ^[63]	0 ^[64]
Units: percentage of participants				
number (confidence interval 95%)				
Strain (A56):Day 61(n=0,0,0,0,0,0)	(to)	(to)	(to)	(to)
Strain (A56):Day211(n=256,263,86,83,90,87,	(to)	(to)	(to)	(to)
Strain (B44): Day 61(n=0,0,0,0,0,0)	(to)	(to)	(to)	(to)
Strain (B44): Day 211(n=255,262,86,82,88,86,91)	(to)	(to)	(to)	(to)
Strain (A10): Day 61(n=0,0,0,0,0,0)	(to)	(to)	(to)	(to)
Strain (A10):Day 211(n=255,260,83,84,89,85,91)	(to)	(to)	(to)	(to)
Strain (B79): Day 61(n=0,0,0,0,0,0)	(to)	(to)	(to)	(to)
Strain (B79):Day 211(n=255,259,87,75,88,88,82)	(to)	(to)	(to)	(to)
Strain (B24): Day 61(n=0,0,0,0,0,0)	(to)	(to)	(to)	(to)
Strain (B24): Day 211(n=129,133,44,41,46,40,0)	(to)	(to)	(to)	(to)
Strain (A22): Day 61(n=0,0,0,0,0,0)	(to)	(to)	(to)	(to)
Strain (A22): Day 211(n=127,128,44,39,43,39,0)	(to)	(to)	(to)	(to)
Strain (A26): Day 61(n=0,0,0,0,0,0)	(to)	(to)	(to)	(to)
Strain (A26): Day 211(n=116,128,40,37,39,36,0)	(to)	(to)	(to)	(to)
Strain (99-A10): Day 61(n=0,0,0,0,0,0)	(to)	(to)	(to)	(to)
Strain (99-A10): Day 211(n=117,118,41,39,44,35,0)	(to)	(to)	(to)	(to)
Strain (A07): Day 61(n=0,0,0,0,0,0)	(to)	(to)	(to)	(to)
Strain (A07): Day 211(n=126,130,43,40,43,40,0)	(to)	(to)	(to)	(to)
Strain (B03): Day 61(n=0,0,0,0,0,0)	(to)	(to)	(to)	(to)
Strain (B03): Day 211(n=126,131,42,39,43,40,0)	(to)	(to)	(to)	(to)
Strain (B09): Day 61(n=0,0,0,0,0,0)	(to)	(to)	(to)	(to)
Strain (B09): Day 211(n=77,81,27,25,28,25,0)	(to)	(to)	(to)	(to)
Strain (A05): Day 61(n=0,0,0,0,0,0)	(to)	(to)	(to)	(to)

Strain (A05): Day 211(n=72,76,25,25,26,18,0)	(to)	(to)	(to)	(to)
Strain (A12): Day 61(n=0,0,0,0,0,0,0)	(to)	(to)	(to)	(to)
Strain (A12): Day 211(n=123,129,41,40,42,40,0)	(to)	(to)	(to)	(to)
Strain (A06): Day 61(n=0,0,0,0,0,0,0)	(to)	(to)	(to)	(to)
Strain (A06): Day 211(n=121,125,41,36,42,38,0)	(to)	(to)	(to)	(to)
Strain (A15): Day 61(n=0,0,0,0,0,0,0)	(to)	(to)	(to)	(to)
Strain (A15): Day 211(n=75,81,26,25,27,25,0)	(to)	(to)	(to)	(to)

Notes:

[61] - No participants analyzed; seroresponse to strains of meningococcal serogroup B was not applicable.

[62] - No participants analyzed; seroresponse to strains of meningococcal serogroup B was not applicable.

[63] - No participants analyzed; seroresponse to strains of meningococcal serogroup B was not applicable.

[64] - No participants analyzed; seroresponse to strains of meningococcal serogroup B was not applicable.

End point values	Adults - Group 5: MenQuadfi	Adults - Group 6: Sanofi MenB	Adolescents - Group 1: MenPenta Formulation 1	Adolescents - Group 2: MenPenta Formulation 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[65]	0 ^[66]	256	263
Units: percentage of participants				
number (confidence interval 95%)				
Strain (A56):Day 61(n=0,0,0,0,0,0,0)	(to)	(to)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (A56):Day211(n=256,263,86,83,90,87,	(to)	(to)	33.2 (27.5 to 39.3)	45.2 (39.1 to 51.5)
Strain (B44): Day 61(n=0,0,0,0,0,0,0)	(to)	(to)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (B44): Day 211(n=255,262,86,82,88,86,91)	(to)	(to)	55.3 (49.0 to 61.5)	65.6 (59.6 to 71.4)
Strain (A10): Day 61(n=0,0,0,0,0,0,0)	(to)	(to)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (A10):Day 211(n=255,260,83,84,89,85,91)	(to)	(to)	40.4 (34.3 to 46.7)	43.1 (37.0 to 49.3)
Strain (B79): Day 61(n=0,0,0,0,0,0,0)	(to)	(to)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (B79):Day 211(n=255,259,87,75,88,88,82)	(to)	(to)	86.3 (81.4 to 90.2)	89.2 (84.8 to 92.7)
Strain (B24): Day 61(n=0,0,0,0,0,0,0)	(to)	(to)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (B24): Day 211(n=129,133,44,41,46,40,0)	(to)	(to)	23.3 (16.3 to 31.5)	25.6 (18.4 to 33.8)
Strain (A22): Day 61(n=0,0,0,0,0,0,0)	(to)	(to)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (A22): Day 211(n=127,128,44,39,43,39,0)	(to)	(to)	28.3 (20.7 to 37.0)	31.3 (23.4 to 40.0)
Strain (A26): Day 61(n=0,0,0,0,0,0,0)	(to)	(to)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (A26): Day 211(n=116,128,40,37,39,36,0)	(to)	(to)	97.4 (92.6 to 99.5)	95.3 (90.1 to 98.3)
Strain (99-A10): Day 61(n=0,0,0,0,0,0,0)	(to)	(to)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (99-A10): Day 211(n=117,118,41,39,44,35,0)	(to)	(to)	96.6 (91.5 to 99.1)	95.8 (90.4 to 98.6)

Strain (A07): Day 61(n=0,0,0,0,0,0)	(to)	(to)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (A07): Day 211(n=126,130,43,40,43,40,0)	(to)	(to)	15.1 (9.3 to 22.5)	26.9 (19.5 to 35.4)
Strain (B03): Day 61(n=0,0,0,0,0,0,0)	(to)	(to)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (B03): Day 211(n=126,131,42,39,43,40,0)	(to)	(to)	52.4 (43.3 to 61.3)	62.6 (53.7 to 70.9)
Strain (B09): Day 61(n=0,0,0,0,0,0,0)	(to)	(to)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (B09): Day 211(n=77,81,27,25,28,25,0)	(to)	(to)	11.7 (5.5 to 21.0)	21.0 (12.7 to 31.5)
Strain (A05): Day 61(n=0,0,0,0,0,0,0)	(to)	(to)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (A05): Day 211(n=72,76,25,25,26,18,0)	(to)	(to)	36.1 (25.1 to 48.3)	42.1 (30.9 to 54.0)
Strain (A12): Day 61(n=0,0,0,0,0,0,0)	(to)	(to)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (A12): Day 211(n=123,129,41,40,42,40,0)	(to)	(to)	13.8 (8.3 to 21.2)	21.7 (14.9 to 29.8)
Strain (A06): Day 61(n=0,0,0,0,0,0,0)	(to)	(to)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (A06): Day 211(n=121,125,41,36,42,38,0)	(to)	(to)	23.1 (16.0 to 31.7)	24.8 (17.5 to 33.3)
Strain (A15): Day 61(n=0,0,0,0,0,0,0)	(to)	(to)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (A15): Day 211(n=75,81,26,25,27,25,0)	(to)	(to)	8.0 (3.0 to 16.6)	9.9 (4.4 to 18.5)

Notes:

[65] - No participants analyzed; seroresponse to strains of meningococcal serogroup B was not applicable.

[66] - No participants analyzed; seroresponse to strains of meningococcal serogroup B was not applicable.

End point values	Adolescents - Group 3: Bexsero + Menveo	Adolescents - Group 4: Trumenba + Menveo	Adolescents - Group 5: MenQuadfi	Adolescents - Group 6: Sanofi MenB
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	87	84	90	88
Units: percentage of participants				
number (confidence interval 95%)				
Strain (A56):Day 61(n=0,0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (A56):Day 211(n=256,263,86,83,90,87,0)	10.5 (4.9 to 18.9)	85.5 (76.1 to 92.3)	1.1 (0 to 6.0)	35.6 (25.6 to 46.6)
Strain (B44): Day 61(n=0,0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (B44): Day 211(n=255,262,86,82,88,86,91)	62.8 (51.7 to 73.0)	80.5 (70.3 to 88.4)	5.7 (1.9 to 12.8)	65.1 (54.1 to 75.1)
Strain (A10): Day 61(n=0,0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (A10):Day 211(n=255,260,83,84,89,85,91)	12.0 (5.9 to 21.0)	0 (0 to 4.3)	1.1 (0 to 6.1)	55.3 (44.1 to 66.1)
Strain (B79): Day 61(n=0,0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (B79):Day 211(n=255,259,87,75,88,88,82)	96.6 (90.3 to 99.3)	14.7 (7.6 to 24.7)	2.3 (0.3 to 8.0)	96.6 (90.4 to 99.3)
Strain (B24): Day 61(n=0,0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (B24): Day 211(n=129,133,44,41,46,40,0)	97.7 (88.0 to 99.9)	58.5 (42.1 to 73.7)	0 (0 to 7.7)	22.5 (10.8 to 38.5)

Strain (A22): Day 61(n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (A22): Day 211(n=127,128,44,39,43,39,0)	38.6 (24.4 to 54.5)	66.7 (49.8 to 80.9)	2.3 (0.1 to 12.3)	17.9 (7.5 to 33.5)
Strain (A26): Day 61(n=0,0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (A26): Day 211(n=116,128,40,37,39,36,0)	97.5 (86.8 to 99.9)	8.1 (1.7 to 21.9)	5.1 (0.6 to 17.3)	100 (90.3 to 100)
Strain (99-A10): Day 61(n=0,0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (99-A10): Day 211(n=117,118,41,39,44,35,0)	97.6 (87.1 to 99.9)	17.9 (7.5 to 33.5)	2.3 (0.1 to 12.0)	100 (90.0 to 100)
Strain (A07): Day 61(n=0,0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (A07): Day 211(n=126,130,43,40,43,40,0)	65.1 (49.1 to 79.0)	12.5 (4.2 to 26.8)	2.3 (0.1 to 12.3)	7.5 (1.6 to 20.4)
Strain (B03): Day 61(n=0,0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (B03): Day 211(n=126,131,42,39,43,40,0)	90.5 (77.4 to 97.3)	46.2 (30.1 to 62.8)	2.3 (0.1 to 12.3)	42.5 (27.0 to 59.1)
Strain (B09): Day 61(n=0,0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (B09): Day 211(n=77,81,27,25,28,25,0)	14.8 (4.2 to 33.7)	12.0 (2.5 to 31.2)	0 (0 to 12.3)	20.0 (6.8 to 40.7)
Strain (A05): Day 61(n=0,0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (A05): Day 211(n=72,76,25,25,26,18,0)	8.0 (1.0 to 26.0)	96.0 (79.6 to 99.9)	0 (0 to 13.2)	50.0 (26.0 to 74.0)
Strain (A12): Day 61(n=0,0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (A12): Day 211(n=123,129,41,40,42,40,0)	41.5 (26.3 to 57.9)	42.5 (27.0 to 59.1)	4.8 (0.6 to 16.2)	17.5 (7.3 to 32.8)
Strain (A06): Day 61(n=0,0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (A06): Day 211(n=121,125,41,36,42,38,0)	24.4 (12.4 to 40.3)	66.7 (49.0 to 81.4)	2.4 (0.1 to 12.6)	28.9 (15.4 to 45.9)
Strain (A15): Day 61(n=0,0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (A15): Day 211(n=75,81,26,25,27,25,0)	7.7 (0.9 to 25.1)	32.0 (14.9 to 53.5)	0 (0 to 12.8)	16.0 (4.5 to 36.1)

End point values	Adolescents - Group 7: PENBRAYA			
Subject group type	Reporting group			
Number of subjects analysed	94			
Units: percentage of participants				
number (confidence interval 95%)				
Strain (A56):Day 61(n=0,0,0,0,0,0,0)	99999 (-99999 to 99999)			
Strain (A56):Day 211(n=256,263,86,83,90,87,0)	85.1 (76.3 to 91.6)			
Strain (B44): Day 61(n=0,0,0,0,0,0,0)	99999 (-99999 to 99999)			
Strain (B44): Day 211(n=255,262,86,82,88,86,91)	72.5 (62.2 to 81.4)			
Strain (A10): Day 61(n=0,0,0,0,0,0,0)	99999 (-99999 to 99999)			

Strain (A10): Day 211(n=255,260,83,84,89,85,91)	0 (0 to 4.0)			
Strain (B79): Day 61(n=0,0,0,0,0,0)	99999 (-99999 to 99999)			
Strain (B79): Day 211(n=255,259,87,75,88,88,82)	15.9 (8.7 to 25.6)			
Strain (B24): Day 61(n=0,0,0,0,0,0)	99999 (-99999 to 99999)			
Strain (B24): Day 211(n=129,133,44,41,46,40,0)	99999 (-99999 to 99999)			
Strain (A22): Day 61(n=0,0,0,0,0,0)	99999 (-99999 to 99999)			
Strain (A22): Day 211(n=127,128,44,39,43,39,0)	99999 (-99999 to 99999)			
Strain (A26): Day 61(n=0,0,0,0,0,0)	99999 (-99999 to 99999)			
Strain (A26): Day 211(n=116,128,40,37,39,36,0)	99999 (-99999 to 99999)			
Strain (99-A10): Day 61(n=0,0,0,0,0,0)	99999 (-99999 to 99999)			
Strain (99-A10): Day 211(n=117,118,41,39,44,35,0)	99999 (-99999 to 99999)			
Strain (A07): Day 61(n=0,0,0,0,0,0)	99999 (-99999 to 99999)			
Strain (A07): Day 211(n=126,130,43,40,43,40,0)	99999 (-99999 to 99999)			
Strain (B03): Day 61(n=0,0,0,0,0,0)	99999 (-99999 to 99999)			
Strain (B03): Day 211(n=126,131,42,39,43,40,0)	99999 (-99999 to 99999)			
Strain (B09): Day 61(n=0,0,0,0,0,0)	99999 (-99999 to 99999)			
Strain (B09): Day 211(n=77,81,27,25,28,25,0)	99999 (-99999 to 99999)			
Strain (A05): Day 61(n=0,0,0,0,0,0)	99999 (-99999 to 99999)			
Strain (A05): Day 211(n=72,76,25,25,26,18,0)	99999 (-99999 to 99999)			
Strain (A12): Day 61(n=0,0,0,0,0,0)	99999 (-99999 to 99999)			
Strain (A12): Day 211(n=123,129,41,40,42,40,0)	99999 (-99999 to 99999)			
Strain (A06): Day 61(n=0,0,0,0,0,0)	99999 (-99999 to 99999)			
Strain (A06): Day 211(n=121,125,41,36,42,38,0)	99999 (-99999 to 99999)			
Strain (A15): Day 61(n=0,0,0,0,0,0)	99999 (-99999 to 99999)			
Strain (A15): Day 211(n=75,81,26,25,27,25,0)	99999 (-99999 to 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Human Complement Serum Bactericidal Assay Titer $\geq 1:4$ and $\geq 1:8$ Against Reference and Additional Strains of Meningococcal Serogroup B at Days 61 and 211

End point title	Percentage of Participants With Human Complement Serum Bactericidal Assay Titer $\geq 1:4$ and $\geq 1:8$ Against Reference and Additional Strains of Meningococcal Serogroup B at Days 61 and 211
End point description:	
The percentage of participants with antibody titers $\geq 1:4$ and $\geq 1:8$ against the reference and additional strains of meningococcal serogroup B was measured by hSBA. The 95% CI for single percentage was based on the Clopper-Pearson method. FAS3 – adolescents included participants who were vaccinated per protocol at Day 181 and had 1 valid post-vaccination blood sample at Day 211, producing at least 1 result for 19 strains of serogroup B. The percentages are rounded off to the tenth decimal place. S-A56= Strain (A56); S-B44= Strain (B44); S-A10= Strain (A10); S-B79= Strain (B79); S-B24= Strain (B24); S-A22= Strain (A22); S-A26= Strain (A26); S-99-A10= Strain (99-A10); S-A07= Strain (A07); S-B03= Strain (B03); S-B09= Strain (B09); S-A05= Strain (A05); S-A12= Strain (A12); S-A06= Strain (A06); S-A15= Strain (A15). Here, n= Number of participants analyzed for each serogroup at specific timepoints for adolescent groups; and -99999 and 99999= No participants analyzed at specific timepoints.	
End point type	Secondary
End point timeframe:	
Adults: 1 month after the second and third vaccination (Day 61 and Day 211, respectively); Adolescents: 1 month after the second vaccination (Day 211)	

End point values	Adults - Group 1: MenPenta Formulation 1	Adults - Group 2: MenPenta Formulation 2	Adults - Group 3: Bexsero + Menveo	Adults - Group 4: Trumenba + Menveo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[67]	0 ^[68]	0 ^[69]	0 ^[70]
Units: percentage of participants				
number (confidence interval 95%)				
S-A56: Day 61, $\geq 1:4$ (n=0,0,0,0,0,0)	(to)	(to)	(to)	(to)
S-A56: Day 61, $\geq 1:8$ (n=0,0,0,0,0,0)	(to)	(to)	(to)	(to)
S-A56: Day 211, $\geq 1:4$ (n=262,266,87,85,91,87,94)	(to)	(to)	(to)	(to)
S-A56: Day 211, $\geq 1:8$ (n=262,266,87,85,91,87,94)	(to)	(to)	(to)	(to)
S-B44: Day 61, $\geq 1:4$ (n=0,0,0,0,0,0)	(to)	(to)	(to)	(to)
S-B44: Day 61, $\geq 1:8$ (n=0,0,0,0,0,0)	(to)	(to)	(to)	(to)
S-B44: Day 211, $\geq 1:4$ (n=260,267,87,84,89,88,94)	(to)	(to)	(to)	(to)
S-B44: Day 211, $\geq 1:8$ (n=260,267,87,84,89,88,94)	(to)	(to)	(to)	(to)
S-A10: Day 61, $\geq 1:4$ (n=0,0,0,0,0,0)	(to)	(to)	(to)	(to)
S-A10: Day 61, $\geq 1:8$ (n=0,0,0,0,0,0)	(to)	(to)	(to)	(to)
S-A10: Day 211, $\geq 1:4$ (n=262,263,85,85,90,86,93)	(to)	(to)	(to)	(to)
S-A10: Day 211, $\geq 1:8$ (n=262,263,85,85,90,86,93)	(to)	(to)	(to)	(to)
S-B79: Day 61, $\geq 1:4$ (n=0,0,0,0,0,0)	(to)	(to)	(to)	(to)
S-B79: Day 61, $\geq 1:8$ (n=0,0,0,0,0,0)	(to)	(to)	(to)	(to)
S-B79: Day 211, $\geq 1:4$ (n=263,267,88,76,90,88,84)	(to)	(to)	(to)	(to)

