Clinical trial results:
A Phase 3, Randomized, Active-controlled, Observer-blinded Study To Assess The Immunogenicity, Safety, And Tolerability Of Bivalent rLP2086 When Administered As A 2-Dose Regimen And A First-in-human Study To Describe The Immunogenicity, Safety, And Tolerability Of A Bivalent rLP2086–Containing Pentavalent Vaccine (MenABCWY) In Healthy Subjects >=10 to <26 Years Of Age

Summary

EudraCT number	2016-004421-17
Trial protocol	CZ FI PL
Global end of trial date	25 October 2022

Results information

Result version number	v1 (current)
This version publication date	10 May 2023
First version publication date	10 May 2023

Trial information

Trial identification

Sponsor protocol code	B1971057

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03135834
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Pfizer Inc.
Sponsor organisation address	235 E 42nd Street, New York, United States, 10017
Public contact	Pfizer ClinicalTrials.gov Call Center, Pfizer Inc., 10017 18007181021, ClinicalTrials.gov_Inquiries@pfizer.com
Scientific contact	Pfizer ClinicalTrials.gov Call Center, Pfizer Inc., 10017 18007181021, ClinicalTrials.gov_Inquiries@pfizer.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMEA-000299-PIP01-08
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	07 April 2023
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	25 October 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess immune response induced by bivalent rLP2086 as measured by hSBA performed with 4 primary MnB test strains, 2 expressing an LP2086 subfamily A protein and 2 expressing an LP2086 subfamily B protein, measured 1 month after second vaccination, in bivalent rLP2086 arms (Group 2 and 4 subjects) combined. To describe safety profile of bivalent rLP2086, as measured by local reactions, systemic events, adverse events (AEs), serious adverse events (SAEs), newly diagnosed chronic medical conditions (NDCMCs), medically attended AEs, and immediate AEs, following Vaccinations 1 and 2 in bivalent rLP2086 arms combined. To describe safety profile of MenABCWY, as measured by local reactions, systemic events, AEs, SAEs, NDCMCs, medically attended AEs, and immediate AEs, after booster vaccination. To describe safety profile of bivalent rLP2086, as measured by local reactions, systemic events, AEs, SAEs, NDCMCs, medically attended AEs, and immediate AEs, after booster vaccination.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Council for Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines. All the local regulatory requirements pertinent to safety of trial subjects were followed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	24 April 2017
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Czechia: 131
Country: Number of subjects enrolled	Finland: 128
Country: Number of subjects enrolled	Poland: 30
Country: Number of subjects enrolled	United States: 1311
Worldwide total number of subjects	1600
EEA total number of subjects	289

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)	337
Adolescents (12-17 years)	560
Adults (18-64 years)	703
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study had 2 stages: 1 and 2. Study was conducted at 68 sites in Stage 1, with 39 of those sites participating in Stage 2. Subjects were randomized as ACWY-naive and ACWY-experienced (received 1 prior dose of a vaccine containing 1 or more ACWY groups greater than or equal to [>=] 4 years prior to randomization).

Pre-assignment

Screening details:

A total of 1610 subjects were randomized in this study, out of which 10 withdrew before vaccination.

Period 1

Period 1 title	Stage 1
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind[1]
Roles blinded	Subject, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Group 1: MenABCWY + Saline (ACWY-Naive)

Arm description:

Stage 1: ACWY-naive subjects were randomized to receive an intramuscular injection of 0.5 milliliter (mL) of Neisseria meningitidis groups A, B, C, W, and Y vaccine (MenABCWY) and 0.5 mL of saline at Month 0, Subjects received 0.5 mL of MenABCWY vaccine intramuscularly at Month 6. Stage 1 was followed by Stage 2. Stage 2: Subjects received 0.5 mL of MenABCWY vaccine (booster vaccination) intramuscularly at Month 54.

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

Dosage and administration details:

Subjects were administered 0.5 mL intramuscular injection of saline solution at Month 0 during Stage 1.

Investigational medicinal product name	Neisseria meningitidis groups A, B, C, W, and Y vaccine (MenABCWY)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects were administered 0.5 mL intramuscular injection of MenABCWY vaccine each at Month 0 and 6 during Stage 1.

Arm title	Group 2: Bivalent rLP2086 + MenACWY-CRM (ACWY-Naive)

Arm description:

Stage 1: ACWY-naive subjects were randomized to receive an intramuscular injection of 0.5 mL bivalent recombinant lipoprotein 2086 (rLP2086) vaccine and 0.5 mL of meningococcal group A, C, W-135, and Y conjugate vaccine (MenACWY-CRM) at Month 0. Subjects received 0.5 mL of bivalent rLP2086 vaccine at Month 6. Stage 1 was followed by Stage 2. Stage 2: Subjects received intramuscularly injection of 0.5 mL of bivalent rLP2086 vaccine and 0.5 mL of MenACWY-CRM vaccine (booster vaccination) at Month 54.

Arm type	Experimental

Investigational medicinal product name	Meningococcal group A, C, W-135, and Y conjugate vaccine (MenACWY-CRM)
Investigational medicinal product code	
Other name	Menveo
Pharmaceutical forms	Concentrate and solvent for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects were administered 0.5 mL intramuscular injection at Month 0 during Stage 1.

Investigational medicinal product name	Bivalent recombinant lipoprotein 2086 vaccine (Bivalent rLP2086)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for suspension for injection in pre-filled syringe
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects were administered 0.5 mL intramuscular injection of bivalent rLP2086 each at Month 0 and 6 during Stage 1.

Arm title	Group 3: MenABCWY + Saline (ACWY-Experienced)

Arm description:

Stage 1: ACWY-experienced subjects were randomized to receive an intramuscular injection of 0.5 milliliter (mL) of Neisseria meningitidis groups A, B, C, W, and Y vaccine (MenABCWY) and 0.5 mL of saline at Month 0, Subjects received 0.5 mL of MenABCWY vaccine intramuscularly at Month 6. Stage 1 was followed by Stage 2. Stage 2: Subjects received 0.5 mL of MenABCWY vaccine (booster vaccination) intramuscularly at Month 54.

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

Dosage and administration details:

Subjects were administered 0.5 mL intramuscular injection of saline solution at Month 0 during Stage 1.

Investigational medicinal product name	Neisseria meningitidis groups A, B, C, W, and Y vaccine (MenABCWY)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects were administered 0.5 mL intramuscular injection of MenABCWY vaccine each at Month 0 and 6 during Stage 1.

Arm title	Group 4: Bivalent rLP2086 + MenACWY-CRM (ACWY-Experienced)

Arm description:

Stage 1: ACWY-experienced subjects were randomized to receive an intramuscular injection of 0.5 mL bivalent recombinant lipoprotein 2086 (rLP2086) vaccine and 0.5 mL of meningococcal group A, C, W-135, and Y conjugate vaccine (MenACWY-CRM) at Month 0. Subjects received 0.5 mL of bivalent rLP2086 vaccine at Month 6. Stage 1 was followed by Stage 2. Stage 2: Subjects received intramuscularly injection of 0.5 mL of bivalent rLP2086 vaccine and 0.5 mL of MenACWY-CRM vaccine (booster vaccination) at Month 54.

Arm type	Experimental

Investigational medicinal product name	Meningococcal group A, C, W-135, and Y conjugate vaccine (MenACWY-CRM)
Investigational medicinal product code	
Other name	Menveo
Pharmaceutical forms	Concentrate and solvent for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects were administered 0.5 mL intramuscular injection at Month 0 during Stage 1.

Investigational medicinal product name	Bivalent recombinant lipoprotein 2086 vaccine (Bivalent rLP2086)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for solution for injection in pre-filled syringe
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects were administered 0.5 mL intramuscular injection of bivalent rLP2086 each at Month 0 and 6 during Stage 1.

Notes:

[1] - The roles blinded appear to be inconsistent with a double blind trial.

Justification: Not all the subjects who completed Stage 1 entered Stage 2.

Number of subjects in period 1	Group 1: MenABCWY + Saline (ACWY-Naive)	Group 2: Bivalent rLP2086 + MenACWY-CRM (ACWY-Naive)	Group 3: MenABCWY + Saline (ACWY-Experienced)
Started	272	534	271
Vaccination 1 at Month 0	272	534	271
Vaccination 2 at Month 6	242	469	244
Completed	233	462	232
Not completed	39	72	39
Adverse event, serious fatal	1	-	-
Consent withdrawn by subject	16	22	7
Physician decision	-	1	-
Adverse event, non-fatal	1	2	2
No longer met eligibility criteria	1	6	2
Pregnancy	-	4	2
Unspecified	-	2	1
Lost to follow-up	17	24	21
Withdrawal by parent/guardian	2	10	2
Protocol deviation	1	1	2

Number of subjects in period 1	Group 4: Bivalent rLP2086 + MenACWY-CRM (ACWY-Experienced)
Started	523
Vaccination 1 at Month 0	523
Vaccination 2 at Month 6	477

Completed	463
Not completed	60
Adverse event, serious fatal	-
Consent withdrawn by subject	10
Physician decision	-
Adverse event, non-fatal	1
No longer met eligibility criteria	5
Pregnancy	4
Unspecified	-
Lost to follow-up	38
Withdrawal by parent/guardian	1
Protocol deviation	1

Period 2

Period 2 title	Stage 2
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Group 1: MenABCWY + Saline (ACWY-Naive)

Arm description:

Stage 1: ACWY-naive subjects were randomized to receive an intramuscular injection of 0.5 milliliter (mL) of Neisseria meningitidis groups A, B, C, W, and Y vaccine (MenABCWY) and 0.5 mL of saline at Month 0, Subjects received 0.5 mL of MenABCWY vaccine intramuscularly at Month 6. Stage 1 was followed by Stage 2. Stage 2: Subjects received 0.5 mL of MenABCWY vaccine (booster vaccination) intramuscularly at Month 54.

Arm type	Experimental
Investigational medicinal product name	Neisseria meningitidis groups A, B, C, W, and Y vaccine (MenABCWY)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects were administered 0.5 mL intramuscular injection of MenABCWY vaccine each at Month 0 and 6 during Stage 1.

Investigational medicinal product name	Normal saline solution
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects were administered 0.5 mL intramuscular injection of saline solution at Month 0 during Stage 1.

Arm title	Group 2: Bivalent rLP2086 + MenACWY-CRM (ACWY-Naive)

Arm description:

Stage 1: ACWY-naive subjects were randomized to receive an intramuscular injection of 0.5 mL bivalent recombinant lipoprotein 2086 (rLP2086) vaccine and 0.5 mL of meningococcal group A, C, W-135, and Y conjugate vaccine (MenACWY-CRM) at Month 0. Subjects received 0.5 mL of bivalent rLP2086 vaccine at Month 6. Stage 1 was followed by Stage 2. Stage 2: Subjects received intramuscularly injection of 0.5 mL of bivalent rLP2086 vaccine and 0.5 mL of MenACWY-CRM vaccine (booster vaccination) at Month 54.

Arm type	Experimental
Investigational medicinal product name	Meningococcal group A, C, W-135, and Y conjugate vaccine (MenACWY-CRM)
Investigational medicinal product code	
Other name	Menveo
Pharmaceutical forms	Concentrate and solvent for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects were administered 0.5 mL intramuscular injection at Month 0 during Stage 1.

Investigational medicinal product name	Bivalent recombinant lipoprotein 2086 vaccine (Bivalent rLP2086)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for suspension for injection in pre-filled syringe
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects were administered 0.5 mL intramuscular injection of bivalent rLP2086 each at Month 0 and 6 during Stage 1.

Arm title	Group 3: MenABCWY + Saline (ACWY-Experienced)

Arm description:

Stage 1: ACWY-experienced subjects were randomized to receive an intramuscular injection of 0.5 milliliter (mL) of Neisseria meningitidis groups A, B, C, W, and Y vaccine (MenABCWY) and 0.5 mL of saline at Month 0, Subjects received 0.5 mL of MenABCWY vaccine intramuscularly at Month 6. Stage 1 was followed by Stage 2. Stage 2: Subjects received 0.5 mL of MenABCWY vaccine (booster vaccination) intramuscularly at Month 54.

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

Dosage and administration details:

Subjects were administered 0.5 mL intramuscular injection of saline solution at Month 0 during Stage 1.

Investigational medicinal product name	Neisseria meningitidis groups A, B, C, W, and Y vaccine (MenABCWY)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects were administered 0.5 mL intramuscular injection of MenABCWY vaccine each at Month 0 and 6 during Stage 1.

Arm title	Group 4: Bivalent rLP2086 + MenACWY-CRM (ACWY-Experienced)

Arm description:

Stage 1: ACWY-experienced subjects were randomized to receive an intramuscular injection of 0.5 mL bivalent recombinant lipoprotein 2086 (rLP2086) vaccine and 0.5 mL of meningococcal group A, C, W-135, and Y conjugate vaccine (MenACWY-CRM) at Month 0. Subjects received 0.5 mL of bivalent rLP2086 vaccine at Month 6. Stage 1 was followed by Stage 2. Stage 2: Subjects received

intramuscularly injection of 0.5 mL of bivalent rLP2086 vaccine and 0.5 mL of MenACWY-CRM vaccine (booster vaccination) at Month 54.

Arm type	Experimental
Investigational medicinal product name	Meningococcal group A, C, W-135, and Y conjugate vaccine (MenACWY-CRM)
Investigational medicinal product code	
Other name	Menveo
Pharmaceutical forms	Concentrate and solvent for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects were administered 0.5 mL intramuscular injection at Month 0 during Stage 1.

Investigational medicinal product name	Bivalent recombinant lipoprotein 2086 vaccine (Bivalent rLP2086)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for suspension for injection in pre-filled syringe
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects were administered 0.5 mL intramuscular injection of bivalent rLP2086 each at Month 0 and 6 during Stage 1.

Number of subjects in period 2[2]	Group 1: MenABCWY + Saline (ACWY-Naive)	Group 2: Bivalent rLP2086 + MenACWY-CRM (ACWY-Naive)	Group 3: MenABCWY + Saline (ACWY-Experienced)
Started	114	65	101
Antibody Persistence:Blood draw Month18	114	63	53 [3]
Antibody Persistence:Blood draw Month24	104	61	96
Antibody Persistence:Blood draw Month42	97	55	97
Completed Persistence Phase	97	55	97
Booster Vaccination at Month 54	67	40	77
Completed	67	38	77
Not completed	47	27	24
Consent withdrawn by subject	-	1	-
Did not receive Booster Vaccination	1	1	-
Lost to follow-up	-	1	-
Withdrawn Before Booster Vaccination	46	24	24

Number of subjects in period 2[2]	Group 4: Bivalent rLP2086 + MenACWY-CRM (ACWY-Experienced)
Started	73
Antibody Persistence:Blood draw Month18	23 [4]
Antibody Persistence:Blood draw Month24	71

Antibody Persistence:Blood draw Month42	68
Completed Persistence Phase	68
Booster Vaccination at Month 54	58
Completed	58
Not completed	15
Consent withdrawn by subject	-
Did not receive Booster Vaccination	-
Lost to follow-up	-
Withdrawn Before Booster Vaccination	15

Notes:

[2] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

Justification: Not all the subjects who completed Stage 1 entered Stage 2.

[3] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: These are the number of subjects with blood drawn at Month 18 for evaluation of antibody persistence.

[4] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: These are the number of subjects with blood drawn at Month 18 for evaluation of antibody persistence.

Baseline characteristics

Reporting groups	
Reporting group title	Group 1: MenABCWY + Saline (ACWY-Naive)
Reporting group description:	
Stage 1: ACWY-naive subjects were randomized to receive an intramuscular injection of 0.5 milliliter (mL) of Neisseria meningitidis groups A, B, C, W, and Y vaccine (MenABCWY) and 0.5 mL of saline at Month 0, Subjects received 0.5 mL of MenABCWY vaccine intramuscularly at Month 6. Stage 1 was followed by Stage 2. Stage 2: Subjects received 0.5 mL of MenABCWY vaccine (booster vaccination) intramuscularly at Month 54.	
Reporting group title	Group 2: Bivalent rLP2086 + MenACWY-CRM (ACWY-Naive)
Reporting group description:	
Stage 1: ACWY-naive subjects were randomized to receive an intramuscular injection of 0.5 mL bivalent recombinant lipoprotein 2086 (rLP2086) vaccine and 0.5 mL of meningococcal group A, C, W-135, and Y conjugate vaccine (MenACWY-CRM) at Month 0. Subjects received 0.5 mL of bivalent rLP2086 vaccine at Month 6. Stage 1 was followed by Stage 2. Stage 2: Subjects received intramuscularly injection of 0.5 mL of bivalent rLP2086 vaccine and 0.5 mL of MenACWY-CRM vaccine (booster vaccination) at Month 54.	
Reporting group title	Group 3: MenABCWY + Saline (ACWY-Experienced)
Reporting group description:	
Stage 1: ACWY-experienced subjects were randomized to receive an intramuscular injection of 0.5 milliliter (mL) of Neisseria meningitidis groups A, B, C, W, and Y vaccine (MenABCWY) and 0.5 mL of saline at Month 0, Subjects received 0.5 mL of MenABCWY vaccine intramuscularly at Month 6. Stage 1 was followed by Stage 2. Stage 2: Subjects received 0.5 mL of MenABCWY vaccine (booster vaccination) intramuscularly at Month 54.	
Reporting group title	Group 4: Bivalent rLP2086 + MenACWY-CRM (ACWY-Experienced)
Reporting group description:	
Stage 1: ACWY-experienced subjects were randomized to receive an intramuscular injection of 0.5 mL bivalent recombinant lipoprotein 2086 (rLP2086) vaccine and 0.5 mL of meningococcal group A, C, W-135, and Y conjugate vaccine (MenACWY-CRM) at Month 0. Subjects received 0.5 mL of bivalent rLP2086 vaccine at Month 6. Stage 1 was followed by Stage 2. Stage 2: Subjects received intramuscularly injection of 0.5 mL of bivalent rLP2086 vaccine and 0.5 mL of MenACWY-CRM vaccine (booster vaccination) at Month 54.	