S-B79: Day 211, >=	(to)	(to)	(to)	(to)
1:8(n=263,267,88,76,90,88,84)				
S-B24: Day 61, >=	(to)	(to)	(to)	(to)
1:4(n=0,0,0,0,0,0)				
S-B24: Day 61, >=	(to)	(to)	(to)	(to)
1:8(n=0,0,0,0,0,0)				
S-B24: Day 211, >=	(to)	(to)	(to)	(to)
1:4(n=130,133,45,41,46,41,0)				
S-B24: Day 211, >=	(to)	(to)	(to)	(to)
1:8(n=130,133,45,41,46,41,0)				
S-A22: Day 61, >=	(to)	(to)	(to)	(to)
1:4(n=0,0,0,0,0,0)				
S-A22: Day 61, >=	(to)	(to)	(to)	(to)
1:8(n=0,0,0,0,0,0)				
S-A22: Day 211, >=	(to)	(to)	(to)	(to)
1:4(n=128,130,45,40,45,40,0)				
S-A22: Day 211, >=	(to)	(to)	(to)	(to)
1:8(n=128,130,45,40,45,40,0)				
S-A26: Day 61, >=	(to)	(to)	(to)	(to)
1:4(n=0,0,0,0,0,0)				
S-A26: Day 61, >=	(to)	(to)	(to)	(to)
1:8(n=0,0,0,0,0,0)				
S-A26:Day211,>=	(to)	(to)	(to)	(to)
1:4(n=122,130,43,39,42,40,0)				
S-A26:Day211,>=	(to)	(to)	(to)	(to)
1:8(n=122,130,43,39,42,40,0)				
S-99-A10: Day 61, >=	(to)	(to)	(to)	(to)
1:4(n=0,0,0,0,0,0)				
S-99-A10: Day 61, >=	(to)	(to)	(to)	(to)
1:8(n=0,0,0,0,0,0)				
S-99-A10:Day 211,>=	(to)	(to)	(to)	(to)
1:4(n=118,118,42,39,45,36,0)				
S-99-A10:Day 211,>=	(to)	(to)	(to)	(to)
1:8(n=118,118,42,39,45,36,0)				
S-A07: Day 61, >=	(to)	(to)	(to)	(to)
1:4(n=0,0,0,0,0,0)				
S-A07: Day 61, >=	(to)	(to)	(to)	(to)
1:8(n=0,0,0,0,0,0)				
S-A07: Day 211, >=	(to)	(to)	(to)	(to)
1:4(n=128,130,44,40,45,41,0)				
S-A07: Day 211, >=	(to)	(to)	(to)	(to)
1:8(n=128,130,44,40,45,41,0)				
S-B03: Day 61, >=	(to)	(to)	(to)	(to)
1:4(n=0,0,0,0,0,0)				
S-B03: Day 61, >=	(to)	(to)	(to)	(to)
1:8(n=0,0,0,0,0,0)				
S-B03: Day 211, >=	(to)	(to)	(to)	(to)
1:4(n=129,131,43,39,44,41,0)				
S-B03: Day 211, >=	(to)	(to)	(to)	(to)
1:8(n=129,131,43,39,44,41,0)				
S-B09: Day 61, >=	(to)	(to)	(to)	(to)
1:4(n=0,0,0,0,0,0)				
S-B09: Day 61, >=	(to)	(to)	(to)	(to)
1:8(n=0,0,0,0,0,0)				
S-B09: Day 211, >=	(to)	(to)	(to)	(to)
1:4(n=78,81,27,25,29,26,0)				
S-B09: Day 211, >=	(to)	(to)	(to)	(to)
1:8(n=78,81,27,25,29,26,0)				
S-A05: Day 61, >=	(to)	(to)	(to)	(to)
1:4(n=0,0,0,0,0,0)				
S-A05: Day 61, >=	(to)	(to)	(to)	(to)
1:8(n=0,0,0,0,0,0)				

S-A05: Day 211, >= 1:4(n=77,78,26,26,29,24,0)	(to)	(to)	(to)	(to)
S-A05: Day 211, >= 1:8(n=77,78,26,26,29,24,0)	(to)	(to)	(to)	(to)
S-A12: Day 61, >= 1:4(n=0,0,0,0,0,0,0)	(to)	(to)	(to)	(to)
S-A12: Day 61, >= 1:8(n=0,0,0,0,0,0,0)	(to)	(to)	(to)	(to)
S-A12: Day 211, >= 1:4(n=126,129,42,40,43,41,0)	(to)	(to)	(to)	(to)
S-A12: Day 211, >= 1:8(n=126,129,42,40,43,41,0)	(to)	(to)	(to)	(to)
S-A06: Day 61, >= 1:4(n=0,0,0,0,0,0,0)	(to)	(to)	(to)	(to)
S-A06: Day 61, >= 1:8(n=0,0,0,0,0,0,0)	(to)	(to)	(to)	(to)
S-A06: Day 211, >= 1:4(n=124,125,42,36,44,39,0)	(to)	(to)	(to)	(to)
S-A06: Day 211, >= 1:8(n=124,125,42,36,44,39,0)	(to)	(to)	(to)	(to)
S-A15: Day 61, >= 1:4(n=0,0,0,0,0,0,0)	(to)	(to)	(to)	(to)
S-A15: Day 61, >= 1:8(n=0,0,0,0,0,0,0)	(to)	(to)	(to)	(to)
S-A15: Day 211, >= 1:4(n=78,81,27,25,29,26,0)	(to)	(to)	(to)	(to)
S-A15: Day 211, >= 1:8(n=78,81,27,25,29,26,0)	(to)	(to)	(to)	(to)

Notes:

[67] - No participants analyzed;antibodies titer to strains of meningococcal serogroupB was not applicable.

[68] - No participants analyzed;antibodies titer to strains of meningococcal serogroupB was not applicable.

[69] - No participants analyzed;antibodies titer to strains of meningococcal serogroupB was not applicable.

[70] - No participants analyzed;antibodies titer to strains of meningococcal serogroupB was not applicable.

End point values	Adults - Group 5: MenQuadfi	Adults - Group 6: Sanofi MenB	Adolescents - Group 1: MenPenta Formulation 1	Adolescents - Group 2: MenPenta Formulation 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[71]	0 ^[72]	263	267
Units: percentage of participants				
number (confidence interval 95%)				
S-A56: Day 61, >= 1:4(n=0,0,0,0,0,0,0)	(to)	(to)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
S-A56: Day 61, >= 1:8(n=0,0,0,0,0,0,0)	(to)	(to)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
S-A56: Day 211, >= 1:4(n=262,266,87,85,91,87,94)	(to)	(to)	100 (98.6 to 100)	100 (98.6 to 100)
S-A56: Day 211, >= 1:8(n=262,266,87,85,91,87,94)	(to)	(to)	57.6 (51.4 to 63.7)	66.2 (60.1 to 71.8)
S-B44: Day 61, >= 1:4(n=0,0,0,0,0,0,0)	(to)	(to)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
S-B44: Day 61, >= 1:8(n=0,0,0,0,0,0,0)	(to)	(to)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
S-B44: Day 211, >= 1:4(n=260,267,87,84,89,88,94)	(to)	(to)	97.3 (94.5 to 98.9)	99.6 (97.9 to 100)
S-B44: Day 211, >= 1:8(n=260,267,87,84,89,88,94)	(to)	(to)	92.3 (88.4 to 95.2)	97.4 (94.7 to 98.9)

S-A10: Day 61, >= 1:4(n=0,0,0,0,0,0)	(to)	(to)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
S-A10: Day 61, >= 1:8(n=0,0,0,0,0,0)	(to)	(to)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
S-A10: Day 211, >= 1:4(n=262,263,85,85,90,86,93)	(to)	(to)	72.5 (66.7 to 77.8)	80.6 (75.3 to 85.2)
S-A10: Day 211, >= 1:8(n=262,263,85,85,90,86,93)	(to)	(to)	63.0 (56.8 to 68.8)	69.6 (63.6 to 75.1)
S-B79: Day 61, >= 1:4(n=0,0,0,0,0,0)	(to)	(to)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
S-B79: Day 61, >= 1:8(n=0,0,0,0,0,0)	(to)	(to)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
S-B79: Day 211, >= 1:4(n=263,267,88,76,90,88,84)	(to)	(to)	93.5 (89.9 to 96.2)	97.8 (95.2 to 99.2)
S-B79: Day 211, >= 1:8(n=263,267,88,76,90,88,84)	(to)	(to)	93.2 (89.4 to 95.9)	97.8 (95.2 to 99.2)
S-B24: Day 61, >= 1:4(n=0,0,0,0,0,0)	(to)	(to)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
S-B24: Day 61, >= 1:8(n=0,0,0,0,0,0)	(to)	(to)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
S-B24: Day 211, >= 1:4(n=130,133,45,41,46,41,0)	(to)	(to)	54.6 (45.7 to 63.4)	57.1 (48.3 to 65.7)
S-B24: Day 211, >= 1:8(n=130,133,45,41,46,41,0)	(to)	(to)	42.3 (33.7 to 51.3)	50.4 (41.6 to 59.2)
S-A22: Day 61, >= 1:4(n=0,0,0,0,0,0)	(to)	(to)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
S-A22: Day 61, >= 1:8(n=0,0,0,0,0,0)	(to)	(to)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
S-A22: Day 211, >= 1:4(n=128,130,45,40,45,40,0)	(to)	(to)	73.4 (64.9 to 80.9)	79.2 (71.2 to 85.8)
S-A22: Day 211, >= 1:8(n=128,130,45,40,45,40,0)	(to)	(to)	67.2 (58.3 to 75.2)	73.1 (64.6 to 80.5)
S-A26: Day 61, >= 1:4(n=0,0,0,0,0,0)	(to)	(to)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
S-A26: Day 61, >= 1:8(n=0,0,0,0,0,0)	(to)	(to)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
S-A26:Day211,>= 1:4(n=122,130,43,39,42,40,0)	(to)	(to)	100 (97.0 to 100)	100 (97.2 to 100)
S-A26:Day211,>= 1:8(n=122,130,43,39,42,40,0)	(to)	(to)	100 (97.0 to 100)	99.2 (95.8 to 100)
S-99-A10: Day 61, >= 1:4(n=0,0,0,0,0,0)	(to)	(to)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
S-99-A10: Day 61, >= 1:8(n=0,0,0,0,0,0)	(to)	(to)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
S-99-A10:Day 211,>= 1:4(n=118,118,42,39,45,36,0)	(to)	(to)	99.2 (95.4 to 100)	100 (96.9 to 100)
S-99-A10:Day 211,>= 1:8(n=118,118,42,39,45,36,0)	(to)	(to)	99.2 (95.4 to 100)	100 (96.9 to 100)
S-A07: Day 61, >= 1:4(n=0,0,0,0,0,0)	(to)	(to)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
S-A07: Day 61, >= 1:8(n=0,0,0,0,0,0)	(to)	(to)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
S-A07: Day 211, >= 1:4(n=128,130,44,40,45,41,0)	(to)	(to)	57.0 (48.0 to 65.7)	66.9 (58.1 to 74.9)
S-A07: Day 211, >= 1:8(n=128,130,44,40,45,41,0)	(to)	(to)	39.8 (31.3 to 48.9)	53.8 (44.9 to 62.6)
S-B03: Day 61, >= 1:4(n=0,0,0,0,0,0)	(to)	(to)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
S-B03: Day 61, >= 1:8(n=0,0,0,0,0,0)	(to)	(to)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
S-B03: Day 211, >= 1:4(n=129,131,43,39,44,41,0)	(to)	(to)	65.1 (56.2 to 73.3)	78.6 (70.6 to 85.3)

S-B03: Day 211, >= 1:8(n=129,131,43,39,44,41,0)	(to)	(to)	57.4 (48.4 to 66.0)	71.8 (63.2 to 79.3)
S-B09: Day 61, >= 1:4(n=0,0,0,0,0,0,0)	(to)	(to)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
S-B09: Day 61, >= 1:8(n=0,0,0,0,0,0,0)	(to)	(to)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
S-B09: Day 211, >= 1:4(n=78,81,27,25,29,26,0)	(to)	(to)	100 (95.4 to 100)	100 (95.5 to 100)
S-B09: Day 211, >= 1:8(n=78,81,27,25,29,26,0)	(to)	(to)	23.1 (14.3 to 34.0)	33.3 (23.2 to 44.7)
S-A05: Day 61, >= 1:4(n=0,0,0,0,0,0,0)	(to)	(to)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
S-A05: Day 61, >= 1:8(n=0,0,0,0,0,0,0)	(to)	(to)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
S-A05: Day 211, >= 1:4(n=77,78,26,26,29,24,0)	(to)	(to)	100 (95.3 to 100)	100 (95.4 to 100)
S-A05: Day 211, >= 1:8(n=77,78,26,26,29,24,0)	(to)	(to)	63.6 (51.9 to 74.3)	71.8 (60.5 to 81.4)
S-A12: Day 61, >= 1:4(n=0,0,0,0,0,0,0)	(to)	(to)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
S-A12: Day 61, >= 1:8(n=0,0,0,0,0,0,0)	(to)	(to)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
S-A12: Day 211, >= 1:4(n=126,129,42,40,43,41,0)	(to)	(to)	82.5 (74.8 to 88.7)	82.9 (75.3 to 89.0)
S-A12: Day 211, >= 1:8(n=126,129,42,40,43,41,0)	(to)	(to)	70.6 (61.9 to 78.4)	74.4 (66.0 to 81.7)
S-A06: Day 61, >= 1:4(n=0,0,0,0,0,0,0)	(to)	(to)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
S-A06: Day 61, >= 1:8(n=0,0,0,0,0,0,0)	(to)	(to)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
S-A06: Day 211, >= 1:4(n=124,125,42,36,44,39,0)	(to)	(to)	100 (97.1 to 100)	100 (97.1 to 100)
S-A06: Day 211, >= 1:8(n=124,125,42,36,44,39,0)	(to)	(to)	36.3 (27.8 to 45.4)	43.2 (34.4 to 52.4)
S-A15: Day 61, >= 1:4(n=0,0,0,0,0,0,0)	(to)	(to)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
S-A15: Day 61, >= 1:8(n=0,0,0,0,0,0,0)	(to)	(to)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
S-A15: Day 211, >= 1:4(n=78,81,27,25,29,26,0)	(to)	(to)	100 (95.4 to 100)	100 (95.5 to 100)
S-A15: Day 211, >= 1:8(n=78,81,27,25,29,26,0)	(to)	(to)	30.8 (20.8 to 42.2)	34.6 (24.3 to 46.0)

Notes:

[71] - No participants analyzed;antibodies titer to strains of meningococcal serogroupB was not applicable.

[72] - No participants analyzed;antibodies titer to strains of meningococcal serogroupB was not applicable.

End point values	Adolescents - Group 3: Bexsero + Menveo	Adolescents - Group 4: Trumenba + Menveo	Adolescents - Group 5: MenQuadfi	Adolescents - Group 6: Sanofi MenB
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	88	85	91	88
Units: percentage of participants				
number (confidence interval 95%)				
S-A56: Day 61, >= 1:4(n=0,0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
S-A56: Day 61, >= 1:8(n=0,0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
S-A56: Day 211, >= 1:4(n=262,266,87,85,91,87,94)	100 (95.8 to 100)	100 (95.8 to 100)	100 (96.0 to 100)	100 (95.8 to 100)

S-A56: Day 211, >= 1:8(n=262,266,87,85,91,87,94)	41.4 (30.9 to 52.4)	96.5 (90.0 to 99.3)	7.7 (3.1 to 15.2)	54.0 (43.0 to 64.8)
S-B44: Day 61, >= 1:4(n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
S-B44: Day 61, >= 1:8(n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
S-B44: Day 211, >= 1:4(n=260,267,87,84,89,88,94)	100 (95.8 to 100)	100 (95.7 to 100)	73.0 (62.6 to 81.9)	98.9 (93.8 to 100)
S-B44: Day 211, >= 1:8(n=260,267,87,84,89,88,94)	98.9 (93.8 to 100)	98.8 (93.5 to 100)	55.1 (44.1 to 65.6)	96.6 (90.4 to 99.3)
S-A10: Day 61, >= 1:4(n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
S-A10: Day 61, >= 1:8(n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
S-A10: Day 211, >= 1:4(n=262,263,85,85,90,86,93)	24.7 (16.0 to 35.3)	4.7 (1.3 to 11.6)	5.6 (1.8 to 12.5)	86.0 (76.9 to 92.6)
S-A10: Day 211, >= 1:8(n=262,263,85,85,90,86,93)	22.4 (14.0 to 32.7)	2.4 (0.3 to 8.2)	4.4 (1.2 to 11.0)	79.1 (69.0 to 87.1)
S-B79: Day 61, >= 1:4(n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
S-B79: Day 61, >= 1:8(n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
S-B79: Day 211, >= 1:4(n=263,267,88,76,90,88,84)	97.7 (92.0 to 99.7)	34.2 (23.7 to 46.0)	10.0 (4.7 to 18.1)	98.9 (93.8 to 100)
S-B79: Day 211, >= 1:8(n=263,267,88,76,90,88,84)	97.7 (92.0 to 99.7)	34.2 (23.7 to 46.0)	10.0 (4.7 to 18.1)	98.9 (93.8 to 100)
S-B24: Day 61, >= 1:4(n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
S-B24: Day 61, >= 1:8(n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
S-B24: Day 211, >= 1:4(n=130,133,45,41,46,41,0)	100 (92.1 to 100)	92.7 (80.1 to 98.5)	23.9 (12.6 to 38.8)	53.7 (37.4 to 69.3)
S-B24: Day 211, >= 1:8(n=130,133,45,41,46,41,0)	100 (92.1 to 100)	87.8 (73.8 to 95.9)	13.0 (4.9 to 26.3)	46.3 (30.7 to 62.6)
S-A22: Day 61, >= 1:4(n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
S-A22: Day 61, >= 1:8(n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
S-A22: Day 211, >= 1:4(n=128,130,45,40,45,40,0)	86.7 (73.2 to 94.9)	92.5 (79.6 to 98.4)	48.9 (33.7 to 64.2)	80.0 (64.4 to 90.9)
S-A22: Day 211, >= 1:8(n=128,130,45,40,45,40,0)	84.4 (70.5 to 93.5)	92.5 (79.6 to 98.4)	46.7 (31.7 to 62.1)	72.5 (56.1 to 85.4)
S-A26: Day 61, >= 1:4(n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
S-A26: Day 61, >= 1:8(n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
S-A26:Day211,>= 1:4(n=122,130,43,39,42,40,0)	100 (91.8 to 100)	100 (91.0 to 100)	100 (91.6 to 100)	100 (91.2 to 100)
S-A26:Day211,>= 1:8(n=122,130,43,39,42,40,0)	97.7 (87.7 to 99.9)	43.6 (27.8 to 60.4)	33.3 (19.6 to 49.5)	100 (91.2 to 100)
S-99-A10: Day 61, >= 1:4(n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
S-99-A10: Day 61, >= 1:8(n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
S-99-A10:Day 211,>= 1:4(n=118,118,42,39,45,36,0)	97.6 (87.4 to 99.9)	64.1 (47.2 to 78.8)	20.0 (9.6 to 34.6)	100 (90.3 to 100)
S-99-A10:Day 211,>= 1:8(n=118,118,42,39,45,36,0)	97.6 (87.4 to 99.9)	64.1 (47.2 to 78.8)	17.8 (8.0 to 32.1)	100 (90.3 to 100)
S-A07: Day 61, >= 1:4(n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
S-A07: Day 61, >= 1:8(n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)