Reporting group values	Group 1: MenABCWY + Saline (ACWY-Naive)	Group 2: Bivalent rLP2086 + MenACWY-CRM (ACWY-Naive)	Group 3: MenABCWY + Saline (ACWY-Experienced)
Number of subjects	272	534	271
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	108	194	13
Adolescents (12-17 years)	46	101	137
Adults (18-64 years)	118	239	121
From 65-84 years	0	0	0
85 years and over	0	0	0
Age Continuous Units: Years			
arithmetic mean	16.0	16.5	17.7

standard deviation	± 5.67	± 5.81	± 3.57

Sex: Female, Male Units: Subjects			
Female	144	333	152
Male	128	201	119
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	10	13	6
Asian	1	4	3
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	27	53	25
White	234	464	237
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	35	73	24
Not Hispanic or Latino	236	461	246
Unknown or Not Reported	1	0	1

Reporting group values	Group 4: Bivalent rLP2086 + MenACWY-CRM (ACWY-Experienced)	Total	
Number of subjects	523	1600	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	22	337	
Adolescents (12-17 years)	276	560	
Adults (18-64 years)	225	703	
From 65-84 years	0	0	
85 years and over	0	0	
Age Continuous Units: Years			
arithmetic mean	17.8		
standard deviation	± 3.66	-	
Sex: Female, Male Units: Subjects			
Female	289	918	
Male	234	682	
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	20	49	
Asian	8	16	

Native Hawaiian or Other Pacific Islander	0	0	
Black or African American	60	165	
White	435	1370	
More than one race	0	0	
Unknown or Not Reported	0	0	
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	61	193	
Not Hispanic or Latino	461	1404	
Unknown or Not Reported	1	3	

End points

End points reporting groups

Reporting group title	Group 1: MenABCWY + Saline (ACWY-Naive)

Reporting group description:

Stage 1: ACWY-naive subjects were randomized to receive an intramuscular injection of 0.5 milliliter (mL) of Neisseria meningitidis groups A, B, C, W, and Y vaccine (MenABCWY) and 0.5 mL of saline at Month 0, Subjects received 0.5 mL of MenABCWY vaccine intramuscularly at Month 6. Stage 1 was followed by Stage 2. Stage 2: Subjects received 0.5 mL of MenABCWY vaccine (booster vaccination) intramuscularly at Month 54.

Reporting group title	Group 2: Bivalent rLP2086 + MenACWY-CRM (ACWY-Naive)

Reporting group description:

Stage 1: ACWY-naive subjects were randomized to receive an intramuscular injection of 0.5 mL bivalent recombinant lipoprotein 2086 (rLP2086) vaccine and 0.5 mL of meningococcal group A, C, W-135, and Y conjugate vaccine (MenACWY-CRM) at Month 0. Subjects received 0.5 mL of bivalent rLP2086 vaccine at Month 6. Stage 1 was followed by Stage 2. Stage 2: Subjects received intramuscularly injection of 0.5 mL of bivalent rLP2086 vaccine and 0.5 mL of MenACWY-CRM vaccine (booster vaccination) at Month 54.

Reporting group title	Group 3: MenABCWY + Saline (ACWY-Experienced)

Reporting group description:

Stage 1: ACWY-experienced subjects were randomized to receive an intramuscular injection of 0.5 milliliter (mL) of Neisseria meningitidis groups A, B, C, W, and Y vaccine (MenABCWY) and 0.5 mL of saline at Month 0, Subjects received 0.5 mL of MenABCWY vaccine intramuscularly at Month 6. Stage 1 was followed by Stage 2. Stage 2: Subjects received 0.5 mL of MenABCWY vaccine (booster vaccination) intramuscularly at Month 54.

Reporting group title	Group 4: Bivalent rLP2086 + MenACWY-CRM (ACWY-Experienced)

Reporting group description:

Stage 1: ACWY-experienced subjects were randomized to receive an intramuscular injection of 0.5 mL bivalent recombinant lipoprotein 2086 (rLP2086) vaccine and 0.5 mL of meningococcal group A, C, W-135, and Y conjugate vaccine (MenACWY-CRM) at Month 0. Subjects received 0.5 mL of bivalent rLP2086 vaccine at Month 6. Stage 1 was followed by Stage 2. Stage 2: Subjects received intramuscularly injection of 0.5 mL of bivalent rLP2086 vaccine and 0.5 mL of MenACWY-CRM vaccine (booster vaccination) at Month 54.

Reporting group title	Group 1: MenABCWY + Saline (ACWY-Naive)

Reporting group description:

Stage 1: ACWY-naive subjects were randomized to receive an intramuscular injection of 0.5 milliliter (mL) of Neisseria meningitidis groups A, B, C, W, and Y vaccine (MenABCWY) and 0.5 mL of saline at Month 0, Subjects received 0.5 mL of MenABCWY vaccine intramuscularly at Month 6. Stage 1 was followed by Stage 2. Stage 2: Subjects received 0.5 mL of MenABCWY vaccine (booster vaccination) intramuscularly at Month 54.

Reporting group title	Group 2: Bivalent rLP2086 + MenACWY-CRM (ACWY-Naive)

Reporting group description:

Stage 1: ACWY-naive subjects were randomized to receive an intramuscular injection of 0.5 mL bivalent recombinant lipoprotein 2086 (rLP2086) vaccine and 0.5 mL of meningococcal group A, C, W-135, and Y conjugate vaccine (MenACWY-CRM) at Month 0. Subjects received 0.5 mL of bivalent rLP2086 vaccine at Month 6. Stage 1 was followed by Stage 2. Stage 2: Subjects received intramuscularly injection of 0.5 mL of bivalent rLP2086 vaccine and 0.5 mL of MenACWY-CRM vaccine (booster vaccination) at Month 54.

Reporting group title	Group 3: MenABCWY + Saline (ACWY-Experienced)

Reporting group description:

Stage 1: ACWY-experienced subjects were randomized to receive an intramuscular injection of 0.5 milliliter (mL) of Neisseria meningitidis groups A, B, C, W, and Y vaccine (MenABCWY) and 0.5 mL of saline at Month 0, Subjects received 0.5 mL of MenABCWY vaccine intramuscularly at Month 6. Stage 1 was followed by Stage 2. Stage 2: Subjects received 0.5 mL of MenABCWY vaccine (booster vaccination) intramuscularly at Month 54.

Reporting group title	Group 4: Bivalent rLP2086 + MenACWY-CRM (ACWY-Experienced)

Reporting group description:

Stage 1: ACWY-experienced subjects were randomized to receive an intramuscular injection of 0.5 mL

bivalent recombinant lipoprotein 2086 (rLP2086) vaccine and 0.5 mL of meningococcal group A, C, W-135, and Y conjugate vaccine (MenACWY-CRM) at Month 0. Subjects received 0.5 mL of bivalent rLP2086 vaccine at Month 6. Stage 1 was followed by Stage 2. Stage 2: Subjects received intramuscularly injection of 0.5 mL of bivalent rLP2086 vaccine and 0.5 mL of MenACWY-CRM vaccine (booster vaccination) at Month 54.

Subject analysis set title	Stage 1: Groups 2+4 Combined
Subject analysis set type	Per protocol

Subject analysis set description:

Stage 1: ACWY-naive and experienced subjects received an intramuscular injection of 0.5 mL of bivalent rLP2086 vaccine and 0.5 mL MenACWY-CRM vaccine at Month 0 and 0.5 mL of bivalent rLP2086 vaccine at Month 6. Stage 1 evaluable immunogenicity population (EIP), included all eligible subjects who were randomised to the study group of interest, received all investigational products as randomised, had blood drawn for assay testing within the required time frames at Months 0 and 7, had valid and determinate assay results, had received no prohibited vaccines or treatment, and had no other major protocol violations as determined by the sponsor’s global medical monitor.

Subject analysis set title	Stage 1: Groups 2+4 Combined
Subject analysis set type	Safety analysis

Subject analysis set description:

Stage 1: ACWY-naive and experienced subjects received an intramuscular injection of 0.5 mL of bivalent rLP2086 vaccine and 0.5 mL MenACWY-CRM vaccine at Month 0and 0.5 mL of bivalent rLP2086 vaccine at Month 6. The safety population for Stage 1 included subjects who had received at least 1 dose of investigational product during Stage 1 and for whom safety data were available.

Subject analysis set title	Stage 1: Group 1+3 Combined
Subject analysis set type	Per protocol

Subject analysis set description:

Stage 1: ACWY-naive and experienced subjects who received an intramuscular injection of 0.5 mL of MenABCWY vaccine and 0.5 mL of saline at Month 0 and 0.5 mL of MenABCWY vaccine intramuscularly at Month 6. Stage 1 evaluable immunogenicity population (EIP), included all eligible subjects who were randomised to the study group of interest, received all investigational products as randomised, had blood drawn for assay testing within the required time frames at Months 0 and 7, had valid and determinate assay results, had received no prohibited vaccines or treatment, and had no other major protocol violations as determined by the sponsor’s global medical monitor.