S-A07: Day 211, >= 1:4(n=128,130,44,40,45,41,0)	97.7 (88.0 to 99.9)	55.0 (38.5 to 70.7)	24.4 (12.9 to 39.5)	39.0 (24.2 to 55.5)
S-A07: Day 211, >= 1:8(n=128,130,44,40,45,41,0)	97.7 (88.0 to 99.9)	40.0 (24.9 to 56.7)	22.2 (11.2 to 37.1)	24.4 (12.4 to 40.3)
S-B03: Day 61, >= 1:4(n=0,0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
S-B03: Day 61, >= 1:8(n=0,0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
S-B03: Day 211, >= 1:4(n=129,131,43,39,44,41,0)	97.7 (87.7 to 99.9)	64.1 (47.2 to 78.8)	6.8 (1.4 to 18.7)	65.9 (49.4 to 79.9)
S-B03: Day 211, >= 1:8(n=129,131,43,39,44,41,0)	97.7 (87.7 to 99.9)	61.5 (44.6 to 76.6)	4.5 (0.6 to 15.5)	51.2 (35.1 to 67.1)
S-B09: Day 61, >= 1:4(n=0,0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
S-B09: Day 61, >= 1:8(n=0,0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
S-B09: Day 211, >= 1:4(n=78,81,27,25,29,26,0)	100 (87.2 to 100)	100 (86.3 to 100)	100 (88.1 to 100)	100 (86.8 to 100)
S-B09: Day 211, >= 1:8(n=78,81,27,25,29,26,0)	44.4 (25.5 to 64.7)	40.0 (21.1 to 61.3)	6.9 (0.8 to 22.8)	34.6 (17.2 to 55.7)
S-A05: Day 61, >= 1:4(n=0,0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
S-A05: Day 61, >= 1:8(n=0,0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
S-A05:Day 211,>= 1:4(n=77,78,26,26,29,24,0)	100 (86.8 to 100)	100 (86.8 to 100)	100 (88.1 to 100)	100 (85.8 to 100)
S-A05:Day 211,>= 1:8(n=77,78,26,26,29,24,0)	50.0 (29.9 to 70.1)	100 (86.8 to 100)	20.7 (8.0 to 39.7)	75.0 (53.3 to 90.2)
S-A12: Day 61, >= 1:4(n=0,0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
S-A12: Day 61, >= 1:8(n=0,0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
S-A12: Day 211, >= 1:4(n=126,129,42,40,43,41,0)	95.2 (83.8 to 99.4)	95.0 (83.1 to 99.4)	72.1 (56.3 to 84.7)	90.2 (76.9 to 97.3)
S-A12: Day 211, >= 1:8(n=126,129,42,40,43,41,0)	90.5 (77.4 to 97.3)	90.0 (76.3 to 97.2)	60.5 (44.4 to 75.0)	78.0 (62.4 to 89.4)
S-A06: Day 61, >= 1:4(n=0,0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
S-A06: Day 61, >= 1:8(n=0,0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
S-A06: Day 211, >= 1:4(n=124,125,42,36,44,39,0)	100 (91.6 to 100)	100 (90.3 to 100)	100 (92.0 to 100)	100 (91.0 to 100)
S-A06: Day 211, >= 1:8(n=124,125,42,36,44,39,0)	47.6 (32.0 to 63.6)	83.3 (67.2 to 93.6)	15.9 (6.6 to 30.1)	43.6 (27.8 to 60.4)
S-A15: Day 61, >= 1:4(n=0,0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
S-A15: Day 61, >= 1:8(n=0,0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
S-A15: Day 211, >= 1:4(n=78,81,27,25,29,26,0)	100 (87.2 to 100)	100 (86.3 to 100)	100 (88.1 to 100)	100 (86.8 to 100)
S-A15: Day 211, >= 1:8(n=78,81,27,25,29,26,0)	44.4 (25.5 to 64.7)	80.0 (59.3 to 93.2)	24.1 (10.3 to 43.5)	42.3 (23.4 to 63.1)

End point values	Adolescents - Group 7: PENBRAYA			
Subject group type	Reporting group			
Number of subjects analysed	94			

Units: percentage of participants				
number (confidence interval 95%)				
S-A56: Day 61, >= 1:4(n=0,0,0,0,0,0)	99999 (-99999 to 99999)			
S-A56: Day 61, >= 1:8(n=0,0,0,0,0,0)	99999 (-99999 to 99999)			
S-A56: Day 211, >= 1:4(n=262,266,87,85,91,87,94)	100 (96.2 to 100)			
S-A56: Day 211, >= 1:8(n=262,266,87,85,91,87,94)	98.9 (94.2 to 100)			
S-B44: Day 61, >= 1:4(n=0,0,0,0,0,0)	99999 (-99999 to 99999)			
S-B44: Day 61, >= 1:8(n=0,0,0,0,0,0)	99999 (-99999 to 99999)			
S-B44: Day 211, >= 1:4(n=260,267,87,84,89,88,94)	100 (96.2 to 100)			
S-B44: Day 211, >= 1:8(n=260,267,87,84,89,88,94)	100 (96.2 to 100)			
S-A10: Day 61, >= 1:4(n=0,0,0,0,0,0)	99999 (-99999 to 99999)			
S-A10: Day 61, >= 1:8(n=0,0,0,0,0,0)	99999 (-99999 to 99999)			
S-A10: Day 211, >= 1:4(n=262,263,85,85,90,86,93)	2.2 (0.3 to 7.6)			
S-A10: Day 211, >= 1:8(n=262,263,85,85,90,86,93)	1.1 (0 to 5.8)			
S-B79: Day 61, >= 1:4(n=0,0,0,0,0,0)	99999 (-99999 to 99999)			
S-B79: Day 61, >= 1:8(n=0,0,0,0,0,0)	99999 (-99999 to 99999)			
S-B79: Day 211, >= 1:4(n=263,267,88,76,90,88,84)	29.8 (20.3 to 40.7)			
S-B79: Day 211, >= 1:8(n=263,267,88,76,90,88,84)	27.4 (18.2 to 38.2)			
S-B24: Day 61, >= 1:4(n=0,0,0,0,0,0)	99999 (-99999 to 99999)			
S-B24: Day 61, >= 1:8(n=0,0,0,0,0,0)	99999 (-99999 to 99999)			
S-B24: Day 211, >= 1:4(n=130,133,45,41,46,41,0)	99999 (-99999 to 99999)			
S-B24: Day 211, >= 1:8(n=130,133,45,41,46,41,0)	99999 (-99999 to 99999)			
S-A22: Day 61, >= 1:4(n=0,0,0,0,0,0)	99999 (-99999 to 99999)			
S-A22: Day 61, >= 1:8(n=0,0,0,0,0,0)	99999 (-99999 to 99999)			
S-A22: Day 211, >= 1:4(n=128,130,45,40,45,40,0)	99999 (-99999 to 99999)			
S-A22: Day 211, >= 1:8(n=128,130,45,40,45,40,0)	99999 (-99999 to 99999)			
S-A26: Day 61, >= 1:4(n=0,0,0,0,0,0)	99999 (-99999 to 99999)			
S-A26: Day 61, >= 1:8(n=0,0,0,0,0,0)	99999 (-99999 to 99999)			
S-A26:Day211,>= 1:4(n=122,130,43,39,42,40,0)	99999 (-99999 to 99999)			
S-A26:Day211,>= 1:8(n=122,130,43,39,42,40,0)	99999 (-99999 to 99999)			
S-99-A10: Day 61, >= 1:4(n=0,0,0,0,0,0)	99999 (-99999 to 99999)			
S-99-A10: Day 61, >= 1:8(n=0,0,0,0,0,0)	99999 (-99999 to 99999)			

S-99-A10:Day 211,>=	99999 (-99999			
1:4(n=118,118,42,39,45,36,0)	to 99999)			
S-99-A10:Day 211,>=	99999 (-99999			
1:8(n=118,118,42,39,45,36,0)	to 99999)			
S-A07: Day 61, >=	99999 (-99999			
1:4(n=0,0,0,0,0,0,0)	to 99999)			
S-A07: Day 61, >=	99999 (-99999			
1:8(n=0,0,0,0,0,0,0)	to 99999)			
S-A07: Day 211, >=	99999 (-99999			
1:4(n=128,130,44,40,45,41,0)	to 99999)			
S-A07: Day 211, >=	99999 (-99999			
1:8(n=128,130,44,40,45,41,0)	to 99999)			
S-B03: Day 61, >=	99999 (-99999			
1:4(n=0,0,0,0,0,0,0)	to 99999)			
S-B03: Day 61, >=	99999 (-99999			
1:8(n=0,0,0,0,0,0,0)	to 99999)			
S-B03: Day 211, >=	99999 (-99999			
1:4(n=129,131,43,39,44,41,0)	to 99999)			
S-B03: Day 211, >=	99999 (-99999			
1:8(n=129,131,43,39,44,41,0)	to 99999)			
S-B09: Day 61, >=	99999 (-99999			
1:4(n=0,0,0,0,0,0,0)	to 99999)			
S-B09: Day 61, >=	99999 (-99999			
1:8(n=0,0,0,0,0,0,0)	to 99999)			
S-B09: Day 211, >=	99999 (-99999			
1:4(n=78,81,27,25,29,26,0)	to 99999)			
S-B09: Day 211, >=	99999 (-99999			
1:8(n=78,81,27,25,29,26,0)	to 99999)			
S-A05: Day 61, >=	99999 (-99999			
1:4(n=0,0,0,0,0,0,0)	to 99999)			
S-A05: Day 61, >=	99999 (-99999			
1:8(n=0,0,0,0,0,0,0)	to 99999)			
S-A05:Day 211,>=	99999 (-99999			
1:4(n=77,78,26,26,29,24,0)	to 99999)			
S-A05:Day 211,>=	99999 (-99999			
1:8(n=77,78,26,26,29,24,0)	to 99999)			
S-A12: Day 61, >=	99999 (-99999			
1:4(n=0,0,0,0,0,0,0)	to 99999)			
S-A12: Day 61, >=	99999 (-99999			
1:8(n=0,0,0,0,0,0,0)	to 99999)			
S-A12: Day 211, >=	99999 (-99999			
1:4(n=126,129,42,40,43,41,0)	to 99999)			
S-A12: Day 211, >=	99999 (-99999			
1:8(n=126,129,42,40,43,41,0)	to 99999)			
S-A06: Day 61, >=	99999 (-99999			
1:4(n=0,0,0,0,0,0,0)	to 99999)			
S-A06: Day 61, >=	99999 (-99999			
1:8(n=0,0,0,0,0,0,0)	to 99999)			
S-A06: Day 211, >=	99999 (-99999			
1:4(n=124,125,42,36,44,39,0)	to 99999)			
S-A06: Day 211, >=	99999 (-99999			
1:8(n=124,125,42,36,44,39,0)	to 99999)			
S-A15: Day 61, >=	99999 (-99999			
1:4(n=0,0,0,0,0,0,0)	to 99999)			
S-A15: Day 61, >=	99999 (-99999			
1:8(n=0,0,0,0,0,0,0)	to 99999)			
S-A15: Day 211, >=	99999 (-99999			
1:4(n=78,81,27,25,29,26,0)	to 99999)			
S-A15: Day 211, >=	99999 (-99999			
1:8(n=78,81,27,25,29,26,0)	to 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric Mean Titers of Antibodies Against Reference and Additional Strains of Meningococcal Serogroup B at Days 61 and 211

End point title	Geometric Mean Titers of Antibodies Against Reference and Additional Strains of Meningococcal Serogroup B at Days 61 and 211
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End point description:

The antibodies titer against the reference and additional strains of the meningococcal serogroup B was measured by hSBA and the results were expressed as GMT. The 95% CI for the single percentage was based on the Clopper-Pearson method. FAS3 – adolescents included participants who were vaccinated per protocol at Day 181 and had 1 valid post-vaccination blood sample at Day 211, producing at least 1 result for the 19 strains of serogroup B. Here, n= Number of participants analyzed for each serogroup at specific timepoints for adolescent groups; and -99999 and 99999= No participants analyzed at specific timepoints.

End point type	Secondary
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End point timeframe:

Adults: 1 month after the second and third vaccination (Day 61 and Day 211, respectively);

Adolescents: 1 month after the second vaccination (Day 211)

End point values	Adults - Group 1: MenPenta Formulation 1	Adults - Group 2: MenPenta Formulation 2	Adults - Group 3: Bexsero + Menveo	Adults - Group 4: Trumenba + Menveo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[73]	0 ^[74]	0 ^[75]	0 ^[76]
Units: titer				
geometric mean (confidence interval 95%)				
Strain (A56):Day 61(n=0,0,0,0,0,0,0)	(to)	(to)	(to)	(to)
Strain (A56):Day211(n=262,266,87,85,91,87,	(to)	(to)	(to)	(to)
Strain (B44): Day 61(n=0,0,0,0,0,0,0)	(to)	(to)	(to)	(to)
Strain (B44): Day 211(n=260,267,87,84,89,88,94)	(to)	(to)	(to)	(to)
Strain (A10): Day 61(n=0,0,0,0,0,0,0)	(to)	(to)	(to)	(to)
Strain (A10):Day 211(n=262,263,85,85,90,86,93)	(to)	(to)	(to)	(to)
Strain (B79): Day 61(n=0,0,0,0,0,0,0)	(to)	(to)	(to)	(to)
Strain (B79):Day 211(n=263,267,88,76,90,88,84)	(to)	(to)	(to)	(to)
Strain (B24): Day 61(n=0,0,0,0,0,0,0)	(to)	(to)	(to)	(to)
Strain (B24): Day 211(n=130,133,45,41,46,41,0)	(to)	(to)	(to)	(to)
Strain (A22): Day 61(n=0,0,0,0,0,0,0)	(to)	(to)	(to)	(to)
Strain (A22): Day 211(n=128,130,45,40,45,40,0)	(to)	(to)	(to)	(to)

Strain (A26): Day 61(n=0,0,0,0,0,0)	(to)	(to)	(to)	(to)
Strain (A26): Day 211(n=122,130,43,39,42,40,0)	(to)	(to)	(to)	(to)
Strain (99-A10): Day 61(n=0,0,0,0,0,0)	(to)	(to)	(to)	(to)
Strain (99-A10): Day 211(n=118,118,42,39,45,36,0)	(to)	(to)	(to)	(to)
Strain (A07): Day 61(n=0,0,0,0,0,0)	(to)	(to)	(to)	(to)
Strain (A07): Day 211(n=128,130,44,40,45,41,0)	(to)	(to)	(to)	(to)
Strain (B03): Day 61(n=0,0,0,0,0,0)	(to)	(to)	(to)	(to)
Strain (B03): Day 211(n=129,131,43,39,44,41,0)	(to)	(to)	(to)	(to)
Strain (B09): Day 61(n=0,0,0,0,0,0)	(to)	(to)	(to)	(to)
Strain (B09): Day 211(n=78,81,27,25,29,26,0)	(to)	(to)	(to)	(to)
Strain (A05): Day 61(n=0,0,0,0,0,0)	(to)	(to)	(to)	(to)
Strain (A05): Day 211(n=77,78,26,26,29,24,0)	(to)	(to)	(to)	(to)
Strain (A12): Day 61(n=0,0,0,0,0,0)	(to)	(to)	(to)	(to)
Strain (A12): Day 211(n=126,129,42,40,43,41,0)	(to)	(to)	(to)	(to)
Strain (A06): Day 61(n=0,0,0,0,0,0)	(to)	(to)	(to)	(to)
Strain (A06): Day 211(n=124,125,42,36,44,39,0)	(to)	(to)	(to)	(to)
Strain (A15): Day 61(n=0,0,0,0,0,0)	(to)	(to)	(to)	(to)
Strain (A15): Day 211(n=78,81,27,25,29,26,0)	(to)	(to)	(to)	(to)

Notes:

[73] - No participants analyzed;antibodies titer to strains of meningococcal serogroupB was not applicable.

[74] - No participants analyzed;antibodies titer to strains of meningococcal serogroupB was not applicable.

[75] - No participants analyzed;antibodies titer to strains of meningococcal serogroupB was not applicable.

[76] - No participants analyzed;antibodies titer to strains of meningococcal serogroupB was not applicable.

End point values	Adults - Group 5: MenQuadfi	Adults - Group 6: Sanofi MenB	Adolescents - Group 1: MenPenta Formulation 1	Adolescents - Group 2: MenPenta Formulation 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[77]	0 ^[78]	263	267
Units: titer				
geometric mean (confidence interval 95%)				
Strain (A56):Day 61(n=0,0,0,0,0,0)	(to)	(to)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (A56):Day211(n=262,266,87,85,91,87,	(to)	(to)	21.2 (17.3 to 25.9)	33.1 (26.6 to 41.0)
Strain (B44): Day 61(n=0,0,0,0,0,0)	(to)	(to)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (B44): Day 211(n=260,267,87,84,89,88,94)	(to)	(to)	57.1 (48.0 to 67.9)	79.4 (67.9 to 93.0)
Strain (A10): Day 61(n=0,0,0,0,0,0)	(to)	(to)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (A10):Day 211(n=262,263,85,85,90,86,93)	(to)	(to)	13.9 (11.6 to 16.6)	17.5 (14.7 to 20.9)

Strain (B79): Day 61(n=0,0,0,0,0,0)	(to)	(to)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (B79): Day 211(n=263,267,88,76,90,88,84)	(to)	(to)	209 (168 to 260)	267 (222 to 322)
Strain (B24): Day 61(n=0,0,0,0,0,0)	(to)	(to)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (B24): Day 211(n=130,133,45,41,46,41,0)	(to)	(to)	9.24 (7.29 to 11.7)	10.5 (8.15 to 13.5)
Strain (A22): Day 61(n=0,0,0,0,0,0)	(to)	(to)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (A22): Day 211(n=128,130,45,40,45,40,0)	(to)	(to)	18.1 (13.8 to 23.7)	24.0 (18.3 to 31.4)
Strain (A26): Day 61(n=0,0,0,0,0,0)	(to)	(to)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (A26): Day 211(n=122,130,43,39,42,40,0)	(to)	(to)	2670 (2003 to 3561)	2650 (2024 to 3469)
Strain (99-A10): Day 61(n=0,0,0,0,0,0)	(to)	(to)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (99-A10): Day 211(n=118,118,42,39,45,36,0)	(to)	(to)	529 (408 to 685)	552 (448 to 680)
Strain (A07): Day 61(n=0,0,0,0,0,0)	(to)	(to)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (A07): Day 211(n=128,130,44,40,45,41,0)	(to)	(to)	6.99 (5.68 to 8.60)	10.1 (8.05 to 12.6)
Strain (B03): Day 61(n=0,0,0,0,0,0)	(to)	(to)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (B03): Day 211(n=129,131,43,39,44,41,0)	(to)	(to)	15.1 (11.0 to 20.7)	25.1 (18.5 to 34.0)
Strain (B09): Day 61(n=0,0,0,0,0,0)	(to)	(to)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (B09): Day 211(n=78,81,27,25,29,26,0)	(to)	(to)	8.27 (6.60 to 10.4)	12.0 (8.82 to 16.3)
Strain (A05): Day 61(n=0,0,0,0,0,0)	(to)	(to)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (A05): Day 211(n=77,78,26,26,29,24,0)	(to)	(to)	22.0 (14.8 to 32.8)	33.9 (21.9 to 52.4)
Strain (A12): Day 61(n=0,0,0,0,0,0)	(to)	(to)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (A12): Day 211(n=126,129,42,40,43,41,0)	(to)	(to)	17.1 (13.6 to 21.4)	20.2 (15.7 to 26.0)
Strain (A06): Day 61(n=0,0,0,0,0,0)	(to)	(to)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (A06): Day 211(n=124,125,42,36,44,39,0)	(to)	(to)	13.5 (10.6 to 17.2)	17.4 (13.2 to 22.8)
Strain (A15): Day 61(n=0,0,0,0,0,0)	(to)	(to)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (A15): Day 211(n=78,81,27,25,29,26,0)	(to)	(to)	7.90 (6.30 to 9.90)	8.85 (6.90 to 11.3)

Notes:

[77] - No participants analyzed;antibodies titer to strains of meningococcal serogroupB was not applicable.

[78] - No participants analyzed;antibodies titer to strains of meningococcal serogroupB was not applicable.

End point values	Adolescents - Group 3: Bexsero + Menveo	Adolescents - Group 4: Trumenba + Menveo	Adolescents - Group 5: MenQuadfi	Adolescents - Group 6: Sanofi MenB
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	88	85	91	88
Units: titer				
geometric mean (confidence interval)				

95%)				
Strain (A56):Day 61(n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (A56):Day211(n=262,266,87,85,91,87,87)	9.00 (7.35 to 11.0)	107 (84.2 to 137)	5.18 (4.64 to 5.78)	19.6 (13.9 to 27.6)
Strain (B44): Day 61(n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (B44): Day 211(n=260,267,87,84,89,88,94)	52.8 (43.4 to 64.3)	111 (88.0 to 140)	9.90 (7.44 to 13.2)	78.0 (58.6 to 104)
Strain (A10): Day 61(n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (A10):Day 211(n=262,263,85,85,90,86,93)	4.57 (3.51 to 5.94)	2.65 (2.49 to 2.81)	2.87 (2.51 to 3.29)	25.5 (18.6 to 34.9)
Strain (B79): Day 61(n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (B79):Day 211(n=263,267,88,76,90,88,84)	584 (444 to 769)	7.79 (5.78 to 10.5)	4.30 (3.73 to 4.95)	516 (371 to 717)
Strain (B24): Day 61(n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (B24): Day 211(n=130,133,45,41,46,41,0)	347 (250 to 480)	36.0 (23.5 to 55.0)	4.27 (3.39 to 5.40)	10.7 (6.59 to 17.4)
Strain (A22): Day 61(n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (A22): Day 211(n=128,130,45,40,45,40,0)	30.9 (20.6 to 46.4)	46.7 (31.8 to 68.5)	9.75 (6.18 to 15.4)	19.2 (12.7 to 29.2)
Strain (A26): Day 61(n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (A26): Day 211(n=122,130,43,39,42,40,0)	4926 (2944 to 8241)	16.9 (10.1 to 28.3)	10.9 (7.12 to 16.7)	3934 (2586 to 5986)
Strain (99-A10): Day 61(n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (99-A10): Day 211(n=118,118,42,39,45,36,0)	917 (647 to 1301)	14.7 (9.60 to 22.6)	5.55 (4.00 to 7.70)	813 (538 to 1230)
Strain (A07): Day 61(n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (A07): Day 211(n=128,130,44,40,45,41,0)	34.8 (25.2 to 48.1)	7.26 (4.88 to 10.8)	4.03 (2.98 to 5.46)	5.05 (3.56 to 7.16)
Strain (B03): Day 61(n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (B03): Day 211(n=129,131,43,39,44,41,0)	51.5 (37.2 to 71.3)	11.0 (6.65 to 18.3)	2.23 (1.96 to 2.54)	13.9 (7.58 to 25.5)
Strain (B09): Day 61(n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (B09): Day 211(n=78,81,27,25,29,26,0)	11.4 (7.17 to 18.2)	10.0 (6.56 to 15.3)	6.00 (4.46 to 8.09)	12.1 (6.81 to 21.5)
Strain (A05): Day 61(n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (A05): Day 211(n=77,78,26,26,29,24,0)	9.72 (6.40 to 14.8)	149 (105 to 210)	6.04 (4.05 to 9.00)	37.4 (18.1 to 77.3)
Strain (A12): Day 61(n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (A12): Day 211(n=126,129,42,40,43,41,0)	37.7 (26.4 to 53.9)	39.2 (26.3 to 58.5)	13.3 (8.42 to 21.1)	19.5 (13.7 to 27.9)
Strain (A06): Day 61(n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (A06): Day 211(n=124,125,42,36,44,39,0)	14.7 (10.2 to 21.3)	67.3 (41.2 to 110)	7.52 (5.81 to 9.74)	16.5 (10.3 to 26.5)
Strain (A15): Day 61(n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (A15): Day 211(n=78,81,27,25,29,26,0)	8.72 (6.16 to 12.3)	23.1 (14.2 to 37.5)	6.17 (4.83 to 7.88)	9.27 (6.12 to 14.0)

End point values	Adolescents - Group 7: PENBRAYA			
Subject group type	Reporting group			
Number of subjects analysed	94			
Units: titer				
geometric mean (confidence interval 95%)				
Strain (A56):Day 61(n=0,0,0,0,0,0)	99999 (-99999 to 99999)			
Strain (A56):Day211(n=262,266,87,85,91,87,	119 (94.8 to 149)			
Strain (B44): Day 61(n=0,0,0,0,0,0)	99999 (-99999 to 99999)			
Strain (B44): Day 211(n=260,267,87,84,89,88,94)	111 (93.7 to 132)			
Strain (A10): Day 61(n=0,0,0,0,0,0)	99999 (-99999 to 99999)			
Strain (A10):Day 211(n=262,263,85,85,90,86,93)	2.56 (2.48 to 2.64)			
Strain (B79): Day 61(n=0,0,0,0,0,0)	99999 (-99999 to 99999)			
Strain (B79):Day 211(n=263,267,88,76,90,88,84)	6.84 (5.29 to 8.83)			
Strain (B24): Day 61(n=0,0,0,0,0,0)	99999 (-99999 to 99999)			
Strain (B24): Day 211(n=130,133,45,41,46,41,0)	99999 (-99999 to 99999)			
Strain (A22): Day 61(n=0,0,0,0,0,0)	99999 (-99999 to 99999)			
Strain (A22): Day 211(n=128,130,45,40,45,40,0)	99999 (-99999 to 99999)			
Strain (A26): Day 61(n=0,0,0,0,0,0)	99999 (-99999 to 99999)			
Strain (A26): Day 211(n=122,130,43,39,42,40,0)	99999 (-99999 to 99999)			
Strain (99-A10): Day 61(n=0,0,0,0,0,0)	99999 (-99999 to 99999)			
Strain (99-A10): Day 211(n=118,118,42,39,45,36,0)	99999 (-99999 to 99999)			
Strain (A07): Day 61(n=0,0,0,0,0,0)	99999 (-99999 to 99999)			
Strain (A07): Day 211(n=128,130,44,40,45,41,0)	99999 (-99999 to 99999)			
Strain (B03): Day 61(n=0,0,0,0,0,0)	99999 (-99999 to 99999)			
Strain (B03): Day 211(n=129,131,43,39,44,41,0)	99999 (-99999 to 99999)			
Strain (B09): Day 61(n=0,0,0,0,0,0)	99999 (-99999 to 99999)			
Strain (B09): Day 211(n=78,81,27,25,29,26,0)	99999 (-99999 to 99999)			
Strain (A05): Day 61(n=0,0,0,0,0,0)	99999 (-99999 to 99999)			
Strain (A05): Day 211(n=77,78,26,26,29,24,0)	99999 (-99999 to 99999)			

Strain (A12): Day 61(n=0,0,0,0,0,0)	99999 (-99999 to 99999)			
Strain (A12): Day 211(n=126,129,42,40,43,41,0)	99999 (-99999 to 99999)			
Strain (A06): Day 61(n=0,0,0,0,0,0)	99999 (-99999 to 99999)			
Strain (A06): Day 211(n=124,125,42,36,44,39,0)	99999 (-99999 to 99999)			
Strain (A15): Day 61(n=0,0,0,0,0,0)	99999 (-99999 to 99999)			
Strain (A15): Day 211(n=78,81,27,25,29,26,0)	99999 (-99999 to 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Human Complement Serum Bactericidal Assay Composite $\geq$ Lower Limit of Quantification Against Reference and Additional Strains of Meningococcal Serogroup B at Days 61 and 211

End point title	Percentage of Participants With Human Complement Serum Bactericidal Assay Composite $\geq$ Lower Limit of Quantification Against Reference and Additional Strains of Meningococcal Serogroup B at Days 61 and 211
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End point description:

The percentage of participants with antibody titers $\geq$ LLOQ against the reference and additional strains of the meningococcal serogroup B was measured by hSBA. The 95% CI for the single percentage was based on the Clopper-Pearson method. FAS3 – adolescents included participants who were vaccinated per protocol at Day 181 and had 1 valid post-vaccination blood sample at Day 211, producing at least 1 result for the 19 strains of serogroup B. The percentages are rounded off to the tenth decimal place. Here, n= Number of participants analyzed for each serogroup at specific timepoints for adolescent groups; and -99999 and 99999= No participants analyzed at specific timepoints.

End point type	Secondary
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End point timeframe:

Adults: 1 month after the second and third vaccination (Day 61 and Day 211, respectively);

Adolescents: 1 month after the second vaccination (Day 211)

End point values	Adults - Group 1: MenPenta Formulation 1	Adults - Group 2: MenPenta Formulation 2	Adults - Group 3: Bexsero + Menveo	Adults - Group 4: Trumenba + Menveo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[79]	0 ^[80]	0 ^[81]	0 ^[82]
Units: percentage of participants				
number (confidence interval 95%)				
Day 61 (n=0,0,0,0,0,0)	(to)	(to)	(to)	(to)
Day 211 (n=68,64,24,17,23,20,0)	(to)	(to)	(to)	(to)

Notes:

[79] - No participants analyzed; antibodies titer to strains of meningococcal serogroup B was not applicable.

[80] - No participants analyzed; antibodies titer to strains of meningococcal serogroup B was not applicable.

[81] - No participants analyzed; antibodies titer to strains of meningococcal serogroup B was not applicable.

applicable.

[82] - No participants analyzed;antibodies titer to strains of meningococcal serogroupB was not applicable.

End point values	Adults - Group 5: MenQuadfi	Adults - Group 6: Sanofi MenB	Adolescents - Group 1: MenPenta Formulation 1	Adolescents - Group 2: MenPenta Formulation 2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0 ^[83]	0 ^[84]	68	64
Units: percentage of participants				
number (confidence interval 95%)				
Day 61 (n=0,0,0,0,0,0,0)	(to)	(to)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Day 211 (n=68,64,24,17,23,20,0)	(to)	(to)	8.8 (3.3 to 18.2)	15.6 (7.8 to 26.9)

Notes:

[83] - No participants analyzed;antibodies titer to strains of meningococcal serogroupB was not applicable.

[84] - No participants analyzed;antibodies titer to strains of meningococcal serogroupB was not applicable.

End point values	Adolescents - Group 3: Bexsero + Menveo	Adolescents - Group 4: Trumenba + Menveo	Adolescents - Group 5: MenQuadfi	Adolescents - Group 6: Sanofi MenB
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	24	17	23	20
Units: percentage of participants				
number (confidence interval 95%)				
Day 61 (n=0,0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Day 211 (n=68,64,24,17,23,20,0)	16.7 (4.7 to 37.4)	0 (0 to 19.5)	0 (0 to 14.8)	15.0 (3.2 to 37.9)

End point values	Adolescents - Group 7: PENBRAYA			
Subject group type	Reporting group			
Number of subjects analysed	0 ^[85]			
Units: percentage of participants				
number (confidence interval 95%)				
Day 61 (n=0,0,0,0,0,0,0)	(to)			
Day 211 (n=68,64,24,17,23,20,0)	(to)			

Notes:

[85] - No participants analyzed;antibodies titer to strains of meningococcal serogroupB was not applicable.

Statistical analyses

No statistical analyses for this end point

Secondary: Adults Only: Percentage of Participants With Seroresponse Against Meningococcal Serogroups A, C, W and Y Strains at Days 1, 31, 61, 181 and 211

End point title	Adults Only: Percentage of Participants With Seroresponse
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End point description:

The seroresponse was defined as post-vaccination titers $\geq 1:16$ for participants with pre-vaccination hSBA titers $< 1:4$, or post-vaccination titers ≥ 4 times the pre-vaccination titer for participants with a pre-vaccination titer $\geq$ the LLOQ. The LLOQ was a titer of 1:4, and it is the same as the LOD for the meningococcal serogroups A, C, W and Y hSBA assay. Day 31 (FAS1-adults): Participants who were vaccinated per protocol at Day 1 and had 1 valid post-vaccination blood sample at Day 31. Day 61 (FAS2-adults): Participants who were vaccinated per protocol at Days 1 and 31, and had 1 valid post-vaccination blood sample at Day 61. Days 181 and 211 (FAS3-adults): Participants who were vaccinated per protocol at Day 181 and had 1 valid post-vaccination blood sample at Day 211. The percentages are rounded off to the tenth decimal place. Here, n= Number of participants analyzed for each serogroup at specific timepoints; and -99999 and 99999= No participants analyzed at specific timepoints.

End point type Secondary

End point timeframe:

Pre-vaccination on Days 1, 31 and 181 and 1 month after second and third vaccination (Day 61 and Day 211, respectively)

Notes:

[86] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As specified in the endpoint title, only adult participants were included in the analysis for this endpoint.

End point values	Adults - Group 1: MenPenta Formulation 1	Adults - Group 2: MenPenta Formulation 2	Adults - Group 3: Bexsero + Menveo	Adults - Group 4: Trumenba + Menveo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	13	16	12
Units: percentage of participants				
number (confidence interval 95%)				
Serogroup A: Day 31 (n=2,3,4,2,1,4)	50.0 (1.3 to 98.7)	66.7 (9.4 to 99.2)	100 (39.8 to 100)	100 (15.8 to 100)
Serogroup A: Day 61 (n=3,1,0,3,0,3)	100 (29.2 to 100)	100 (2.5 to 100)	99999 (-99999 to 99999)	66.7 (9.4 to 99.2)
Serogroup A: Day 181 (n=10,11,9,8,11,8)	60.0 (26.2 to 87.8)	63.6 (30.8 to 89.1)	66.7 (29.9 to 92.5)	75.0 (34.9 to 96.8)
Serogroup A: Day 211 (n=11,11,16,12,15,13)	100 (71.5 to 100)	100 (71.5 to 100)	68.8 (41.3 to 89.0)	50.0 (21.1 to 78.9)
Serogroup C: Day 31 (n=1,3,5,5,4,10)	100 (2.5 to 100)	66.7 (9.4 to 99.2)	100 (47.8 to 100)	100 (47.8 to 100)
Serogroup C: Day 61 (n=5,2,5,4,5,6)	100 (47.8 to 100)	100 (15.8 to 100)	100 (47.8 to 100)	100 (39.8 to 100)
Serogroup C: Day 181 (n=9,13,13,8,13,9)	100 (66.4 to 100)	92.3 (64.0 to 99.8)	92.3 (64.0 to 99.8)	87.5 (47.3 to 99.7)
Serogroup C: Day 211 (n=11,12,15,11,16,15)	100 (71.5 to 100)	91.7 (61.5 to 99.8)	60.0 (32.3 to 83.7)	81.8 (48.2 to 97.7)
Serogroup W: Day 31 (n=1,2,3,2,1,3)	100 (2.5 to 100)	100 (15.8 to 100)	100 (29.2 to 100)	50.0 (1.3 to 98.7)
Serogroup W: Day 61 (n=2,1,0,1,0,3)	100 (15.8 to 100)	100 (2.5 to 100)	99999 (-99999 to 99999)	100 (2.5 to 100)
Serogroup W: Day 181 (n=10,11,11,11,14,16)	90.0 (55.5 to 99.7)	72.7 (39.0 to 94.0)	36.4 (10.9 to 69.2)	72.7 (39.0 to 94.0)
Serogroup W: Day 211 (n=12,12,15,12,16,15)	91.7 (61.5 to 99.8)	91.7 (61.5 to 99.8)	53.3 (26.6 to 78.7)	83.3 (51.6 to 97.9)
Serogroup Y: Day 31 (n=2,1,4,3,4,10)	100 (15.8 to 100)	100 (2.5 to 100)	100 (39.8 to 100)	100 (29.2 to 100)
Serogroup Y: Day 61 (n=1,0,0,2,0,3)	100 (2.5 to 100)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	50.0 (1.3 to 98.7)
Serogroup Y: Day 181 (n=3,3,5,2,5,7)	100 (29.2 to 100)	66.7 (9.4 to 99.2)	40.0 (5.3 to 85.3)	50.0 (1.3 to 98.7)

Serogroup Y: Day 211 (n=13,12,14,11,15,16)	92.3 (64.0 to 99.8)	100 (73.5 to 100)	50.0 (23.0 to 77.0)	90.9 (58.7 to 99.8)
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End point values	Adults - Group 5: MenQuadfi	Adults - Group 6: Sanofi MenB		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	16		
Units: percentage of participants				
number (confidence interval 95%)				
Serogroup A: Day 31 (n=2,3,4,2,1,4)	100 (2.5 to 100)	100 (39.8 to 100)		
Serogroup A: Day 61 (n=3,1,0,3,0,3)	99999 (-99999 to 99999)	100 (29.2 to 100)		
Serogroup A: Day 181 (n=10,11,9,8,11,8)	72.7 (39.0 to 94.0)	75.0 (34.9 to 96.8)		
Serogroup A: Day 211 (n=11,11,16,12,15,13)	86.7 (59.5 to 98.3)	100 (75.3 to 100)		
Serogroup C: Day 31 (n=1,3,5,5,4,10)	100 (39.8 to 100)	40.0 (12.2 to 73.8)		
Serogroup C: Day 61 (n=5,2,5,4,5,6)	100 (47.8 to 100)	83.3 (35.9 to 99.6)		
Serogroup C: Day 181 (n=9,13,13,8,13,9)	69.2 (38.6 to 90.9)	33.3 (7.5 to 70.1)		
Serogroup C: Day 211 (n=11,12,15,11,16,15)	93.8 (69.8 to 99.8)	73.3 (44.9 to 92.2)		
Serogroup W: Day 31 (n=1,2,3,2,1,3)	100 (2.5 to 100)	0 (0 to 70.8)		
Serogroup W: Day 61 (n=2,1,0,1,0,3)	99999 (-99999 to 99999)	0 (0 to 70.8)		
Serogroup W: Day 181 (n=10,11,11,11,14,16)	85.7 (57.2 to 98.2)	6.3 (0.2 to 30.2)		
Serogroup W: Day 211 (n=12,12,15,12,16,15)	93.8 (69.8 to 99.8)	26.7 (7.8 to 55.1)		
Serogroup Y: Day 31 (n=2,1,4,3,4,10)	75.0 (19.4 to 99.4)	0 (0 to 30.8)		
Serogroup Y: Day 61 (n=1,0,0,2,0,3)	99999 (-99999 to 99999)	0 (0 to 70.8)		
Serogroup Y: Day 181 (n=3,3,5,2,5,7)	80.0 (28.4 to 99.5)	0 (0 to 41.0)		
Serogroup Y: Day 211 (n=13,12,14,11,15,16)	93.3 (68.1 to 99.8)	6.3 (0.2 to 30.2)		

Statistical analyses

No statistical analyses for this end point

Secondary: Adults Only: Percentage of Participants With Human Complement Serum Bactericidal Assay Titer $\geq 1:8$ Against Meningococcal Serogroups A, C, W and Y Strains at Days 1, 31, 61, 181 and 211

End point title	Adults Only: Percentage of Participants With Human Complement Serum Bactericidal Assay Titer $\geq 1:8$ Against Meningococcal Serogroups A, C, W and Y Strains at Days 1, 31, 61, 181 and 211 ^[87]
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End point description:

The percentage of participants with antibody titers $\geq 1:8$ against meningococcal serogroups A, C, W and Y was measured by hSBA. The 95% CI for the single percentage was based on the Clopper-Pearson method. Day 31 (FAS1–adults): Participants who were vaccinated per protocol at Day 1 and had 1 valid post-vaccination blood sample at Day 31. Day 61 (FAS2–adults): Participants who were vaccinated per protocol at Days 1 and 31, and had 1 valid post-vaccination blood sample at Day 61. Days 181 and 211 (FAS3–adults): Participants who were vaccinated per protocol at Day 181 and had 1 valid post-vaccination blood sample at Day 211. The percentages are rounded off to the tenth decimal place. Here, n= Number of participants analyzed for each serogroup at specific timepoints; and -99999 and 99999= No participants analyzed at specific timepoints.