Subject analysis set title	Stage 2: Group 1+3 Combined
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Stage 2: Subjects received 0.5 mL of MenABCWY vaccine (booster vaccination) intramuscularly at Month 54. Stage 2 modified intent to treat (mITT) population included all subjects who signed the ICD at Month 18 and who had at least 1 valid and determinate primary strain MenB or MenA/C/W/Y assay result available in Stage 2.

Subject analysis set title	Stage 2: Groups 2+4 Combined
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

Stage 2: Subjects received an intramuscular injection of 0.5 mL of bivalent rLP2086 vaccine and 0.5 mL MenACWY-CRM vaccine at Month 54. Stage 2 modified intent to treat (mITT) population included all subjects who signed the ICD at Month 18 and who had at least 1 valid and determinate primary strain MenB or MenA/C/W/Y assay result available in Stage 2.

Subject analysis set title	Stage 2: Group 1+3 Combined
Subject analysis set type	Per protocol

Subject analysis set description:

Stage 2: Subjects received 0.5 mL of MenABCWY vaccine (booster vaccination) intramuscularly at Month 54. The booster evaluable immunogenicity population (EIP) included subjects who were eligible for the study (ie, met all Stage 1 eligibility criteria as well as continually met Stage 2 eligibility criteria), received a booster dose as intended (the same vaccine as they received in Stage 1), had blood drawn for assay testing within the required time frame at Month 55 (Visit 11), and had a valid and determinate MenB or MenA/C/W/Y assay result after the booster dose, as well as no major protocol violations as determined by the sponsor’s global medical monitor.

Subject analysis set title	Stage 2: Groups 2+4 Combined
Subject analysis set type	Per protocol

Subject analysis set description:

Stage 2: Subjects received an intramuscular injection of 0.5 mL of bivalent rLP2086 vaccine and 0.5 mL MenACWY-CRM vaccine at Month 54. The booster evaluable immunogenicity population (EIP) included

subjects who were eligible for the study (ie, met all Stage 1 eligibility criteria as well as continually met Stage 2 eligibility criteria), received a booster dose as intended (the same vaccine as they received in Stage 1), had blood drawn for assay testing within the required time frame at Month 55 (Visit 11), and had a valid and determinate MenB or MenA/C/W/Y assay result after the booster dose, as well as no major protocol violations as determined by the sponsor's global medical monitor.

Primary: Stage1: Percentage of Subjects Achieving Serum Bactericidal Assay Using Human Complement (hSBA) Titer Level >= Lower Limit of Quantitation (LLOQ) for all 4 Primary Test Strains Combined 1 Month After Vaccination 2 (Group 2 and 4 Combined)

End point title	Stage1: Percentage of Subjects Achieving Serum Bactericidal Assay Using Human Complement (hSBA) Titer Level >= Lower Limit of Quantitation (LLOQ) for all 4 Primary Test Strains Combined 1 Month After Vaccination 2 (Group 2 and 4 Combined)[1]

End point description:

Percentage of subjects who achieved an hSBA titer >= LLOQ for all 4 primary MenB test strains combined (LLOQ was 1:16 for A22 and 1:8 for A56, B24, and B44) was reported in this endpoint. Stage 1 evaluable immunogenicity population (EIP), included all eligible subjects who were randomised to the study group of interest, received all investigational products as randomised, had blood drawn for assay testing within the required time frames at Months 0 and 7, had valid and determinate assay results, had received no prohibited vaccines or treatment, and had no other major protocol violations as determined by the sponsor's global medical monitor. Here, 'Number of subjects Analysed' signifies number of subjects with valid and determinate hSBA results on all 4 strains at the given time point. Analysis was planned for combined Group 2 and 4.

End point type	Primary

End point timeframe:

1 month after Vaccination 2

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: Only descriptive analysis was planned for this endpoint.

End point values	Stage 1: Groups 2+4 Combined			
Subject group type	Subject analysis set			
Number of subjects analysed	814			
Units: Percentage of subjects				
number (confidence interval 95%)	74.3 (71.2 to 77.3)			

Statistical analyses

No statistical analyses for this end point

Primary: Stage1: Percentage of Subjects With Fold Rise >= 4 in hSBA for Each of the 4 Primary MenB Test Strains From Baseline to 1 Month After Vaccination 2 (Group 2 and 4 Combined)

End point title	Stage1: Percentage of Subjects With Fold Rise >= 4 in hSBA for Each of the 4 Primary MenB Test Strains From Baseline to 1 Month After Vaccination 2 (Group 2 and 4 Combined)[2]

End point description:

The 4-fold increase: a) subjects with baseline hSBA titer below limit of detection (LOD or an hSBA titer <1:4), response was defined as hSBA titer >=1:16 or LLOQ (whichever titer is higher); b) subjects with baseline hSBA titer >= LOD and < LLOQ, response was defined as hSBA titer >= 4 times the LLOQ; c) subjects with baseline hSBA titer >= LLOQ, response was defined as hSBA titer >=4 times baseline

titer. Stage 1 EIP: all eligible subjects who were randomised to the study group of interest, received all investigational products as randomised, had blood drawn for assay testing within the required time frames at Months 0 and 7, had valid and determinate assay results, had received no prohibited vaccines or treatment, and had no other major protocol violations as determined by the sponsor's global medical monitor. "n": subjects with valid and determinate hSBA titers for the given strain at both the specified time point and baseline. Analysis was planned for combined Group 2 and 4.

End point type	Primary

End point timeframe:

From Baseline (blood draw prior to Vaccination 1) to 1 month after Vaccination 2

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: Only descriptive analysis was planned for this endpoint.

End point values	Stage 1: Groups 2+4 Combined			
Subject group type	Subject analysis set			
Number of subjects analysed	864			
Units: Percentage of subjects				
number (confidence interval 95%)				
PMB80 (A22) (n =827)	73.8 (70.6 to 76.7)			
PMB2001 (A56) (n =823)	95.0 (93.3 to 96.4)			
PMB2948 (B24) (n =835)	67.4 (64.1 to 70.6)			
PMB2707 (B44) (n =850)	86.4 (83.9 to 88.6)			

Statistical analyses

No statistical analyses for this end point

Primary: Stage1: Percentage of Subjects With Local Reactions Within 7 Days After Vaccination 1 (Group 2 and 4 Combined)

End point title	Stage1: Percentage of Subjects With Local Reactions Within 7 Days After Vaccination 1 (Group 2 and 4 Combined)[3]

End point description:

Local reactions (redness, swelling, and pain) at the site of investigational product administration were recorded in e-diary. Redness and swelling were measured and recorded in caliper units. Each caliper unit represented 0.5 cm. Redness and swelling were graded as mild (>2.0 to 5.0 cm), moderate (>5.0 to 10.0 cm) and severe (>10.0 cm). Pain at injection site was graded as mild (did not interfere with activity), moderate (interfered with activity), and severe (prevented daily activity). The safety population for Stage 1 included subjects who had received at least 1 dose of investigational product during Stage 1 and for whom safety data were available. Here, 'Number of subjects Analyzed' signifies number of subjects with known values. Analysis was planned for combined Group 2 and 4.

End point type	Primary

End point timeframe:

7 days after Vaccination 1

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: Only descriptive analysis was planned for this endpoint.

End point values	Stage 1: Groups 2+4 Combined			
Subject group type	Subject analysis set			
Number of subjects analysed	1044			
Units: Percentage of subjects				
number (confidence interval 95%)				
Redness: Mild	6.8 (5.3 to 8.5)			
Redness: Moderate	8.0 (6.5 to 9.9)			
Redness: Severe	2.0 (1.2 to 3.1)			
Swelling: Mild	9.8 (8.0 to 11.7)			
Swelling: Moderate	6.9 (5.4 to 8.6)			
Swelling: Severe	0.3 (0.1 to 0.8)			
Pain at injection site: Mild	41.2 (38.2 to 44.2)			
Pain at injection site: Moderate	39.1 (36.1 to 42.1)			
Pain at injection site: Severe	4.7 (3.5 to 6.2)			

Statistical analyses

No statistical analyses for this end point

Primary: Stage1: Percentage of Subjects With Local Reactions Within 7 Days After Vaccination 2 (Group 2 and 4 Combined)

End point title	Stage1: Percentage of Subjects With Local Reactions Within 7 Days After Vaccination 2 (Group 2 and 4 Combined)[4]

End point description:

Local reactions (redness, swelling, and pain) at the site of investigational product administration were recorded in e-diary. Redness and swelling were measured and recorded in caliper units. Each caliper unit represented 0.5 cm. Redness and swelling were graded as mild (>2.0 to 5.0 cm), moderate (>5.0 to 10.0 cm) and severe (>10.0 cm). Pain at injection site was graded as mild (did not interfere with activity), moderate (interfered with activity), and severe (prevented daily activity). The safety population for Stage 1 included subjects who had received at least 1 dose of investigational product during Stage 1 and for whom safety data were available. Here, 'Number of subjects Analyzed' signifies number of subjects with known values. Analysis was planned for combined Group 2 and 4.

End point type	Primary

End point timeframe:

7 days after Vaccination 2

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: Only descriptive analysis was planned for this endpoint.