End point type	Secondary
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End point timeframe:

Pre-vaccination on Days 1, 31 and 181 and 1 month after second and third vaccination (Day 61 and Day 211, respectively)

Notes:

[87] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As specified in the endpoint title, only adult participants were included in the analysis for this endpoint.

End point values	Adults - Group 1: MenPenta Formulation 1	Adults - Group 2: MenPenta Formulation 2	Adults - Group 3: Bexsero + Menveo	Adults - Group 4: Trumenba + Menveo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	15	17	14
Units: percentage of participants				
number (confidence interval 95%)				
Serogroup A: Day 1 (n=5,8,8,8,7,12)	100 (47.8 to 100)	87.5 (47.3 to 99.7)	62.5 (24.5 to 91.5)	75.0 (34.9 to 96.8)
Serogroup A: Day 31 (n=2,3,4,2,1,4)	50.0 (1.3 to 98.7)	100 (29.2 to 100)	100 (39.8 to 100)	100 (15.8 to 100)
Serogroup A: Day 61 (n=3,1,0,3,0,3)	100 (29.2 to 100)	100 (2.5 to 100)	99999 (-99999 to 99999)	100 (29.2 to 100)
Serogroup A: Day 181 (n=11,12,10,8,12,8)	90.9 (58.7 to 99.8)	100 (73.5 to 100)	100 (69.2 to 100)	100 (63.1 to 100)
Serogroup A: Day 211 (n=12,12,17,12,15,14)	100 (73.5 to 100)	100 (73.5 to 100)	100 (80.5 to 100)	91.7 (61.5 to 99.8)
Serogroup C: Day 1 (n=2,6,7,7,8,13)	0 (0 to 84.2)	50.0 (11.8 to 88.2)	71.4 (29.0 to 96.3)	57.1 (18.4 to 90.1)
Serogroup C: Day 31 (n=2,4,6,5,4,10)	100 (15.8 to 100)	100 (39.8 to 100)	100 (54.1 to 100)	100 (47.8 to 100)
Serogroup C: Day 61 (n=5,3,6,5,5,6)	100 (47.8 to 100)	100 (29.2 to 100)	100 (54.1 to 100)	100 (47.8 to 100)
Serogroup C: Day 181 (n=9,14,14,9,13,9)	100 (66.4 to 100)	100 (76.8 to 100)	100 (76.8 to 100)	88.9 (51.8 to 99.7)
Serogroup C: Day 211 (n=12,12,16,12,16,15)	100 (73.5 to 100)	100 (73.5 to 100)	93.8 (69.8 to 99.8)	91.7 (61.5 to 99.8)
Serogroup W: Day 1 (n=5,7,8,7,7,13)	20.0 (0.5 to 71.6)	57.1 (18.4 to 90.1)	75.0 (34.9 to 96.8)	57.1 (18.4 to 90.1)
Serogroup W: Day 31 (n=1,2,3,2,2,3)	100 (2.5 to 100)	100 (15.8 to 100)	100 (29.2 to 100)	100 (15.8 to 100)
Serogroup W: Day 61 (n=3,2,0,1,1,3)	100 (29.2 to 100)	100 (15.8 to 100)	99999 (-99999 to 99999)	100 (2.5 to 100)
Serogroup W: Day 181 (n=12,12,13,12,16,16)	100 (73.5 to 100)	91.7 (61.5 to 99.8)	100 (75.3 to 100)	91.7 (61.5 to 99.8)
Serogroup W: Day 211 (n=13,12,17,12,16,15)	100 (75.3 to 100)	100 (73.5 to 100)	100 (80.5 to 100)	100 (73.5 to 100)
Serogroup Y: Day 1 (n=3,5,7,6,7,13)	33.3 (0.8 to 90.6)	40.0 (5.3 to 85.3)	71.4 (29.0 to 96.3)	50.0 (11.8 to 88.2)

Serogroup Y: Day 31 (n=3,2,5,5,4,10)	100 (29.2 to 100)	100 (15.8 to 100)	100 (47.8 to 100)	100 (47.8 to 100)
Serogroup Y: Day 61 (n=1,1,0,2,1,3)	100 (2.5 to 100)	100 (2.5 to 100)	99999 (-99999 to 99999)	100 (15.8 to 100)
Serogroup Y: Day 181 (n=6,5,6,4,6,7)	100 (54.1 to 100)	100 (47.8 to 100)	100 (54.1 to 100)	100 (39.8 to 100)
Serogroup Y: Day 211 (n=16,15,17,14,18,16)	100 (79.4 to 100)	100 (78.2 to 100)	94.1 (71.3 to 99.9)	100 (76.8 to 100)

End point values	Adults - Group 5: MenQuadfi	Adults - Group 6: Sanofi MenB		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	18	16		
Units: percentage of participants				
number (confidence interval 95%)				
Serogroup A: Day 1 (n=5,8,8,8,7,12)	71.4 (29.0 to 96.3)	58.3 (27.7 to 84.8)		
Serogroup A: Day 31 (n=2,3,4,2,1,4)	100 (2.5 to 100)	100 (39.8 to 100)		
Serogroup A: Day 61 (n=3,1,0,3,0,3)	99999 (-99999 to 99999)	100 (29.2 to 100)		
Serogroup A: Day 181 (n=11,12,10,8,12,8)	100 (73.5 to 100)	100 (63.1 to 100)		
Serogroup A: Day 211 (n=12,12,17,12,15,14)	100 (78.2 to 100)	100 (76.8 to 100)		
Serogroup C: Day 1 (n=2,6,7,7,8,13)	50.0 (15.7 to 84.3)	15.4 (1.9 to 45.4)		
Serogroup C: Day 31 (n=2,4,6,5,4,10)	100 (39.8 to 100)	70.0 (34.8 to 93.3)		
Serogroup C: Day 61 (n=5,3,6,5,5,6)	100 (47.8 to 100)	83.3 (35.9 to 99.6)		
Serogroup C: Day 181 (n=9,14,14,9,13,9)	100 (75.3 to 100)	66.7 (29.9 to 92.5)		
Serogroup C: Day 211 (n=12,12,16,12,16,15)	100 (79.4 to 100)	93.3 (68.1 to 99.8)		
Serogroup W: Day 1 (n=5,7,8,7,7,13)	57.1 (18.4 to 90.1)	23.1 (5.0 to 53.8)		
Serogroup W: Day 31 (n=1,2,3,2,2,3)	100 (15.8 to 100)	0 (0 to 70.8)		
Serogroup W: Day 61 (n=3,2,0,1,1,3)	100 (2.5 to 100)	66.7 (9.4 to 99.2)		
Serogroup W: Day 181 (n=12,12,13,12,16,16)	100 (79.4 to 100)	50.0 (24.7 to 75.3)		
Serogroup W: Day 211 (n=13,12,17,12,16,15)	100 (79.4 to 100)	60.0 (32.3 to 83.7)		
Serogroup Y: Day 1 (n=3,5,7,6,7,13)	28.6 (3.7 to 71.0)	15.4 (1.9 to 45.4)		
Serogroup Y: Day 31 (n=3,2,5,5,4,10)	100 (39.8 to 100)	10.0 (0.3 to 44.5)		
Serogroup Y: Day 61 (n=1,1,0,2,1,3)	100 (2.5 to 100)	33.3 (0.8 to 90.6)		
Serogroup Y: Day 181 (n=6,5,6,4,6,7)	100 (54.1 to 100)	28.6 (3.7 to 71.0)		
Serogroup Y: Day 211 (n=16,15,17,14,18,16)	100 (81.5 to 100)	25.0 (7.3 to 52.4)		

Statistical analyses

No statistical analyses for this end point

Secondary: Adults Only: Geometric Mean Titers of Antibodies Against Meningococcal Serogroups A, C, W and Y Strains at Days 1, 31, 61, 181 and 211

End point title	Adults Only: Geometric Mean Titers of Antibodies Against Meningococcal Serogroups A, C, W and Y Strains at Days 1, 31, 61, 181 and 211 ^[88]
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End point description:

The antibodies titer against meningococcal serogroups A, C, W and Y was measured by hSBA and the results were expressed as GMT. The 95% CI for the single percentage was based on the Clopper-Pearson method. Day 31 (FAS1–adults): Participants who were vaccinated per protocol at Day 1 and had 1 valid post-vaccination blood sample at Day 31. Day 61 (FAS2–adults): Participants who were vaccinated per protocol at Days 1 and 31, and had 1 valid post-vaccination blood sample at Day 61. Days 181 and 211 (FAS3–adults): Participants who were vaccinated per protocol at Day 181 and had 1 valid post-vaccination blood sample at Day 211. Here, n= Number of participants analyzed for each serogroup at specific timepoints; -9999 and 9999= The 95% CI was not computed, if number analyzed was ≤5 or standard deviation was 0; and -99999 and 99999= No participants analyzed at specific timepoints.

End point type	Secondary
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End point timeframe:

Pre-vaccination on Days 1, 31 and 181 and 1 month after second and third vaccination (Day 61 and Day 211, respectively)

Notes:

[88] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As specified in the endpoint title, only adult participants were included in the analysis for this endpoint.

End point values	Adults - Group 1: MenPenta Formulation 1	Adults - Group 2: MenPenta Formulation 2	Adults - Group 3: Bexsero + Menveo	Adults - Group 4: Trumenba + Menveo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	15	17	14
Units: titer				
geometric mean (confidence interval 95%)				
Serogroup A: Day 1 (n=5,8,8,8,7,12)	10.6 (-9999 to 9999)	24.7 (8.86 to 68.7)	14.7 (4.02 to 53.5)	22.6 (5.29 to 96.7)
Serogroup A: Day 31 (n=2,3,4,2,1,4)	8.00 (-9999 to 9999)	256 (-9999 to 9999)	256 (-9999 to 9999)	45.3 (-9999 to 9999)
Serogroup A: Day 61 (n=3,1,0,3,0,3)	323 (-9999 to 9999)	512 (-9999 to 9999)	99999 (-99999 to 99999)	64.0 (-9999 to 9999)
Serogroup A: Day 181 (n=11,12,10,8,12,8)	77.3 (22.5 to 265)	95.9 (44.8 to 205)	59.7 (31.5 to 113)	140 (30.2 to 645)
Serogroup A: Day 211 (n=12,12,17,12,15,14)	1722 (685 to 4332)	1085 (474 to 2484)	157 (67.6 to 365)	53.8 (19.5 to 148)
Serogroup C: Day 1 (n=2,6,7,7,8,13)	2.00 (-9999 to 9999)	8.98 (1.90 to 42.5)	14.5 (3.55 to 59.1)	6.56 (2.20 to 19.6)
Serogroup C: Day 31 (n=2,4,6,5,4,10)	45.3 (-9999 to 9999)	215 (-9999 to 9999)	724 (486 to 1078)	512 (-9999 to 9999)

Serogroup C: Day 61 (n=5,3,6,5,5,6)	676 (-9999 to 9999)	203 (-9999 to 9999)	203 (56.8 to 726)	388 (-9999 to 9999)
Serogroup C: Day 181 (n=9,14,14,9,13,9)	219 (99.7 to 483)	312 (165 to 590)	122 (52.7 to 281)	87.1 (22.9 to 331)
Serogroup C: Day 211 (n=12,12,16,12,16,15)	912 (558 to 1490)	724 (266 to 1973)	76.1 (30.6 to 189)	85.4 (28.8 to 253)
Serogroup W: Day 1 (n=5,7,8,7,7,13)	2.64 (-9999 to 9999)	16.0 (2.18 to 117)	17.4 (4.02 to 75.7)	10.8 (2.86 to 40.6)
Serogroup W: Day 31 (n=1,2,3,2,2,3)	1024 (-9999 to 9999)	512 (-9999 to 9999)	512 (-9999 to 9999)	181 (-9999 to 9999)
Serogroup W: Day 61 (n=3,2,0,1,1,3)	203 (-9999 to 9999)	724 (-9999 to 9999)	99999 (-99999 to 99999)	64.0 (-9999 to 9999)
Serogroup W: Day 181 (n=12,12,13,12,16,16)	228 (96.8 to 537)	108 (35.9 to 322)	93.0 (46.3 to 187)	102 (39.5 to 261)
Serogroup W: Day 211 (n=13,12,17,12,16,15)	436 (195 to 976)	384 (127 to 1155)	163 (70.2 to 380)	136 (68.1 to 270)
Serogroup Y: Day 1 (n=3,5,7,6,7,13)	3.17 (-9999 to 9999)	6.06 (-9999 to 9999)	23.8 (3.62 to 156)	10.1 (1.13 to 90.1)
Serogroup Y: Day 31 (n=3,2,5,5,4,10)	203 (-9999 to 9999)	181 (-9999 to 9999)	588 (-9999 to 9999)	294 (-9999 to 9999)
Serogroup Y: Day 61 (n=1,1,0,2,1,3)	128 (-9999 to 9999)	1024 (-9999 to 9999)	99999 (-99999 to 99999)	362 (-9999 to 9999)
Serogroup Y: Day 181 (n=6,5,6,4,6,7)	181 (23.4 to 1398)	294 (-9999 to 9999)	128 (26.0 to 630)	215 (-9999 to 9999)
Serogroup Y: Day 211 (n=16,15,17,14,18,16)	724 (409 to 1283)	371 (185 to 741)	128 (52.5 to 312)	256 (99.8 to 657)

End point values	Adults - Group 5: MenQuadfi	Adults - Group 6: Sanofi MenB		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	18	16		
Units: titer				
geometric mean (confidence interval 95%)				
Serogroup A: Day 1 (n=5,8,8,8,7,12)	14.5 (4.15 to 50.6)	8.48 (4.05 to 17.7)		
Serogroup A: Day 31 (n=2,3,4,2,1,4)	256 (-9999 to 9999)	45.3 (-9999 to 9999)		
Serogroup A: Day 61 (n=3,1,0,3,0,3)	99999 (-99999 to 99999)	102 (-9999 to 9999)		
Serogroup A: Day 181 (n=11,12,10,8,12,8)	60.4 (25.8 to 141)	58.7 (33.0 to 104)		
Serogroup A: Day 211 (n=12,12,17,12,15,14)	140 (66.2 to 298)	2048 (879 to 4769)		
Serogroup C: Day 1 (n=2,6,7,7,8,13)	10.4 (3.41 to 31.6)	4.45 (2.30 to 8.60)		
Serogroup C: Day 31 (n=2,4,6,5,4,10)	256 (-9999 to 9999)	14.9 (4.93 to 45.2)		
Serogroup C: Day 61 (n=5,3,6,5,5,6)	588 (-9999 to 9999)	35.9 (6.66 to 194)		
Serogroup C: Day 181 (n=9,14,14,9,13,9)	207 (88.9 to 481)	13.7 (4.32 to 43.5)		
Serogroup C: Day 211 (n=12,12,16,12,16,15)	450 (214 to 944)	80.6 (32.7 to 199)		
Serogroup W: Day 1 (n=5,7,8,7,7,13)	11.9 (2.85 to 49.5)	4.22 (2.02 to 8.80)		
Serogroup W: Day 31 (n=1,2,3,2,2,3)	362 (-9999 to 9999)	2.52 (-9999 to 9999)		

Serogroup W: Day 61 (n=3,2,0,1,1,3)	128 (-9999 to 9999)	6.35 (-9999 to 9999)		
Serogroup W: Day 181 (n=12,12,13,12,16,16)	123 (58.2 to 258)	5.91 (3.05 to 11.4)		
Serogroup W: Day 211 (n=13,12,17,12,16,15)	378 (195 to 732)	8.77 (4.08 to 18.9)		
Serogroup Y: Day 1 (n=3,5,7,6,7,13)	6.56 (1.45 to 29.8)	3.06 (1.63 to 5.75)		
Serogroup Y: Day 31 (n=3,2,5,5,4,10)	304 (-9999 to 9999)	3.25 (1.75 to 6.04)		
Serogroup Y: Day 61 (n=1,1,0,2,1,3)	256 (-9999 to 9999)	4.00 (-9999 to 9999)		
Serogroup Y: Day 181 (n=6,5,6,4,6,7)	181 (35.0 to 936)	3.62 (1.42 to 9.26)		
Serogroup Y: Day 211 (n=16,15,17,14,18,16)	310 (165 to 585)	4.97 (1.98 to 12.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: Adults Only: Percentage of Participants With Human Complement Serum Bactericidal Assay Titer $\geq$ Lower Limit of Quantification Against Meningococcal Serogroups A, C, W and Y Strains at Days 1, 31, 61, 181 and 211

End point title	Adults Only: Percentage of Participants With Human Complement Serum Bactericidal Assay Titer $\geq$ Lower Limit of Quantification Against Meningococcal Serogroups A, C, W and Y Strains at Days 1, 31, 61, 181 and 211 ^[89]
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End point description:

The percentage of participants with antibody titers $\geq$ LLOQ against meningococcal serogroups A, C, W and Y was measured by hSBA. The LLOQ was a titer of 1:4, and it is the same as the LOD for the meningococcal serogroups A, C, W and Y hSBA assay. The 95% CI for the single percentage was based on the Clopper-Pearson method. Day 31 (FAS1–adults): Participants who were vaccinated per protocol at Day 1 and had 1 valid post-vaccination blood sample at Day 31. Day 61 (FAS2–adults): Participants who were vaccinated per protocol at Days 1 and 31, and had 1 valid post-vaccination blood sample at Day 61. Days 181 and 211 (FAS3–adults): Participants who were vaccinated per protocol at Day 181 and had 1 valid post-vaccination blood sample at Day 211. The percentages are rounded off to the tenth decimal place. Here, n= Number of participants analyzed for each serogroup at specific timepoints; and -99999 and 99999= No participants analyzed at specific timepoints.

End point type	Secondary
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End point timeframe:

Pre-vaccination on Days 1, 31 and 181 and 1 month after second and third vaccination (Day 61 and Day 211, respectively)

Notes:

[89] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As specified in the endpoint title, only adult participants were included in the analysis for this endpoint.

End point values	Adults - Group 1: MenPenta Formulation 1	Adults - Group 2: MenPenta Formulation 2	Adults - Group 3: Bexsero + Menveo	Adults - Group 4: Trumenba + Menveo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	15	17	14
Units: percentage of participants				
number (confidence interval 95%)				

Serogroup A: Day 1 (n=5,8,8,8,7,12)	100 (47.8 to 100)	87.5 (47.3 to 99.7)	75.0 (34.9 to 96.8)	100 (63.1 to 100)
Serogroup A: Day 31 (n=2,3,4,2,1,4)	50.0 (1.3 to 98.7)	100 (29.2 to 100)	100 (39.8 to 100)	100 (15.8 to 100)
Serogroup A: Day 61 (n=3,1,0,3,0,3)	100 (29.2 to 100)	100 (2.5 to 100)	99999 (-99999 to 99999)	100 (29.2 to 100)
Serogroup A: Day 181 (n=11,12,10,8,12,8)	90.9 (58.7 to 99.8)	100 (73.5 to 100)	100 (69.2 to 100)	100 (63.1 to 100)
Serogroup A: Day 211 (n=12,12,17,12,15,14)	100 (73.5 to 100)	100 (73.5 to 100)	100 (80.5 to 100)	91.7 (61.5 to 99.8)
Serogroup C: Day 1 (n=2,6,7,7,8,13)	0 (0 to 84.2)	66.7 (22.3 to 95.7)	71.4 (29.0 to 96.3)	71.4 (29.0 to 96.3)
Serogroup C: Day 31 (n=2,4,6,5,4,10)	100 (15.8 to 100)	100 (39.8 to 100)	100 (54.1 to 100)	100 (47.8 to 100)
Serogroup C: Day 61 (n=5,3,6,5,5,6)	100 (47.8 to 100)	100 (29.2 to 100)	100 (54.1 to 100)	100 (47.8 to 100)
Serogroup C: Day 181 (n=9,14,14,9,13,9)	100 (66.4 to 100)	100 (76.8 to 100)	100 (76.8 to 100)	88.9 (51.8 to 99.7)
Serogroup C: Day 211 (n=12,12,16,12,16,15)	100 (73.5 to 100)	100 (73.5 to 100)	100 (79.4 to 100)	91.7 (61.5 to 99.8)
Serogroup W: Day 1 (n=5,7,8,7,7,13)	20.0 (0.5 to 71.6)	57.1 (18.4 to 90.1)	87.5 (47.3 to 99.7)	71.4 (29.0 to 96.3)
Serogroup W: Day 31 (n=1,2,3,2,2,3)	100 (2.5 to 100)	100 (15.8 to 100)	100 (29.2 to 100)	100 (15.8 to 100)
Serogroup W: Day 61 (n=3,2,0,1,1,3)	100 (29.2 to 100)	100 (15.8 to 100)	99999 (-99999 to 99999)	100 (2.5 to 100)
Serogroup W: Day 181 (n=12,12,13,12,16,16)	100 (73.5 to 100)	91.7 (61.5 to 99.8)	100 (75.3 to 100)	100 (73.5 to 100)
Serogroup W: Day 211 (n=13,12,17,12,16,15)	100 (75.3 to 100)	100 (73.5 to 100)	100 (80.5 to 100)	100 (73.5 to 100)
Serogroup Y: Day 1 (n=3,5,7,6,7,13)	33.3 (0.8 to 90.6)	60.0 (14.7 to 94.7)	71.4 (29.0 to 96.3)	50.0 (11.8 to 88.2)
Serogroup Y: Day 31 (n=3,2,5,5,4,10)	100 (29.2 to 100)	100 (15.8 to 100)	100 (47.8 to 100)	100 (47.8 to 100)
Serogroup Y: Day 61 (n=1,1,0,2,1,3)	100 (2.5 to 100)	100 (2.5 to 100)	99999 (-99999 to 99999)	100 (15.8 to 100)
Serogroup Y: Day 181 (n=6,5,6,4,6,7)	100 (54.1 to 100)	100 (47.8 to 100)	100 (54.1 to 100)	100 (39.8 to 100)
Serogroup Y: Day 211 (n=16,15,17,14,18,16)	100 (79.4 to 100)	100 (78.2 to 100)	94.1 (71.3 to 99.9)	100 (76.8 to 100)

End point values	Adults - Group 5: MenQuadfi	Adults - Group 6: Sanofi MenB		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	18	16		
Units: percentage of participants				
number (confidence interval 95%)				
Serogroup A: Day 1 (n=5,8,8,8,7,12)	85.7 (42.1 to 99.6)	83.3 (51.6 to 97.9)		
Serogroup A: Day 31 (n=2,3,4,2,1,4)	100 (2.5 to 100)	100 (39.8 to 100)		
Serogroup A: Day 61 (n=3,1,0,3,0,3)	99999 (-99999 to 99999)	100 (29.2 to 100)		
Serogroup A: Day 181 (n=11,12,10,8,12,8)	100 (73.5 to 100)	100 (63.1 to 100)		
Serogroup A: Day 211 (n=12,12,17,12,15,14)	100 (78.2 to 100)	100 (76.8 to 100)		

Serogroup C: Day 1 (n=2,6,7,7,8,13)	87.5 (47.3 to 99.7)	69.2 (38.6 to 90.9)		
Serogroup C: Day 31 (n=2,4,6,5,4,10)	100 (39.8 to 100)	90.0 (55.5 to 99.7)		
Serogroup C: Day 61 (n=5,3,6,5,5,6)	100 (47.8 to 100)	100 (54.1 to 100)		
Serogroup C: Day 181 (n=9,14,14,9,13,9)	100 (75.3 to 100)	77.8 (40.0 to 97.2)		
Serogroup C: Day 211 (n=12,12,16,12,16,15)	100 (79.4 to 100)	100 (78.2 to 100)		
Serogroup W: Day 1 (n=5,7,8,7,7,13)	85.7 (42.1 to 99.6)	46.2 (19.2 to 74.9)		
Serogroup W: Day 31 (n=1,2,3,2,2,3)	100 (15.8 to 100)	33.3 (0.8 to 90.6)		
Serogroup W: Day 61 (n=3,2,0,1,1,3)	100 (2.5 to 100)	66.7 (9.4 to 99.2)		
Serogroup W: Day 181 (n=12,12,13,12,16,16)	100 (79.4 to 100)	50.0 (24.7 to 75.3)		
Serogroup W: Day 211 (n=13,12,17,12,16,15)	100 (79.4 to 100)	60.0 (32.3 to 83.7)		
Serogroup Y: Day 1 (n=3,5,7,6,7,13)	57.1 (18.4 to 90.1)	15.4 (1.9 to 45.4)		
Serogroup Y: Day 31 (n=3,2,5,5,4,10)	100 (39.8 to 100)	40.0 (12.2 to 73.8)		
Serogroup Y: Day 61 (n=1,1,0,2,1,3)	100 (2.5 to 100)	33.3 (0.8 to 90.6)		
Serogroup Y: Day 181 (n=6,5,6,4,6,7)	100 (54.1 to 100)	28.6 (3.7 to 71.0)		
Serogroup Y: Day 211 (n=16,15,17,14,18,16)	100 (81.5 to 100)	37.5 (15.2 to 64.6)		

Statistical analyses

No statistical analyses for this end point

Secondary: Adults Only: Percentage of Participants With Seroresponse Against Reference Strains of Meningococcal Serogroup B at Days 1, 31, 61, 181 and 211

End point title	Adults Only: Percentage of Participants With Seroresponse Against Reference Strains of Meningococcal Serogroup B at Days 1, 31, 61, 181 and 211 ^[90]
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End point description:

The seroresponse was defined as a 4-fold increase in hSBA titers from pre-vaccination to post-vaccination. The seroresponse against reference strains of meningococcal serogroup B at Days 31, 61 and 181 was not applicable. Therefore, no data collected and analyzed. Day 31 (FAS1-adults): Participants who were vaccinated per protocol at Day 1 and had 1 valid post-vaccination blood sample at Day 31. Day 61 (FAS2-adults): Participants who were vaccinated per protocol at Days 1 and 31, and had 1 valid post-vaccination blood sample at Day 61. Days 181 and 211 (FAS3-adults): Participants who were vaccinated per protocol at Day 181 and had 1 valid post-vaccination blood sample at Day 211. The percentages are rounded off to the tenth decimal place. Here, n= Number of participants analyzed for each serogroup at specific timepoints; and -99999 and 99999= No participants analyzed at specific timepoints.

End point type	Secondary
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End point timeframe:

Pre-vaccination on Days 1, 31 and 181 and 1 month after second and third vaccination (Day 61 and Day 211, respectively)

Notes:

[90] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As specified in the endpoint title, only adult participants were included in the analysis for this endpoint.

End point values	Adults - Group 1: MenPenta Formulation 1	Adults - Group 2: MenPenta Formulation 2	Adults - Group 3: Bexsero + Menveo	Adults - Group 4: Trumenba + Menveo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	17	17	14
Units: percentage of participants				
number (confidence interval 95%)				
Strain (A56): Day 31 (n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (A56): Day 61 (n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (A56): Day 181 (n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (A56): Day 211 (n=16,17,17,14,18,16)	75.0 (47.6 to 92.7)	64.7 (38.3 to 85.8)	0 (0 to 19.5)	85.7 (57.2 to 98.2)
Strain (B44): Day 31 (n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (B44): Day 61 (n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (B44): Day 181 (n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (B44): Day 211 (n=16,16,17,13,18,16)	50.0 (24.7 to 75.3)	56.3 (29.9 to 80.2)	29.4 (10.3 to 56.0)	76.9 (46.2 to 95.0)
Strain (A10): Day 31 (n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (A10): Day 61 (n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (A10): Day 181 (n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (A10): Day 211 (n=16,15,17,14,18,16)	37.5 (15.2 to 64.6)	40.0 (16.3 to 67.7)	0 (0 to 19.5)	7.1 (0.2 to 33.9)
Strain (B79): Day 31 (n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (B79): Day 61 (n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (B79): Day 181 (n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (B79): Day 211 (n=16,16,15,14,18,16)	81.3 (54.4 to 96.0)	81.3 (54.4 to 96.0)	60.0 (32.3 to 83.7)	28.6 (8.4 to 58.1)

End point values	Adults - Group 5: MenQuadfi	Adults - Group 6: Sanofi MenB		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	18	16		
Units: percentage of participants				
number (confidence interval 95%)				
Strain (A56): Day 31 (n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)		
Strain (A56): Day 61 (n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)		

Strain (A56): Day 181 (n=0,0,0,0,0)	99999 (-99999 to 99999) 0 (0 to 18.5)	99999 (-99999 to 99999) 75.0 (47.6 to 92.7)		
Strain (A56): Day 211 (n=16,17,17,14,18,16)				
Strain (B44): Day 31 (n=0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)		
Strain (B44): Day 61 (n=0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)		
Strain (B44): Day 181 (n=0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)		
Strain (B44): Day 211 (n=16,16,17,13,18,16)	0 (0 to 18.5)	62.5 (35.4 to 84.8)		
Strain (A10): Day 31 (n=0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)		
Strain (A10): Day 61 (n=0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)		
Strain (A10): Day 181 (n=0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)		
Strain (A10): Day 211 (n=16,15,17,14,18,16)	5.6 (0.1 to 27.3)	62.5 (35.4 to 84.8)		
Strain (B79): Day 31 (n=0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)		
Strain (B79): Day 61 (n=0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)		
Strain (B79): Day 181 (n=0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)		
Strain (B79): Day 211 (n=16,16,15,14,18,16)	0 (0 to 18.5)	100 (79.4 to 100)		

Statistical analyses

No statistical analyses for this end point

Secondary: Adults Only: Percentage of Participants With Human Complement Serum Bactericidal Assay Titer $\geq 1:4$ and $\geq 1:8$ Against Reference Strains of Meningococcal Serogroup B at Days 1, 31, 61, 181 and 211

End point title	Adults Only: Percentage of Participants With Human Complement Serum Bactericidal Assay Titer $\geq 1:4$ and $\geq 1:8$ Against Reference Strains of Meningococcal Serogroup B at Days 1, 31, 61, 181 and 211 ^[91]
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End point description:

Percentage of participants with antibody titers $\geq 1:4$ and $\geq 1:8$ against reference strains of meningococcal serogroup B was measured by hSBA. 95% CI for single percentage was based on Clopper-Pearson method. Antibodies titer against reference strains of meningococcal serogroup B at Days 31, 61 and 181 was not applicable. Therefore, no data collected and analyzed. Day 31 (FAS1–adults): Participants who were vaccinated per protocol at Day 1 and had 1 valid post-vaccination blood sample at Day 31. Day 61 (FAS2–adults): Participants who were vaccinated per protocol at Days 1 and 31, and had 1 valid post-vaccination blood sample at Day 61. Days 181 and 211 (FAS3–adults): Participants who were vaccinated per protocol at Day 181 and had 1 valid post-vaccination blood sample at Day 211. Percentages are rounded off to tenth decimal place. Here, n=Number of participants analyzed for each serogroup at specific timepoints; and -99999 and 99999=No participants analyzed at specific timepoints.

End point type	Secondary
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End point timeframe:

Pre-vaccination on Days 1, 31 and 181 and 1 month after second and third vaccination (Day 61 and Day 211, respectively)

Notes:

[91] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As specified in the endpoint title, only adult participants were included in the analysis for this endpoint.

End point values	Adults - Group 1: MenPenta Formulation 1	Adults - Group 2: MenPenta Formulation 2	Adults - Group 3: Bexsero + Menveo	Adults - Group 4: Trumenba + Menveo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	17	17	14
Units: percentage of participants				
number (confidence interval 95%)				
Strain (A56): Day 1, >= 1:4 (n=5,8,8,8,13)	100 (47.8 to 100)	100 (63.1 to 100)	100 (63.1 to 100)	100 (63.1 to 100)
Strain (A56): Day 1, >= 1:8 (n=5,8,8,8,13)	0 (0 to 52.2)	25.0 (3.2 to 65.1)	37.5 (8.5 to 75.5)	25.0 (3.2 to 65.1)
Strain (A56): Day 31, >= 1:4 (n=0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain(A56): Day 31, >= 1:8 (n=0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (A56): Day 61, >= 1:4 (n=0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (A56): Day 61, >= 1:8 (n=0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (A56): Day 181, >= 1:4 (n=0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (A56): Day 181, >= 1:8 (n=0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (A56):Day211,>=1:4(n=16,17,17,14,1)	100 (79.4 to 100)	100 (80.5 to 100)	100 (80.5 to 100)	100 (76.8 to 100)
Strain (A56):Day211,>=1:8(n=16,17,17,14,1)	87.5 (61.7 to 98.4)	82.4 (56.6 to 96.2)	35.3 (14.2 to 61.7)	100 (76.8 to 100)
Strain (B44): Day 1, >= 1:4 (n=5,8,8,7,8,13)	20.0 (0.5 to 71.6)	75.0 (34.9 to 96.8)	100 (63.1 to 100)	100 (59.0 to 100)
Strain (B44): Day 1, >= 1:8 (n=5,8,8,7,8,13)	0 (0 to 52.2)	62.5 (24.5 to 91.5)	87.5 (47.3 to 99.7)	85.7 (42.1 to 99.6)
Strain (B44): Day 31, >= 1:4 (n=0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (B44): Day 31, >= 1:8 (n=0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (B44): Day 61, >= 1:4 (n=0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (B44): Day 61, >= 1:8 (n=0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (B44): Day 181, >= 1:4 (n=0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (B44): Day 181, >= 1:8 (n=0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (B44):Day 211, >= 1:4 (n=16,17,17,14,18,16)	100 (79.4 to 100)	94.1 (71.3 to 99.9)	100 (80.5 to 100)	100 (76.8 to 100)
Strain (B44):Day 211, >= 1:8 (n=16,17,17,14,18,16)	100 (79.4 to 100)	94.1 (71.3 to 99.9)	100 (80.5 to 100)	100 (76.8 to 100)
Strain (A10): Day 1, >= 1:4 (n=5,8,8,8,13)	0 (0 to 52.2)	25.0 (3.2 to 65.1)	25.0 (3.2 to 65.1)	12.5 (0.3 to 52.7)
Strain (A10): Day 1, >= 1:8 (n=5,8,8,8,13)	0 (0 to 52.2)	25.0 (3.2 to 65.1)	25.0 (3.2 to 65.1)	12.5 (0.3 to 52.7)
Strain (A10): Day 31, >= 1:4 (n=0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)

Strain (A10): Day 31, >= 1:8 (n=0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (A10): Day 61, >= 1:4 (n=0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (A10): Day 61, >= 1:8 (n=0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (A10): Day 181, >= 1:4 (n=0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (A10): Day 181, >= 1:8 (n=0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (A10):Day211,>=1:4(n=16,16,17,14,1	75.0 (47.6 to 92.7)	87.5 (61.7 to 98.4)	29.4 (10.3 to 56.0)	28.6 (8.4 to 58.1)
Strain (A10):Day211,>=1:8(n=16,16,17,14,1	68.8 (41.3 to 89.0)	81.3 (54.4 to 96.0)	23.5 (6.8 to 49.9)	21.4 (4.7 to 50.8)
Strain (B79): Day 1, >= 1:4 (n=5,8,7,8,8,13)	0 (0 to 52.2)	12.5 (0.3 to 52.7)	0 (0 to 41.0)	25.0 (3.2 to 65.1)
Strain (B79): Day 1, >= 1:8 (n=5,8,7,8,8,13)	0 (0 to 52.2)	12.5 (0.3 to 52.7)	0 (0 to 41.0)	25.0 (3.2 to 65.1)
Strain (B79): Day 31, >= 1:4 (n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (B79): Day 31, >= 1:8 (n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (B79): Day 61, >= 1:4 (n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (B79): Day 61, >= 1:8 (n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (B79): Day 181, >= 1:4 (n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (B79): Day 181, >= 1:8 (n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (B79):Day211,>=1:4(n=16,17,16,14,1	81.3 (54.4 to 96.0)	94.1 (71.3 to 99.9)	87.5 (61.7 to 98.4)	50.0 (23.0 to 77.0)
Strain (B79):Day211,>=1:8(n=16,17,16,14,1	81.3 (54.4 to 96.0)	94.1 (71.3 to 99.9)	87.5 (61.7 to 98.4)	50.0 (23.0 to 77.0)