End point values	Stage 1: Groups 2+4 Combined			
Subject group type	Subject analysis set			
Number of subjects analysed	903			
Units: Percentage of subjects				
number (confidence interval 95%)				
Redness: Mild	5.2 (3.8 to 6.9)			

Redness: Moderate	8.4 (6.7 to 10.4)			
Redness: Severe	1.1 (0.5 to 2.0)			
Swelling: Mild	6.4 (4.9 to 8.2)			
Swelling: Moderate	7.5 (5.9 to 9.4)			
Swelling: Severe	0.3 (0.1 to 1.0)			
Pain at injection site: Mild	38.9 (35.7 to 42.1)			
Pain at injection site: Moderate	37.9 (34.7 to 41.1)			
Pain at injection site: Severe	5.4 (4.0 to 7.1)			

Statistical analyses

No statistical analyses for this end point

Primary: Stage1: Percentage of Subjects With Systemic Events Within 7 Days After Vaccination 1 (Group 2 and 4 Combined)

End point title	Stage1: Percentage of Subjects With Systemic Events Within 7 Days After Vaccination 1 (Group 2 and 4 Combined)[5]

End point description:

Systemic events fever, vomiting, diarrhea, headache, fatigue, chills, muscle pain other than muscle pain at the injection site, and joint pain were recorded by using an e-diary. Fever was defined as >=38.0 degree Celsius (C) and categorized to 38.0 to 38.4 degree C, 38.5 to 38.9 degree C, 39.0 to 40.0 degree C and >40.0 degree C. Headache, fatigue, chills, muscle pain and joint pain were graded as mild (did not interfere with activity), moderate (some interference with activity) and severe (prevented daily activity). Vomiting was graded as mild (1-2 times in 24 hours), moderate (>2 times in 24 hours) and severe (required IV hydration). Diarrhea was graded as mild (2-3 loose stools in 24 hours), moderate (4-5 loose stools in 24 hours) and severe (>=6 in 24 hours). Stage 1 Safety population: subjects who had received at least 1 dose of investigational product during Stage 1 and for whom safety data were available. "Number of subjects Analysed": number of subjects with known values.

End point type	Primary

End point timeframe:

7 days after Vaccination 1

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: Only descriptive analysis was planned for this endpoint.

End point values	Stage 1: Groups 2+4 Combined			
Subject group type	Subject analysis set			
Number of subjects analysed	1044			
Units: Percentage of subjects				
number (confidence interval 95%)				
Fever: 38.0 to 38.4 degree C	4.0 (2.9 to 5.4)			
Fever: 38.5 to 38.9 degree C	2.1 (1.3 to 3.2)			
Fever: 39.0 to 40.0 degree C	0.6 (0.2 to 1.2)			
Fever: > 40.0 degree C	0.0 (0.0 to 0.4)			
Fatigue: Mild	25.4 (22.8 to 28.1)			
Fatigue: Moderate	23.7 (21.1 to 26.4)			
Fatigue: Severe	2.9 (1.9 to 4.1)			

Headache: Mild	25.1 (22.5 to 27.8)			
Headache: Moderate	19.0 (16.6 to 21.5)			
Headache: Severe	2.4 (1.6 to 3.5)			
Chills: Mild	11.5 (9.6 to 13.6)			
Chills: Moderate	5.7 (4.4 to 7.3)			
Chills: Severe	1.2 (0.7 to 2.1)			
Vomiting: Mild	2.9 (1.9 to 4.1)			
Vomiting: Moderate	0.9 (0.4 to 1.6)			
Vomiting: severe	0.0 (0.0 to 0.4)			
Diarrhea: Mild	10.7 (8.9 to 12.8)			
Diarrhea: Moderate	3.3 (2.3 to 4.5)			
Diarrhea: Severe	0.1 (0.0 to 0.5)			
Muscle pain: Mild	15.8 (13.6 to 18.2)			
Muscle pain: Moderate	11.6 (9.7 to 13.7)			
Muscle pain: Severe	1.1 (0.5 to 1.9)			
Joint pain: Mild	10.2 (8.5 to 12.3)			
Joint pain: Moderate	8.6 (7.0 to 10.5)			
Joint pain: Severe	0.8 (0.3 to 1.5)			

Statistical analyses

No statistical analyses for this end point

Primary: Stage1: Percentage of Subjects With Systemic Events Within 7 Days After Vaccination 2 (Group 2 and 4 Combined)

End point title	Stage1: Percentage of Subjects With Systemic Events Within 7 Days After Vaccination 2 (Group 2 and 4 Combined)[6]

End point description:

Systemic events fever, vomiting, diarrhea, headache, fatigue, chills, muscle pain other than muscle pain at the injection site, and joint pain were recorded by using an e-diary. Fever was defined as >=38.0 degree Celsius (C) and categorized to 38.0 to 38.4 degree C, 38.5 to 38.9 degree C, 39.0 to 40.0 degree C and >40.0 degree C. Headache, fatigue, chills, muscle pain and joint pain were graded as mild (did not interfere with activity), moderate (some interference with activity) and severe (prevented daily activity). Vomiting was graded as mild (1-2 times in 24 hours), moderate (>2 times in 24 hours) and severe (required IV hydration). Diarrhea was graded as mild (2-3 loose stools in 24 hours), moderate (4-5 loose stools in 24 hours) and severe (>=6 in 24 hours). Stage 1 Safety population: subjects who had received at least 1 dose of investigational product during Stage 1 and for whom safety data were available. "Number of subjects Analysed": number of subjects with known values.

End point type	Primary

End point timeframe:

7 days after Vaccination 2

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: Only descriptive analysis was planned for this endpoint.

End point values	Stage 1: Groups 2+4 Combined			
Subject group type	Subject analysis set			
Number of subjects analysed	903			
Units: Percentage of subjects				
number (confidence interval 95%)				
Fever: 38.0 to 38.4 degree C	1.9 (1.1 to 3.0)			
Fever: 38.5 to 38.9 degree C	0.7 (0.2 to 1.4)			
Fever: 39.0 to 40.0 degree C	0.7 (0.2 to 1.4)			
Fever: > 40.0 degree C	0.0 (0.0 to 0.4)			
Fatigue: Mild	23.0 (20.3 to 25.9)			
Fatigue: Moderate	19.2 (16.6 to 21.9)			
Fatigue: Severe	3.0 (2.0 to 4.3)			
Headache: Mild	23.1 (20.4 to 26.0)			
Headache: Moderate	16.5 (14.1 to 19.1)			
Headache: Severe	2.0 (1.2 to 3.1)			
Chills: Mild	11.6 (9.6 to 13.9)			
Chills: Moderate	6.2 (4.7 to 8.0)			
Chills: Severe	0.7 (0.2 to 1.4)			
Vomiting: Mild	2.0 (1.2 to 3.1)			
Vomiting: Moderate	0.8 (0.3 to 1.6)			
Vomiting: Severe	0.0 (0.0 to 0.4)			
Diarrhea: Mild	7.6 (6.0 to 9.6)			
Diarrhea: Moderate	2.5 (1.6 to 3.8)			
Diarrhea: Severe	0.4 (0.1 to 1.1)			
Muscle pain: Mild	11.5 (9.5 to 13.8)			
Muscle pain: Moderate	7.8 (6.1 to 9.7)			
Muscle pain: Severe	2.1 (1.3 to 3.3)			
Joint pain: Mild	11.2 (9.2 to 13.4)			
Joint pain: Moderate	6.5 (5.0 to 8.3)			
Joint pain: Severe	1.0 (0.5 to 1.9)			

Statistical analyses

No statistical analyses for this end point

Primary: Stage1: Percentage of Subjects With Antipyretic Medication use Within 7 Days After Vaccination 1 (Group 2 and 4 Combined)

End point title	Stage1: Percentage of Subjects With Antipyretic Medication use Within 7 Days After Vaccination 1 (Group 2 and 4 Combined)[7]

End point description:

Stage 1 Safety population: subjects who had received at least 1 dose of investigational product during Stage 1 and for whom safety data were available. "Number of subjects Analysed": number of subjects with known values. Analysis was planned for combined Group 2 and 4.

End point type	Primary

End point timeframe:

7 days after Vaccination 1

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: Only descriptive analysis was planned for this endpoint.

End point values	Stage 1: Groups 2+4 Combined			
Subject group type	Subject analysis set			
Number of subjects analysed	1044			
Units: Percentage of subjects				
number (confidence interval 95%)	18.6 (16.3 to 21.1)			

Statistical analyses

No statistical analyses for this end point

Primary: Stage1: Percentage of Subjects With Antipyretic Medication use Within 7 Days After Vaccination 2 (Group 2 and 4 Combined)

End point title	Stage1: Percentage of Subjects With Antipyretic Medication use Within 7 Days After Vaccination 2 (Group 2 and 4 Combined)[8]

End point description:

Stage 1 Safety population: subjects who had received at least 1 dose of investigational product during Stage 1 and for whom safety data were available. "Number of subjects Analysed": number of subjects with known values. Analysis was planned for combined Group 2 and 4.

End point type	Primary

End point timeframe:

7 days after Vaccination 2

Notes:

[8] - 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: Only descriptive analysis was planned for this endpoint.