End point values	Adults - Group 5: MenQuadfi	Adults - Group 6: Sanofi MenB		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	18	16		
Units: percentage of participants				
number (confidence interval 95%)				
Strain (A56): Day 1, >= 1:4 (n=5,8,8,8,8,13)	100 (63.1 to 100)	100 (75.3 to 100)		
Strain (A56): Day 1, >= 1:8 (n=5,8,8,8,8,13)	25.0 (3.2 to 65.1)	7.7 (0.2 to 36.0)		
Strain (A56): Day 31, >= 1:4 (n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)		
Strain(A56): Day 31, >= 1:8 (n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)		
Strain (A56): Day 61, >= 1:4 (n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)		
Strain (A56): Day 61, >= 1:8 (n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)		
Strain (A56): Day 181, >= 1:4 (n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)		
Strain (A56): Day 181, >= 1:8 (n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)		

Strain (A56):Day211,>=1:4(n=16,17,17,14,1	100 (81.5 to 100)	100 (79.4 to 100)		
Strain (A56):Day211,>=1:8(n=16,17,17,14,1	16.7 (3.6 to 41.4)	93.8 (69.8 to 99.8)		
Strain (B44): Day 1, >= 1:4 (n=5,8,8,7,8,13)	62.5 (24.5 to 91.5)	76.9 (46.2 to 95.0)		
Strain (B44): Day 1, >= 1:8 (n=5,8,8,7,8,13)	62.5 (24.5 to 91.5)	69.2 (38.6 to 90.9)		
Strain (B44): Day 31, >= 1:4 (n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)		
Strain (B44): Day 31, >= 1:8 (n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)		
Strain (B44): Day 61, >= 1:4 (n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)		
Strain (B44): Day 61, >= 1:8 (n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)		
Strain (B44): Day 181, >= 1:4 (n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)		
Strain (B44): Day 181, >= 1:8 (n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)		
Strain (B44):Day 211, >= 1:4 (n=16,17,17,14,18,16)	72.2 (46.5 to 90.3)	100 (79.4 to 100)		
Strain (B44):Day 211, >= 1:8 (n=16,17,17,14,18,16)	66.7 (41.0 to 86.7)	100 (79.4 to 100)		
Strain (A10): Day 1, >= 1:4 (n=5,8,8,8,8,13)	25.0 (3.2 to 65.1)	0 (0 to 24.7)		
Strain (A10): Day 1, >= 1:8 (n=5,8,8,8,8,13)	12.5 (0.3 to 52.7)	0 (0 to 24.7)		
Strain (A10): Day 31, >= 1:4 (n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)		
Strain (A10): Day 31, >= 1:8 (n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)		
Strain (A10): Day 61, >= 1:4 (n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)		
Strain (A10): Day 61, >= 1:8 (n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)		
Strain (A10): Day 181, >= 1:4 (n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)		
Strain (A10): Day 181, >= 1:8 (n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)		
Strain (A10):Day211,>=1:4(n=16,16,17,14,1	22.2 (6.4 to 47.6)	87.5 (61.7 to 98.4)		
Strain (A10):Day211,>=1:8(n=16,16,17,14,1	16.7 (3.6 to 41.4)	87.5 (61.7 to 98.4)		
Strain (B79): Day 1, >= 1:4 (n=5,8,7,8,8,13)	37.5 (8.5 to 75.5)	0 (0 to 24.7)		
Strain (B79): Day 1, >= 1:8 (n=5,8,7,8,8,13)	37.5 (8.5 to 75.5)	0 (0 to 24.7)		
Strain (B79): Day 31, >= 1:4 (n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)		
Strain (B79): Day 31, >= 1:8 (n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)		
Strain (B79): Day 61, >= 1:4 (n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)		
Strain (B79): Day 61, >= 1:8 (n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)		
Strain (B79): Day 181, >= 1:4 (n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)		
Strain (B79): Day 181, >= 1:8 (n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)		
Strain (B79):Day211,>=1:4(n=16,17,16,14,1	33.3 (13.3 to 59.0)	100 (79.4 to 100)		

Strain (B79):Day211,>=1:8(n=16,17,16,14,1	33.3 (13.3 to 59.0)	100 (79.4 to 100)		
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Statistical analyses

No statistical analyses for this end point

Secondary: Adults Only: Geometric Mean Titers of Antibodies Against Reference Strains of Meningococcal Serogroup B at Days 1, 31, 61, 181 and 211

End point title	Adults Only: Geometric Mean Titers of Antibodies Against Reference Strains of Meningococcal Serogroup B at Days 1, 31, 61, 181 and 211 ^[92]
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End point description:

The antibodies titer against the reference strains of the meningococcal serogroup B was measured by hSBA and the results were expressed as GMT. The 95% CI for the single percentage was based on the Clopper-Pearson method. The antibodies titer against reference strains of meningococcal serogroup B at Days 31, 61 and 181 was not applicable. Therefore, no data collected and analyzed. Day 31 (FAS1-adults), Day 61 (FAS2-adults), and Days 181 and 211 (FAS3-adults) analysis set. Here, n= Number of participants analyzed for each serogroup at specific timepoints; -9999 and 9999= The 95% CI was not computed, if number analyzed was <=5 or standard deviation was 0; and -99999 and 99999= No participants analyzed at specific timepoints.

End point type	Secondary
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End point timeframe:

Pre-vaccination on Days 1, 31 and 181 and 1 month after second and third vaccination (Day 61 and Day 211, respectively)

Notes:

[92] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As specified in the endpoint title, only adult participants were included in the analysis for this endpoint.

End point values	Adults - Group 1: MenPenta Formulation 1	Adults - Group 2: MenPenta Formulation 2	Adults - Group 3: Bexsero + Menveo	Adults - Group 4: Trumenba + Menveo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	17	17	14
Units: titer				
geometric mean (confidence interval 95%)				
Strain (A56): Day 1 (n=5,8,8,8,13)	4.50 (-9999 to 9999)	7.77 (3.10 to 19.5)	7.78 (3.99 to 15.2)	6.10 (3.73 to 9.98)
Strain (A56): Day 31 (n=0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (A56): Day 61 (n=0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (A56): Day 181 (n=0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (A56): Day 211 (n=16,17,17,14,18,16)	82.3 (32.4 to 209)	53.4 (25.3 to 113)	6.78 (4.77 to 9.63)	159 (81.5 to 312)
Strain (B44): Day 1 (n=5,8,8,7,8,13)	2.49 (-9999 to 9999)	15.0 (3.97 to 56.7)	19.8 (6.96 to 56.4)	31.0 (8.86 to 108)
Strain (B44): Day 31 (n=0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (B44): Day 61 (n=0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)

Strain (B44): Day 181 (n=0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (B44): Day 211 (n=16,17,17,14,18,16)	84.9 (45.2 to 159)	77.0 (38.7 to 153)	29.4 (17.2 to 50.3)	215 (116 to 396)
Strain (A10): Day 1 (n=5,8,8,8,8,13)	2.50 (-9999 to 9999)	4.57 (1.67 to 12.5)	3.83 (1.93 to 7.60)	3.15 (1.82 to 5.46)
Strain (A10): Day 31 (n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (A10): Day 61 (n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (A10): Day 181 (n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (A10): Day 211 (n=16,16,17,14,18,16)	14.0 (7.25 to 27.0)	22.2 (11.3 to 43.4)	3.87 (2.64 to 5.69)	4.45 (2.33 to 8.50)
Strain (B79): Day 1 (n=5,8,7,8,8,13)	3.50 (-9999 to 9999)	6.63 (1.46 to 30.1)	3.50 (-9999 to 9999)	6.50 (2.45 to 17.3)
Strain (B79): Day 31 (n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (B79): Day 61 (n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (B79): Day 181 (n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (B79): Day 211 (n=16,17,16,14,18,16)	271 (75.5 to 972)	299 (121 to 738)	53.0 (18.2 to 154)	15.3 (5.31 to 44.3)

End point values	Adults - Group 5: MenQuadfi	Adults - Group 6: Sanofi MenB		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	18	16		
Units: titer				
geometric mean (confidence interval 95%)				
Strain (A56): Day 1 (n=5,8,8,8,8,13)	5.55 (3.99 to 7.72)	4.75 (4.23 to 5.33)		
Strain (A56): Day 31 (n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)		
Strain (A56): Day 61 (n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)		
Strain (A56): Day 181 (n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)		
Strain (A56): Day 211 (n=16,17,17,14,18,16)	5.38 (4.26 to 6.79)	98.3 (45.8 to 211)		
Strain (B44): Day 1 (n=5,8,8,7,8,13)	9.83 (2.67 to 36.2)	12.4 (5.05 to 30.7)		
Strain (B44): Day 31 (n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)		
Strain (B44): Day 61 (n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)		
Strain (B44): Day 181 (n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)		
Strain (B44): Day 211 (n=16,17,17,14,18,16)	12.2 (6.15 to 24.3)	126 (67.5 to 235)		
Strain (A10): Day 1 (n=5,8,8,8,8,13)	4.35 (1.53 to 12.3)	2.50 (-9999 to 9999)		
Strain (A10): Day 31 (n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)		
Strain (A10): Day 61 (n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)		

Strain (A10): Day 181 (n=0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)		
Strain (A10): Day 211 (n=16,16,17,14,18,16)	4.09 (2.35 to 7.12)	32.4 (15.6 to 67.4)		
Strain (B79): Day 1 (n=5,8,7,8,8,13)	7.16 (3.07 to 16.7)	3.50 (-9999 to 9999)		
Strain (B79): Day 31 (n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)		
Strain (B79): Day 61 (n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)		
Strain (B79): Day 181 (n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)		
Strain (B79): Day 211 (n=16,17,16,14,18,16)	6.43 (3.98 to 10.4)	1222 (640 to 2332)		

Statistical analyses

No statistical analyses for this end point

Secondary: Adults Only: Percentage of Participants With Human Complement Serum Bactericidal Assay Titer $\geq$ Lower Limit of Quantification Against Reference Strains of Meningococcal Serogroup B at Days 1, 31, 61, 181 and 211

End point title	Adults Only: Percentage of Participants With Human Complement Serum Bactericidal Assay Titer $\geq$ Lower Limit of Quantification Against Reference Strains of Meningococcal Serogroup B at Days 1, 31, 61, 181 and 211 ^[93]
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End point description:

Percentage of participants with antibody titers $\geq$ LLOQ against reference strains of meningococcal serogroup B was measured by hSBA. The 95% CI for single percentage was based on Clopper-Pearson method. Antibodies titer against reference strains of meningococcal serogroup B at Days 31, 61 and 181 was not applicable. Therefore, no data collected and analyzed. Day 31 (FAS1-adults), Day 61 (FAS2-adults), and Days 181 and 211 (FAS3-adults) analysis set. The percentages are rounded off to tenth decimal place. Here, n= Number of participants analyzed for each serogroup at specific timepoints; and -99999 and 99999= No participants analyzed at specific timepoints.

End point type	Secondary
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End point timeframe:

Pre-vaccination on Days 1, 31 and 181 and 1 month after second and third vaccination (Day 61 and Day 211, respectively)

Notes:

[93] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: As specified in the endpoint title, only adult participants were included in the analysis for this endpoint.

End point values	Adults - Group 1: MenPenta Formulation 1	Adults - Group 2: MenPenta Formulation 2	Adults - Group 3: Bexsero + Menveo	Adults - Group 4: Trumenba + Menveo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	17	17	14
Units: percentage of participants				
number (confidence interval 95%)				
Strain (A56): Day 1 (n=5,8,8,8,8,13)	0 (0 to 52.2)	25.0 (3.2 to 65.1)	37.5 (8.5 to 75.5)	25.0 (3.2 to 65.1)
Strain (A56): Day 31 (n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)

Strain (A56): Day 61 (n=0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (A56): Day 181 (n=0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (A56): Day 211 (n=16,17,17,14,18,16)	87.5 (61.7 to 98.4)	82.4 (56.6 to 96.2)	35.3 (14.2 to 61.7)	100 (76.8 to 100)
Strain (B44): Day 1 (n=5,8,8,7,8,13)	20.0 (0.5 to 71.6)	75.0 (34.9 to 96.8)	100 (63.1 to 100)	100 (59.0 to 100)
Strain (B44): Day 31 (n=0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (B44): Day 61 (n=0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (B44): Day 181 (n=0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (B44): Day 211 (n=16,17,17,14,18,16)	100 (79.4 to 100)	94.1 (71.3 to 99.9)	100 (80.5 to 100)	100 (76.8 to 100)
Strain (A10): Day 1 (n=5,8,8,8,8,13)	0 (0 to 52.2)	25.0 (3.2 to 65.1)	25.0 (3.2 to 65.1)	12.5 (0.3 to 52.7)
Strain (A10): Day 31 (n=0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (A10): Day 61 (n=0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (A10): Day 181 (n=0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (A10): Day 211 (n=16,16,17,14,18,16)	75.0 (47.6 to 92.7)	87.5 (61.7 to 98.4)	29.4 (10.3 to 56.0)	28.6 (8.4 to 58.1)
Strain (B79): Day 1 (n=5,8,7,8,8,13)	0 (0 to 52.2)	12.5 (0.3 to 52.7)	0 (0 to 41.0)	25.0 (3.2 to 65.1)
Strain (B79): Day 31 (n=0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (B79): Day 61 (n=0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (B79): Day 181 (n=0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Strain (B79): Day 211 (n=16,17,16,14,18,16)	81.3 (54.4 to 96.0)	94.1 (71.3 to 99.9)	87.5 (61.7 to 98.4)	50.0 (23.0 to 77.0)

End point values	Adults - Group 5: MenQuadfi	Adults - Group 6: Sanofi MenB		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	18	16		
Units: percentage of participants				
number (confidence interval 95%)				
Strain (A56): Day 1 (n=5,8,8,8,8,13)	25.0 (3.2 to 65.1)	7.7 (0.2 to 36.0)		
Strain (A56): Day 31 (n=0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)		
Strain (A56): Day 61 (n=0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)		
Strain (A56): Day 181 (n=0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)		
Strain (A56): Day 211 (n=16,17,17,14,18,16)	16.7 (3.6 to 41.4)	93.8 (69.8 to 99.8)		
Strain (B44): Day 1 (n=5,8,8,7,8,13)	62.5 (24.5 to 91.5)	76.9 (46.2 to 95.0)		
Strain (B44): Day 31 (n=0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)		

Strain (B44): Day 61 (n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)		
Strain (B44): Day 181 (n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)		
Strain (B44): Day 211 (n=16,17,17,14,18,16)	72.2 (46.5 to 90.3)	100 (79.4 to 100)		
Strain (A10): Day 1 (n=5,8,8,8,8,13)	25.0 (3.2 to 65.1)	0 (0 to 24.7)		
Strain (A10): Day 31 (n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)		
Strain (A10): Day 61 (n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)		
Strain (A10): Day 181 (n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)		
Strain (A10): Day 211 (n=16,16,17,14,18,16)	22.2 (6.4 to 47.6)	87.5 (61.7 to 98.4)		
Strain (B79): Day 1 (n=5,8,7,8,8,13)	37.5 (8.5 to 75.5)	0 (0 to 24.7)		
Strain (B79): Day 31 (n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)		
Strain (B79): Day 61 (n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)		
Strain (B79): Day 181 (n=0,0,0,0,0,0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)		
Strain (B79): Day 211 (n=16,17,16,14,18,16)	33.3 (13.3 to 59.0)	100 (79.4 to 100)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

SAEs, other AEs and all-cause mortality were collected from the first vaccine administration (Day 1) until 180 days after last vaccine administration (Day 181), approximately 361 days

Adverse event reporting additional description:

Analysis was performed on the SafAS.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	28.0
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Reporting groups

Reporting group title	Adults - Group 1: MenPenta Formulation 1
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Reporting group description:

Participants aged 18 to 25 years received MenPenta formulation 1 (pentavalent meningococcal ABCYW standard dose) vaccine via IM injection on Days 1, 31 and 181. Additionally, participants received a placebo IM injection on Day 1.

Reporting group title	Adults - Group 2: MenPenta Formulation 2
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Reporting group description:

Participants aged 18 to 25 years received MenPenta formulation 2 (pentavalent meningococcal ABCYW high dose) vaccine via IM injection on Days 1, 31 and 181. Additionally, participants received a placebo IM injection on Day 1.

Reporting group title	Adults - Group 3: Bexsero + Menveo
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Reporting group description:

Participants aged 18 to 25 years received Bexsero (meningococcal group B) + Menveo (meningococcal ACYW conjugate) vaccine via IM injection on Day 1 and only Bexsero vaccine via IM injection on Day 31. Additionally, participants received a placebo IM injection on Day 181.

Reporting group title	Adults - Group 4: Trumenba + Menveo
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Reporting group description:

Participants aged 18 to 25 years received Trumenba (meningococcal group B) + Menveo (meningococcal ACYW conjugate) vaccine via IM injection on Day 1 and only Trumenba vaccine via IM injection on Days 31 and 181.

Reporting group title	Adults - Group 5: MenQuadfi
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Reporting group description:

Participants aged 18 to 25 years received MenQuadfi (meningococcal ACYW conjugate) vaccine via IM injection on Days 1 and 181. Additionally, participants received a placebo IM injection on Days 1 and 31.

Reporting group title	Adults - Group 6: Sanofi MenB
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Reporting group description:

Participants aged 18 to 25 years received Sanofi MenB (meningococcal B antigens standard dose) vaccine via IM injection on Days 1, 31 and 181. Additionally, participants received a placebo IM injection on Day 1.

Reporting group title	Adolescents - Group 1: MenPenta Formulation 1
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Reporting group description:

Participants aged 10 to 17 years received MenPenta formulation 1 (pentavalent meningococcal ABCYW standard dose) vaccine via IM injection on Days 1 and 181. Additionally, participants received a placebo IM injection on Day 1.

Reporting group title	Adolescents - Group 3: Bexsero + Menveo
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Reporting group description:

Participants aged 10 to 17 years received Bexsero (meningococcal group B) + Menveo (meningococcal ACYW conjugate) vaccine via IM injection on Day 1 and only Bexsero vaccine via IM injection on Day 181.

Reporting group title	Adolescents - Group 2: MenPenta Formulation 2
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Reporting group description:

Participants aged 10 to 17 years received MenPenta formulation 2 (pentavalent meningococcal ABCYW

high dose) vaccine via IM injection on Days 1 and 181. Additionally, participants received a placebo IM injection on Day 1.

Reporting group title	Adolescents - Group 4: Trumenba + Menveo
-----------------------	--

Reporting group description:

Participants aged 10 to 17 years received Trumenba (meningococcal group B) + Menveo (meningococcal ACYW conjugate) vaccine via IM injection on Day 1 and only Trumenba vaccine via IM injection on Day 181.

Reporting group title	Adolescents - Group 6: Sanofi MenB
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Reporting group description:

Participants aged 10 to 17 years received Sanofi MenB (meningococcal B antigens standard dose) vaccine via IM injection on Days 1 and 181. Additionally, participants received a placebo IM injection on Day 1.

Reporting group title	Adolescents - Group 5: MenQuadfi
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Reporting group description:

Participants aged 10 to 17 years received MenQuadfi (meningococcal ACYW conjugate) vaccine via IM injection on Days 1 and 181. Additionally, participants received a placebo IM injection on Day 1.