End point values	Stage 1: Groups 2+4 Combined			
Subject group type	Subject analysis set			
Number of subjects analysed	903			
Units: Percentage of subjects				
number (confidence interval 95%)	14.4 (12.2 to 16.9)			

Statistical analyses

No statistical analyses for this end point

Primary: Stage1: Percentage of Subjects With at Least 1 Serious Adverse Event

(SAE) Within 30 Days After Vaccination 1 (Group 2 and 4 Combined)

End point title	Stage1: Percentage of Subjects With at Least 1 Serious Adverse Event (SAE) Within 30 Days After Vaccination 1 (Group 2 and 4 Combined)[9]

End point description:

An AE was any untoward medical occurrence in a subject who received study drug without regard to possibility of causal relationship. SAE was any untoward medical occurrence at any dose that: resulted in death, was life threatening (immediate risk of death), required hospitalization or prolongation of existing hospitalization, resulted in persistent or significant disability/incapacity (substantial disruption of the ability to conduct normal life functions), resulted in congenital anomaly/birth defect. Or that was considered to be an important medical event. Stage 1 Safety population: subjects who had received at least 1 dose of investigational product during Stage 1 and for whom safety data were available. Analysis was planned for combined Group 2 and 4.

End point type	Primary

End point timeframe:

30 days after Vaccination 1

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: Only descriptive analysis was planned for this endpoint.

End point values	Stage 1: Groups 2+4 Combined			
Subject group type	Subject analysis set			
Number of subjects analysed	1057			
Units: Percentage of subjects				
number (confidence interval 95%)	0.0 (0.0 to 0.3)			

Statistical analyses

No statistical analyses for this end point

Primary: Stage1: Percentage of Subjects With at Least 1 SAE Within 30 Days After any Vaccination (Group 2 and 4 Combined)

End point title	Stage1: Percentage of Subjects With at Least 1 SAE Within 30 Days After any Vaccination (Group 2 and 4 Combined)[10]

End point description:

An AE was any untoward medical occurrence in a subject who received study drug without regard to possibility of causal relationship. SAE was any untoward medical occurrence at any dose that: resulted in death, was life threatening (immediate risk of death), required hospitalization or prolongation of existing hospitalization, resulted in persistent or significant disability/incapacity (substantial disruption of the ability to conduct normal life functions), resulted in congenital anomaly/birth defect. Or that was considered to be an important medical event. Stage 1 Safety population: subjects who had received at least 1 dose of investigational product during Stage 1 and for whom safety data were available. Analysis was planned for combined Group 2 and 4.

End point type	Primary

End point timeframe:

30 days after any vaccination

Notes:

[10] - 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: Only descriptive analysis was planned for this endpoint.

End point values	Stage 1: Groups 2+4 Combined			
Subject group type	Subject analysis set			
Number of subjects analysed	1057			
Units: Percentage of subjects				
number (confidence interval 95%)	0.0 (0.0 to 0.3)			

Statistical analyses

No statistical analyses for this end point

Primary: Stage1: Percentage of Subjects With at Least 1 Serious Adverse Event (SAE) Within 30 Days After Vaccination 2 (Group 2 and 4 Combined)

End point title	Stage1: Percentage of Subjects With at Least 1 Serious Adverse Event (SAE) Within 30 Days After Vaccination 2 (Group 2 and 4 Combined)[11]

End point description:

An AE was any untoward medical occurrence in a subject who received study drug without regard to possibility of causal relationship. SAE was any untoward medical occurrence at any dose that: resulted in death, was life threatening (immediate risk of death), required hospitalization or prolongation of existing hospitalization, resulted in persistent or significant disability/incapacity (substantial disruption of the ability to conduct normal life functions), resulted in congenital anomaly/birth defect. Or that was considered to be an important medical event. Stage 1 Safety population: subjects who had received at least 1 dose of investigational product during Stage 1 and for whom safety data were available. "Number of subjects Analysed": evaluable subjects. Analysis was planned for combined Group 2 and 4.

End point type	Primary

End point timeframe:

30 days after Vaccination 2

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: Only descriptive analysis was planned for this endpoint.

End point values	Stage 1: Groups 2+4 Combined			
Subject group type	Subject analysis set			
Number of subjects analysed	946			
Units: Percentage of subjects				
number (confidence interval 95%)	0.0 (0.0 to 0.4)			

Statistical analyses

No statistical analyses for this end point

Primary: Stage1: Percentage of Subjects With at Least 1 SAE During the Vaccination Phase (Group 2 and 4 Combined)

End point title	Stage1: Percentage of Subjects With at Least 1 SAE During the Vaccination Phase (Group 2 and 4 Combined)[12]

End point description:

An AE was any untoward medical occurrence in a subject who received study drug without regard to possibility of causal relationship. SAE was any untoward medical occurrence at any dose that: resulted in death, was life threatening (immediate risk of death), required hospitalization or prolongation of existing hospitalization, resulted in persistent or significant disability/incapacity (substantial disruption of the ability to conduct normal life functions), resulted in congenital anomaly/birth defect. Or that was considered to be an important medical event. Stage 1 Safety population: subjects who had received at least 1 dose of investigational product during Stage 1 and for whom safety data were available. Analysis was planned for combined Group 2 and 4.

End point type	Primary

End point timeframe:

Stage 1 Vaccination Phase: From Vaccination 1 through 1 month after Vaccination 2 (7 Months)

Notes:

[12] - 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: Only descriptive analysis was planned for this endpoint.

End point values	Stage 1: Groups 2+4 Combined			
Subject group type	Subject analysis set			
Number of subjects analysed	1057			
Units: Percentage of subjects				
number (confidence interval 95%)	0.8 (0.3 to 1.5)			

Statistical analyses

No statistical analyses for this end point

Primary: Stage1: Percentage of Subjects With at Least 1 SAE Throughout the Stage 1 (Group 2 and 4 Combined)

End point title	Stage1: Percentage of Subjects With at Least 1 SAE Throughout the Stage 1 (Group 2 and 4 Combined)[13]

End point description:

An AE was any untoward medical occurrence in a subject who received study drug without regard to possibility of causal relationship. SAE was any untoward medical occurrence at any dose that: resulted in death, was life threatening (immediate risk of death), required hospitalization or prolongation of existing hospitalization, resulted in persistent or significant disability/incapacity (substantial disruption of the ability to conduct normal life functions), resulted in congenital anomaly/birth defect. Or that was considered to be an important medical event. Stage 1 Safety population: subjects who had received at least 1 dose of investigational product during Stage 1 and for whom safety data were available. Analysis was planned for combined Group 2 and 4.

End point type	Primary

End point timeframe:

Throughout Stage 1: From the Vaccination 1 through 6 months after Vaccination 2 (12 Months)

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: Only descriptive analysis was planned for this endpoint.

End point values	Stage 1: Groups 2+4 Combined			
Subject group type	Subject analysis set			
Number of subjects analysed	1057			
Units: Percentage of subjects				
number (confidence interval 95%)	1.3 (0.7 to 2.2)			

Statistical analyses

No statistical analyses for this end point

Primary: Stage1: Percentage of Subjects With at Least 1 SAE During the Follow-up Phase (Group 2 and 4 Combined)

End point title	Stage1: Percentage of Subjects With at Least 1 SAE During the Follow-up Phase (Group 2 and 4 Combined)[14]

End point description:

An AE was any untoward medical occurrence in a subject who received study drug without regard to possibility of causal relationship. SAE was any untoward medical occurrence at any dose that: resulted in death, was life threatening (immediate risk of death), required hospitalization or prolongation of existing hospitalization, resulted in persistent or significant disability/incapacity (substantial disruption of the ability to conduct normal life functions), resulted in congenital anomaly/birth defect. Or that was considered to be an important medical event. Stage 1 Safety population: subjects who had received at least 1 dose of investigational product during Stage 1 and for whom safety data were available. "Number of subjects Analysed": evaluable subjects. Analysis was planned for combined Group 2 and 4.

End point type	Primary

End point timeframe:

Stage 1 Follow-up phase: From 1 month after Vaccination 2 through 6 months after Vaccination 2 (5 Months)

Notes:

[14] - 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: Only descriptive analysis was planned for this endpoint.

End point values	Stage 1: Groups 2+4 Combined			
Subject group type	Subject analysis set			
Number of subjects analysed	950			
Units: Percentage of subjects				
number (confidence interval 95%)	0.5 (0.2 to 1.2)			

Statistical analyses

No statistical analyses for this end point

Primary: Stage1: Percentage of Subjects With at Least 1 Medically Attended AE Within 30 Days After Vaccination 1 (Group 2 and 4 Combined)

End point title	Stage1: Percentage of Subjects With at Least 1 Medically Attended AE Within 30 Days After Vaccination 1 (Group 2 and 4 Combined)[15]

End point description:

Medically attended AE was defined as a nonserious AE that resulted in an evaluation at a medical facility. Stage 1 Safety population: subjects who had received at least 1 dose of investigational product during Stage 1 and for whom safety data were available. Analysis was planned for combined Group 2 and 4.

End point type	Primary

End point timeframe:

30 days after Vaccination 1

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: Only descriptive analysis was planned for this endpoint.

End point values	Stage 1: Groups 2+4 Combined			
Subject group type	Subject analysis set			
Number of subjects analysed	1057			
Units: Percentage of subjects				
number (confidence interval 95%)	6.3 (4.9 to 8.0)			

Statistical analyses

No statistical analyses for this end point

Primary: Stage1: Percentage of Subjects With at Least 1 Medically Attended AE Within 30 Days After Vaccination 2 (Group 2 and 4 Combined)

End point title	Stage1: Percentage of Subjects With at Least 1 Medically Attended AE Within 30 Days After Vaccination 2 (Group 2 and 4 Combined)[16]

End point description:

Medically attended AE was defined as a nonserious AE that resulted in an evaluation at a medical facility. Stage 1 Safety population: subjects who had received at least 1 dose of investigational product during Stage 1 and for whom safety data were available. "Number of subjects Analysed": evaluable subjects. Analysis was planned for combined Group 2 and 4.

End point type	Primary

End point timeframe:

30 days after Vaccination 2

Notes:

[16] - 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: Only descriptive analysis was planned for this endpoint.

End point values	Stage 1: Groups 2+4 Combined			
Subject group type	Subject analysis set			
Number of subjects analysed	946			
Units: Percentage of subjects				
number (confidence interval 95%)	8.8 (7.0 to 10.8)			

Statistical analyses

No statistical analyses for this end point

Primary: Stage1: Percentage of Subjects With at Least 1 Medically Attended AE Within 30 Days After any Vaccination (Group 2 and 4 Combined)

End point title	Stage1: Percentage of Subjects With at Least 1 Medically Attended AE Within 30 Days After any Vaccination (Group 2 and 4 Combined)[17]

End point description:

Medically attended AE was defined as a nonserious AE that resulted in an evaluation at a medical facility. Stage 1 Safety population: subjects who had received at least 1 dose of investigational product during Stage 1 and for whom safety data were available. Analysis was planned for combined Group 2 and 4.

End point type	Primary

End point timeframe:

30 days after any vaccination

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: Only descriptive analysis was planned for this endpoint.

End point values	Stage 1: Groups 2+4 Combined			
Subject group type	Subject analysis set			
Number of subjects analysed	1057			
Units: Percentage of subjects				
number (confidence interval 95%)	13.3 (11.3 to 15.5)			

Statistical analyses

No statistical analyses for this end point

Primary: Stage1: Percentage of Subjects With at Least 1 Medically Attended AE During the Vaccination Phase (Group 2 and 4 Combined)

End point title	Stage1: Percentage of Subjects With at Least 1 Medically Attended AE During the Vaccination Phase (Group 2 and 4 Combined)[18]

End point description:

Medically attended AE was defined as a nonserious AE that resulted in an evaluation at a medical facility. Stage 1 Safety population: subjects who had received at least 1 dose of investigational product during Stage 1 and for whom safety data were available. Analysis was planned for combined Group 2 and 4.

End point type	Primary

End point timeframe:

Stage 1 Vaccination Phase: From Vaccination 1 through 1 month after Vaccination 2 (7 Months)

Notes:

[18] - 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: Only descriptive analysis was planned for this endpoint.

End point values	Stage 1: Groups 2+4 Combined			
Subject group type	Subject analysis set			
Number of subjects analysed	1057			
Units: Percentage of subjects				
number (confidence interval 95%)	26.7 (24.0 to 29.5)			

Statistical analyses

No statistical analyses for this end point

Primary: Stage1: Percentage of Subjects With at Least 1 Newly Diagnosed Chronic Medical Condition (NDCMC) Within 30 Days After any Vaccination (Group 2 and 4 Combined)

End point title	Stage1: Percentage of Subjects With at Least 1 Newly Diagnosed Chronic Medical Condition (NDCMC) Within 30 Days After any Vaccination (Group 2 and 4 Combined)[19]

End point description:

A NDCMC was defined as a disease or medical condition, not previously identified, that was expected to be persistent or otherwise long-lasting in its effects. The safety population for Stage 1 included subjects who had received at least 1 dose of investigational product during Stage 1 and for whom safety data were available. Analysis was planned for combined Group 2 and 4.

End point type	Primary

End point timeframe:

30 days after any Vaccination

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: Only descriptive analysis was planned for this endpoint.

End point values	Stage 1: Groups 2+4 Combined			
Subject group type	Subject analysis set			
Number of subjects analysed	1057			
Units: Percentage of subjects				
number (confidence interval 95%)	0.5 (0.2 to 1.1)			

Statistical analyses

No statistical analyses for this end point

Primary: Stage1: Percentage of Subjects With at Least 1 Newly Diagnosed Chronic Medical Condition (NDCMC) During the Vaccination Phase (Group 2 and 4 Combined)

End point title	Stage1: Percentage of Subjects With at Least 1 Newly Diagnosed Chronic Medical Condition (NDCMC) During the Vaccination Phase (Group 2 and 4 Combined)[20]

End point description:

A NDCMC was defined as a disease or medical condition, not previously identified, that was expected to be persistent or otherwise long-lasting in its effects. The safety population for Stage 1 included subjects who had received at least 1 dose of investigational product during Stage 1 and for whom safety data were available. Analysis was planned for combined Group 2 and 4.

End point type	Primary

End point timeframe:

Stage 1 Vaccination Phase: From Vaccination 1 through 1 month after Vaccination 2 (7 Months)

Notes:

[20] - 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: Only descriptive analysis was planned for this endpoint.

End point values	Stage 1: Groups 2+4 Combined			
Subject group type	Subject analysis set			
Number of subjects analysed	1057			
Units: Percentage of subjects				
number (confidence interval 95%)	0.8 (0.3 to 1.5)			

Statistical analyses

No statistical analyses for this end point

Primary: Stage1: Percentage of Subjects With at Least 1 Newly Diagnosed Chronic Medical Condition (NDCMC) Within 30 Days After Vaccination 2 (Group 2 and 4 Combined)

End point title	Stage1: Percentage of Subjects With at Least 1 Newly Diagnosed Chronic Medical Condition (NDCMC) Within 30 Days After Vaccination 2 (Group 2 and 4 Combined)[21]

End point description:

A NDCMC was defined as a disease or medical condition, not previously identified, that was expected to be persistent or otherwise long-lasting in its effects. The safety population for Stage 1 included subjects who had received at least 1 dose of investigational product during Stage 1 and for whom safety data were available. "Number of subjects Analysed": evaluable subjects. Analysis was planned for combined Group 2 and 4.

End point type	Primary

End point timeframe:

30 days after Vaccination 2

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: Only descriptive analysis was planned for this endpoint.

End point values	Stage 1: Groups 2+4 Combined			
Subject group type	Subject analysis set			
Number of subjects analysed	946			
Units: Percentage of subjects				
number (confidence interval 95%)	0.2 (0.0 to 0.8)			

Statistical analyses

No statistical analyses for this end point

Primary: Stage1: Percentage of Subjects With at Least 1 Newly Diagnosed Chronic Medical Condition (NDCMC) Within 30 Days After Vaccination 1 (Group 2 and 4 Combined)

End point title	Stage1: Percentage of Subjects With at Least 1 Newly Diagnosed Chronic Medical Condition (NDCMC) Within 30 Days After Vaccination 1 (Group 2 and 4 Combined)[22]

End point description:

A NDCMC was defined as a disease or medical condition, not previously identified, that was expected to be persistent or otherwise long-lasting in its effects. The safety population for Stage 1 included subjects who had received at least 1 dose of investigational product during Stage 1 and for whom safety data were available. Analysis was planned for combined Group 2 and 4.

End point type	Primary

End point timeframe:

30 days after Vaccination 1

Notes:

[22] - 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: Only descriptive analysis was planned for this endpoint.

End point values	Stage 1: Groups 2+4 Combined			
Subject group type	Subject analysis set			
Number of subjects analysed	1057			
Units: Percentage of subjects				
number (confidence interval 95%)	0.3 (0.1 to 0.8)			

Statistical analyses

No statistical analyses for this end point

Primary: Stage1: Percentage of Subjects With at Least 1 Medically Attended AE Throughout the Stage 1 (Group 2 and 4 Combined)

End point title	Stage1: Percentage of Subjects With at Least 1 Medically Attended AE Throughout the Stage 1 (Group 2 and 4 Combined)[23]

End point description:

Medically attended AE was defined as a nonserious AE that resulted in an evaluation at a medical facility. Stage 1 Safety population: subjects who had received at least 1 dose of investigational product

during Stage 1 and for whom safety data were available. Analysis was planned for combined Group 2 and 4.

End point type	Primary

End point timeframe:

Throughout Stage 1: From the Vaccination 1 through 6 months after Vaccination 2 (12 Months)

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: Only descriptive analysis was planned for this endpoint.

End point values	Stage 1: Groups 2+4 Combined			
Subject group type	Subject analysis set			
Number of subjects analysed	1057			
Units: Percentage of subjects				
number (confidence interval 95%)	33.7 (30.8 to 36.6)			

Statistical analyses

No statistical analyses for this end point

Primary: Stage1: Percentage of Subjects With at Least 1 Medically Attended AE During the Follow-up Phase (Group 2 and 4 Combined)

End point title	Stage1: Percentage of Subjects With at Least 1 Medically Attended AE During the Follow-up Phase (Group 2 and 4 Combined)[24]

End point description:

Medically attended AE was defined as a nonserious AE that resulted in an evaluation at a medical facility. Stage 1 Safety population: subjects who had received at least 1 dose of investigational product during Stage 1 and for whom safety data were available. "Number of subjects Analysed": evaluable subjects. Analysis was planned for combined Group 2 and 4.

End point type	Primary

End point timeframe:

Stage 1 Follow-up phase: From 1 month after Vaccination 2 through 6 months after Vaccination 2 (5 Months)

Notes:

[24] - 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: Only descriptive analysis was planned for this endpoint.

End point values	Stage 1: Groups 2+4 Combined			
Subject group type	Subject analysis set			
Number of subjects analysed	950			
Units: Percentage of subjects				
number (confidence interval 95%)	16.6 (14.3 to 19.2)			

Statistical analyses

No statistical analyses for this end point

Primary: Stage1: Percentage of Subjects With at Least 1 Newly Diagnosed Chronic Medical Condition (NDCMC) During the Follow-up Phase (Group 2 and 4 Combined)

End point title	Stage1: Percentage of Subjects With at Least 1 Newly Diagnosed Chronic Medical Condition (NDCMC) During the Follow-up Phase (Group 2 and 4 Combined)[25]

End point description:

A NDCMC was defined as a disease or medical condition, not previously identified, that was expected to be persistent or otherwise long-lasting in its effects. The safety population for Stage 1 included subjects who had received at least 1 dose of investigational product during Stage 1 and for whom safety data were available. "Number of subjects Analysed": evaluable subjects. Analysis was planned for combined Group 2 and 4.

End point type	Primary

End point timeframe:

Stage 1 Follow-up phase: From 1 month after Vaccination 2 through 6 months after Vaccination 2 (5 Months)

Notes:

[25] - 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: Only descriptive analysis was planned for this endpoint.

End point values	Stage 1: Groups 2+4 Combined			
Subject group type	Subject analysis set			
Number of subjects analysed	950			
Units: Percentage of subjects				
number (confidence interval 95%)	0.3 (0.1 to 0.9)			

Statistical analyses

No statistical analyses for this end point

Primary: Stage1: Percentage of Subjects With at Least 1 Newly Diagnosed Chronic Medical Condition (NDCMC) Throughout the Stage 1 (Group 2 and 4)

End point title	Stage1: Percentage of Subjects With at Least 1 Newly Diagnosed Chronic Medical Condition (NDCMC) Throughout the Stage 1 (Group 2 and 4)[26]

End point description:

A NDCMC was defined as a disease or medical condition, not previously identified, that was expected to be persistent or otherwise long-lasting in its effects. The safety population for Stage 1 included subjects who had received at least 1 dose of investigational product during Stage 1 and for whom safety data were available. Analysis was planned for combined Group 2 and 4.

End point type	Primary

End point timeframe:

Throughout Stage 1: From the Vaccination 1 through 6 months after Vaccination 2 (12 Months)

Notes:

[26] - 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: Only descriptive analysis was planned for this endpoint.

End point values	Stage 1: Groups 2+4 Combined			
Subject group type	Subject analysis set			
Number of subjects analysed	1057			
Units: Percentage of subjects				
number (confidence interval 95%)	0.9 (0.5 to 1.7)			

Statistical analyses

No statistical analyses for this end point

Primary: Stage1: Percentage of Subjects With at Least 1 AE Within 30 Days After Vaccination 1 (Group 2 and 4 Combined)

End point title	Stage1: Percentage of Subjects With at Least 1 AE Within 30 Days After Vaccination 1 (Group 2 and 4 Combined)[27]

End point description:

An AE was any untoward medical occurrence in a subject who received study drug without regard to possibility of causal relationship. Stage 1 Safety population: subjects who had received at least 1 dose of investigational product during Stage 1 and for whom safety data were available. Analysis was planned for combined Group 2 and 4.

End point type	Primary

End point timeframe:

30 days after Vaccination 1

Notes:

[27] - 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: Only descriptive analysis was planned for this endpoint.

End point values	Stage 1: Groups 2+4 Combined			
Subject group type	Subject analysis set			
Number of subjects analysed	1057			
Units: Percentage of subjects				
number (confidence interval 95%)	13.8 (11.8 to 16.0)			

Statistical analyses

No statistical analyses for this end point

Primary: Stage1: Percentage of Subjects With at Least 1 AE Within 30 Days After Vaccination 2 (Group 2 and 4 Combined)

End point title	Stage1: Percentage of Subjects With at Least 1 AE Within 30 Days After Vaccination 2 (Group 2 and 4 Combined)[28]

End point description:

An AE was any untoward medical occurrence in a subject who received study drug without regard to possibility of causal relationship. Stage 1 Safety population: subjects who had received at least 1 dose of investigational product during Stage 1 and for whom safety data were available. "Number of subjects Analysed": evaluable subjects. Analysis was planned for combined Group 2 and 4.

End point type	Primary

End point timeframe:

30 days after Vaccination 2

Notes:

[28] - 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: Only descriptive analysis was planned for this endpoint.

End point values	Stage 1: Groups 2+4 Combined			
Subject group type	Subject analysis set			
Number of subjects analysed	946			
Units: Percentage of subjects				
number (confidence interval 95%)	14.7 (12.5 to 17.1)			

Statistical analyses

No statistical analyses for this end point

Primary: Stage1: Percentage of Subjects With at Least 1 AE Within 30 Days After any Vaccination (Group 2 and 4 Combined)

End point title	Stage1: Percentage of Subjects With at Least 1 AE Within 30 Days After any Vaccination (Group 2 and 4 Combined)[29]

End point description:

An AE was any untoward medical occurrence in a subject who received study drug without regard to possibility of causal relationship. Stage 1 Safety population: subjects who had received at least 1 dose of investigational product during Stage 1 and for whom safety data were available. Analysis was planned for combined Group 2 and 4.

End point type	Primary

End point timeframe:

30 days after any vaccination

Notes:

[29] - 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: Only descriptive analysis was planned for this endpoint.

End point values	Stage 1: Groups 2+4 Combined			
Subject group type	Subject analysis set			
Number of subjects analysed	1057			
Units: Percentage of subjects				
number (confidence interval 95%)	24.1 (21.6 to 26.8)			

Statistical analyses

No statistical analyses for this end point

Primary: Stage1: Percentage of Subjects With at Least 1 AE During Vaccination Phase (Group 2 and 4 Combined)

End point title	Stage1: Percentage of Subjects With at Least 1 AE During Vaccination Phase (Group 2 and 4 Combined)[30]

End point description:

An AE was any untoward medical occurrence in a subject who received study drug without regard to possibility of causal relationship. Stage 1 Safety population: subjects who had received at least 1 dose of investigational product during Stage 1 and for whom safety data were available. Analysis was planned for combined Group 2 and 4.

End point type	Primary

End point timeframe:

Stage 1 Vaccination Phase: From Vaccination 1 through 1 month after Vaccination 2 (7 Months)

Notes:

[30] - 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: Only descriptive analysis was planned for this endpoint.

End point values	Stage 1: Groups 2+4 Combined			
Subject group type	Subject analysis set			
Number of subjects analysed	1057			
Units: Percentage of subjects				
number (confidence interval 95%)	40.7 (37.7 to 43.7)			

Statistical analyses

No statistical analyses for this end point

Primary: Stage1: Percentage of Subjects With at Least 1 Immediate AE After Vaccination 1 (Group 2 and 4 Combined)

End point title	Stage1: Percentage of Subjects With at Least 1 Immediate AE After Vaccination 1 (Group 2 and 4 Combined)[31]

End point description:

Immediate AE was defined as AE occurring within the first 30 minutes after investigational product administration. The safety population for Stage 1 included subjects who had received at least 1 dose of investigational product during Stage 1 and for whom safety data were available. Analysis was planned for combined Group 2 and 4.

End point type	Primary

End point timeframe:

30 minutes after Vaccination 1

Notes:

[31] - 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: Only descriptive analysis was planned for this endpoint.

End point values	Stage 1: Groups 2+4 Combined			
Subject group type	Subject analysis set			
Number of subjects analysed	1057			
Units: Percentage of subjects				
number (confidence interval 95%)	0.9 (0.4 to 1.6)			

Statistical analyses

No statistical analyses for this end point

Primary: Stage1: Percentage of Subjects With at Least 1 Immediate AE After Vaccination 2 (Group 2 and 4 Combined)

End point title	Stage1: Percentage of Subjects With at Least 1 Immediate AE After Vaccination 2 (Group 2 and 4 Combined)[32]

End point description:

Immediate AE was defined as AE occurring within the first 30 minutes after investigational product administration. The safety population for Stage 1 included subjects who had received at least 1 dose of investigational product during Stage 1 and for whom safety data were available. "Number of subjects Analysed": evaluable subjects. Analysis was planned for combined Group 2 and 4.

End point type	Primary

End point timeframe:