Reporting group title	Adolescents - Group 7: PENBRAYA
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Reporting group description:

Participants aged 10 to 17 years received PENBRAYA (meningococcal ABCYW conjugate) vaccine via IM injection on Days 1 and 181.

Serious adverse events	Adults - Group 1: MenPenta Formulation 1	Adults - Group 2: MenPenta Formulation 2	Adults - Group 3: Bexsero + Menveo
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	1 / 19 (5.26%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Gun Shot Wound			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skull Fractured Base			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Irritable Bowel Syndrome			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			

Adenoidal Hypertrophy			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillar Hypertrophy			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Vitiligo			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory Syncytial Virus Infection			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			

subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Adults - Group 4: Trumenba + Menveo	Adults - Group 5: MenQuadfi	Adults - Group 6: Sanofi MenB
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 20 (5.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Gun Shot Wound			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skull Fractured Base			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Irritable Bowel Syndrome			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Adenoidal Hypertrophy			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillar Hypertrophy			

subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Vitiligo			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory Syncytial Virus Infection			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	1 / 20 (5.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Adolescents - Group 1: MenPenta Formulation 1	Adolescents - Group 3: Bexsero + Menveo	Adolescents - Group 2: MenPenta Formulation 2
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 296 (0.68%)	1 / 100 (1.00%)	3 / 300 (1.00%)
number of deaths (all causes)	0	0	1
number of deaths resulting from adverse events	0	0	1
Injury, poisoning and procedural complications			
Gun Shot Wound			

subjects affected / exposed	0 / 296 (0.00%)	0 / 100 (0.00%)	1 / 300 (0.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Skull Fractured Base			
subjects affected / exposed	0 / 296 (0.00%)	0 / 100 (0.00%)	1 / 300 (0.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Irritable Bowel Syndrome			
subjects affected / exposed	1 / 296 (0.34%)	0 / 100 (0.00%)	0 / 300 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Adenoidal Hypertrophy			
subjects affected / exposed	0 / 296 (0.00%)	0 / 100 (0.00%)	1 / 300 (0.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma			
subjects affected / exposed	0 / 296 (0.00%)	1 / 100 (1.00%)	0 / 300 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillar Hypertrophy			
subjects affected / exposed	0 / 296 (0.00%)	0 / 100 (0.00%)	1 / 300 (0.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Vitiligo			
subjects affected / exposed	0 / 296 (0.00%)	0 / 100 (0.00%)	0 / 300 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis			

subjects affected / exposed	0 / 296 (0.00%)	0 / 100 (0.00%)	0 / 300 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory Syncytial Virus Infection			
subjects affected / exposed	1 / 296 (0.34%)	0 / 100 (0.00%)	0 / 300 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 296 (0.00%)	1 / 100 (1.00%)	0 / 300 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 296 (0.00%)	0 / 100 (0.00%)	0 / 300 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Adolescents - Group 4: Trumenba + Menveo	Adolescents - Group 6: Sanofi MenB	Adolescents - Group 5: MenQuadfi
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 97 (1.03%)	0 / 97 (0.00%)	0 / 99 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Gun Shot Wound			
subjects affected / exposed	0 / 97 (0.00%)	0 / 97 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skull Fractured Base			
subjects affected / exposed	0 / 97 (0.00%)	0 / 97 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Irritable Bowel Syndrome			

subjects affected / exposed	0 / 97 (0.00%)	0 / 97 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Adenoidal Hypertrophy			
subjects affected / exposed	0 / 97 (0.00%)	0 / 97 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma			
subjects affected / exposed	0 / 97 (0.00%)	0 / 97 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillar Hypertrophy			
subjects affected / exposed	0 / 97 (0.00%)	0 / 97 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Vitiligo			
subjects affected / exposed	1 / 97 (1.03%)	0 / 97 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 97 (0.00%)	0 / 97 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory Syncytial Virus Infection			
subjects affected / exposed	0 / 97 (0.00%)	0 / 97 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral Upper Respiratory Tract Infection			

subjects affected / exposed	0 / 97 (0.00%)	0 / 97 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 97 (0.00%)	0 / 97 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Adolescents - Group 7: PENBRAYA		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 100 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Injury, poisoning and procedural complications			
Gun Shot Wound			
subjects affected / exposed	0 / 100 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skull Fractured Base			
subjects affected / exposed	0 / 100 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Irritable Bowel Syndrome			
subjects affected / exposed	0 / 100 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Adenoidal Hypertrophy			
subjects affected / exposed	0 / 100 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Asthma			

subjects affected / exposed	0 / 100 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tonsillar Hypertrophy			
subjects affected / exposed	0 / 100 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Vitiligo			
subjects affected / exposed	0 / 100 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 100 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory Syncytial Virus Infection			
subjects affected / exposed	0 / 100 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Viral Upper Respiratory Tract Infection			
subjects affected / exposed	0 / 100 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 100 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Adults - Group 1: MenPenta Formulation 1	Adults - Group 2: MenPenta Formulation 2	Adults - Group 3: Bexsero + Menveo
Total subjects affected by non-serious adverse events			
subjects affected / exposed	17 / 20 (85.00%)	17 / 21 (80.95%)	16 / 19 (84.21%)
Injury, poisoning and procedural complications			
Accidental Overdose			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Nervous system disorders			
Headache			
subjects affected / exposed	3 / 20 (15.00%)	10 / 21 (47.62%)	7 / 19 (36.84%)
occurrences (all)	5	17	9
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	7 / 20 (35.00%)	11 / 21 (52.38%)	6 / 19 (31.58%)
occurrences (all)	9	20	8
Injection Site Erythema			
subjects affected / exposed	1 / 20 (5.00%)	2 / 21 (9.52%)	0 / 19 (0.00%)
occurrences (all)	1	2	0
Pyrexia			
subjects affected / exposed	1 / 20 (5.00%)	1 / 21 (4.76%)	1 / 19 (5.26%)
occurrences (all)	1	1	1
Injection Site Swelling			
subjects affected / exposed	3 / 20 (15.00%)	2 / 21 (9.52%)	0 / 19 (0.00%)
occurrences (all)	3	2	0
Injection Site Pain			
subjects affected / exposed	14 / 20 (70.00%)	16 / 21 (76.19%)	15 / 19 (78.95%)
occurrences (all)	25	37	30
Injection Site Pruritus			
subjects affected / exposed	0 / 20 (0.00%)	0 / 21 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	1 / 20 (5.00%)	0 / 21 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			

Cough subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0	0 / 21 (0.00%) 0	0 / 19 (0.00%) 0
Oropharyngeal Pain subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0	0 / 21 (0.00%) 0	1 / 19 (5.26%) 1
Skin and subcutaneous tissue disorders Ecchymosis subjects affected / exposed occurrences (all)	2 / 20 (10.00%) 2	0 / 21 (0.00%) 0	0 / 19 (0.00%) 0
Psychiatric disorders Depression subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0	0 / 21 (0.00%) 0	1 / 19 (5.26%) 1
Anxiety subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0	0 / 21 (0.00%) 0	1 / 19 (5.26%) 1
Musculoskeletal and connective tissue disorders Myalgia subjects affected / exposed occurrences (all)	8 / 20 (40.00%) 10	13 / 21 (61.90%) 21	9 / 19 (47.37%) 11
Infections and infestations Nasopharyngitis subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0	0 / 21 (0.00%) 0	0 / 19 (0.00%) 0
Urinary Tract Infection subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0	0 / 21 (0.00%) 0	0 / 19 (0.00%) 0

Non-serious adverse events	Adults - Group 4: Trumenba + Menveo	Adults - Group 5: MenQuadfi	Adults - Group 6: Sanofi MenB
Total subjects affected by non-serious adverse events subjects affected / exposed	19 / 20 (95.00%)	15 / 20 (75.00%)	19 / 20 (95.00%)
Injury, poisoning and procedural complications Accidental Overdose subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0	0 / 20 (0.00%) 0	0 / 20 (0.00%) 0
Nervous system disorders			

Headache subjects affected / exposed occurrences (all)	10 / 20 (50.00%) 15	9 / 20 (45.00%) 12	8 / 20 (40.00%) 16
General disorders and administration site conditions			
Fatigue subjects affected / exposed occurrences (all)	11 / 20 (55.00%) 17	9 / 20 (45.00%) 15	15 / 20 (75.00%) 23
Injection Site Erythema subjects affected / exposed occurrences (all)	5 / 20 (25.00%) 7	0 / 20 (0.00%) 0	2 / 20 (10.00%) 3
Pyrexia subjects affected / exposed occurrences (all)	1 / 20 (5.00%) 1	1 / 20 (5.00%) 1	1 / 20 (5.00%) 1
Injection Site Swelling subjects affected / exposed occurrences (all)	3 / 20 (15.00%) 4	0 / 20 (0.00%) 0	1 / 20 (5.00%) 1
Injection Site Pain subjects affected / exposed occurrences (all)	14 / 20 (70.00%) 38	10 / 20 (50.00%) 19	19 / 20 (95.00%) 46
Injection Site Pruritus subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0	0 / 20 (0.00%) 0	2 / 20 (10.00%) 3
Gastrointestinal disorders			
Nausea subjects affected / exposed occurrences (all)	1 / 20 (5.00%) 1	0 / 20 (0.00%) 0	2 / 20 (10.00%) 3
Respiratory, thoracic and mediastinal disorders			
Cough subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0	1 / 20 (5.00%) 1	0 / 20 (0.00%) 0
Oropharyngeal Pain subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0	0 / 20 (0.00%) 0	0 / 20 (0.00%) 0
Skin and subcutaneous tissue disorders			
Ecchymosis			

subjects affected / exposed occurrences (all)	0 / 20 (0.00%) 0	0 / 20 (0.00%) 0	0 / 20 (0.00%) 0
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	0 / 20 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed	12 / 20 (60.00%)	8 / 20 (40.00%)	11 / 20 (55.00%)
occurrences (all)	15	10	23
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	0 / 20 (0.00%)	1 / 20 (5.00%)	2 / 20 (10.00%)
occurrences (all)	0	1	2
Urinary Tract Infection			
subjects affected / exposed	0 / 20 (0.00%)	2 / 20 (10.00%)	0 / 20 (0.00%)
occurrences (all)	0	2	0

Non-serious adverse events	Adolescents - Group 1: MenPenta Formulation 1	Adolescents - Group 3: Bexsero + Menveo	Adolescents - Group 2: MenPenta Formulation 2
Total subjects affected by non-serious adverse events			
subjects affected / exposed	243 / 296 (82.09%)	90 / 100 (90.00%)	237 / 300 (79.00%)
Injury, poisoning and procedural complications			
Accidental Overdose			
subjects affected / exposed	0 / 296 (0.00%)	0 / 100 (0.00%)	0 / 300 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	107 / 296 (36.15%)	37 / 100 (37.00%)	96 / 300 (32.00%)
occurrences (all)	131	45	119
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	116 / 296 (39.19%)	46 / 100 (46.00%)	114 / 300 (38.00%)
occurrences (all)	154	61	148

Injection Site Erythema subjects affected / exposed occurrences (all)	21 / 296 (7.09%) 26	17 / 100 (17.00%) 25	37 / 300 (12.33%) 41
Pyrexia subjects affected / exposed occurrences (all)	19 / 296 (6.42%) 21	6 / 100 (6.00%) 6	15 / 300 (5.00%) 15
Injection Site Swelling subjects affected / exposed occurrences (all)	30 / 296 (10.14%) 37	16 / 100 (16.00%) 23	35 / 300 (11.67%) 45
Injection Site Pain subjects affected / exposed occurrences (all)	217 / 296 (73.31%) 388	89 / 100 (89.00%) 169	218 / 300 (72.67%) 397
Injection Site Pruritus subjects affected / exposed occurrences (all)	1 / 296 (0.34%) 1	0 / 100 (0.00%) 0	0 / 300 (0.00%) 0
Gastrointestinal disorders Nausea subjects affected / exposed occurrences (all)	4 / 296 (1.35%) 4	0 / 100 (0.00%) 0	5 / 300 (1.67%) 6
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all)	1 / 296 (0.34%) 1	1 / 100 (1.00%) 1	5 / 300 (1.67%) 5
Oropharyngeal Pain subjects affected / exposed occurrences (all)	5 / 296 (1.69%) 5	2 / 100 (2.00%) 2	5 / 300 (1.67%) 5
Skin and subcutaneous tissue disorders Ecchymosis subjects affected / exposed occurrences (all)	0 / 296 (0.00%) 0	0 / 100 (0.00%) 0	0 / 300 (0.00%) 0
Psychiatric disorders Depression subjects affected / exposed occurrences (all)	0 / 296 (0.00%) 0	0 / 100 (0.00%) 0	0 / 300 (0.00%) 0
Anxiety			

subjects affected / exposed occurrences (all)	1 / 296 (0.34%) 1	0 / 100 (0.00%) 0	2 / 300 (0.67%) 2
Musculoskeletal and connective tissue disorders Myalgia subjects affected / exposed occurrences (all)	144 / 296 (48.65%) 195	66 / 100 (66.00%) 92	146 / 300 (48.67%) 202
Infections and infestations Nasopharyngitis subjects affected / exposed occurrences (all)	6 / 296 (2.03%) 6	0 / 100 (0.00%) 0	4 / 300 (1.33%) 4
Urinary Tract Infection subjects affected / exposed occurrences (all)	1 / 296 (0.34%) 1	0 / 100 (0.00%) 0	0 / 300 (0.00%) 0

Non-serious adverse events	Adolescents - Group 4: Trumenba + Menveo	Adolescents - Group 6: Sanofi MenB	Adolescents - Group 5: MenQuadfi
Total subjects affected by non-serious adverse events subjects affected / exposed	83 / 97 (85.57%)	80 / 97 (82.47%)	58 / 99 (58.59%)
Injury, poisoning and procedural complications Accidental Overdose subjects affected / exposed occurrences (all)	0 / 97 (0.00%) 0	0 / 97 (0.00%) 0	0 / 99 (0.00%) 0
Nervous system disorders Headache subjects affected / exposed occurrences (all)	36 / 97 (37.11%) 50	29 / 97 (29.90%) 36	33 / 99 (33.33%) 40
General disorders and administration site conditions Fatigue subjects affected / exposed occurrences (all)	48 / 97 (49.48%) 60	35 / 97 (36.08%) 48	34 / 99 (34.34%) 43
Injection Site Erythema subjects affected / exposed occurrences (all)	8 / 97 (8.25%) 12	6 / 97 (6.19%) 8	3 / 99 (3.03%) 4
Pyrexia subjects affected / exposed occurrences (all)	10 / 97 (10.31%) 10	2 / 97 (2.06%) 2	4 / 99 (4.04%) 4
Injection Site Swelling			

subjects affected / exposed occurrences (all)	7 / 97 (7.22%) 11	7 / 97 (7.22%) 9	6 / 99 (6.06%) 9
Injection Site Pain subjects affected / exposed occurrences (all)	75 / 97 (77.32%) 134	72 / 97 (74.23%) 128	30 / 99 (30.30%) 47
Injection Site Pruritus subjects affected / exposed occurrences (all)	0 / 97 (0.00%) 0	1 / 97 (1.03%) 1	2 / 99 (2.02%) 2
Gastrointestinal disorders Nausea subjects affected / exposed occurrences (all)	2 / 97 (2.06%) 2	6 / 97 (6.19%) 7	2 / 99 (2.02%) 2
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all)	3 / 97 (3.09%) 3	2 / 97 (2.06%) 2	5 / 99 (5.05%) 5
Oropharyngeal Pain subjects affected / exposed occurrences (all)	1 / 97 (1.03%) 1	2 / 97 (2.06%) 2	2 / 99 (2.02%) 2
Skin and subcutaneous tissue disorders Ecchymosis subjects affected / exposed occurrences (all)	0 / 97 (0.00%) 0	0 / 97 (0.00%) 0	0 / 99 (0.00%) 0
Psychiatric disorders Depression subjects affected / exposed occurrences (all)	0 / 97 (0.00%) 0	0 / 97 (0.00%) 0	1 / 99 (1.01%) 1
Anxiety subjects affected / exposed occurrences (all)	0 / 97 (0.00%) 0	0 / 97 (0.00%) 0	0 / 99 (0.00%) 0
Musculoskeletal and connective tissue disorders Myalgia subjects affected / exposed occurrences (all)	57 / 97 (58.76%) 76	52 / 97 (53.61%) 70	30 / 99 (30.30%) 39
Infections and infestations			

Nasopharyngitis			
subjects affected / exposed	1 / 97 (1.03%)	1 / 97 (1.03%)	3 / 99 (3.03%)
occurrences (all)	1	1	3
Urinary Tract Infection			
subjects affected / exposed	0 / 97 (0.00%)	1 / 97 (1.03%)	0 / 99 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	Adolescents - Group 7: PENBRAYA		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	87 / 100 (87.00%)		
Injury, poisoning and procedural complications			
Accidental Overdose			
subjects affected / exposed	0 / 100 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Headache			
subjects affected / exposed	43 / 100 (43.00%)		
occurrences (all)	56		
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	52 / 100 (52.00%)		
occurrences (all)	78		
Injection Site Erythema			
subjects affected / exposed	20 / 100 (20.00%)		
occurrences (all)	29		
Pyrexia			
subjects affected / exposed	6 / 100 (6.00%)		
occurrences (all)	8		
Injection Site Swelling			
subjects affected / exposed	13 / 100 (13.00%)		
occurrences (all)	18		
Injection Site Pain			
subjects affected / exposed	79 / 100 (79.00%)		
occurrences (all)	130		
Injection Site Pruritus			

subjects affected / exposed occurrences (all)	0 / 100 (0.00%) 0		
Gastrointestinal disorders Nausea subjects affected / exposed occurrences (all)	2 / 100 (2.00%) 2		
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all) Oropharyngeal Pain subjects affected / exposed occurrences (all)	2 / 100 (2.00%) 2 0 / 100 (0.00%) 0		
Skin and subcutaneous tissue disorders Ecchymosis subjects affected / exposed occurrences (all)	0 / 100 (0.00%) 0		
Psychiatric disorders Depression subjects affected / exposed occurrences (all) Anxiety subjects affected / exposed occurrences (all)	0 / 100 (0.00%) 0 1 / 100 (1.00%) 1		
Musculoskeletal and connective tissue disorders Myalgia subjects affected / exposed occurrences (all)	62 / 100 (62.00%) 92		
Infections and infestations Nasopharyngitis subjects affected / exposed occurrences (all) Urinary Tract Infection subjects affected / exposed occurrences (all)	2 / 100 (2.00%) 2 0 / 100 (0.00%) 0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
27 October 2023	Clarified the definition of sentinel cohort participant and the number of adolescent participants included in the sentinel cohort.
10 January 2024	Added an additional study group in the adolescent cohort to receive the PENBRAYA vaccine. Clarified some elements of the study design based on Center for Biologics Evaluation and Research's feedback.
08 April 2024	Added interim analysis for business purpose. Clarified some elements and align with the statistical analysis plan.
04 July 2024	Updated the safety information and potential and identified risks with MenQuadfi. Updated interim analysis strategy.
18 October 2024	Updated the objectives and endpoints wording for clarification. Clarified the unblinding strategy for the interim analyses.
13 March 2025	Updated the strategy for the interim analysis.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported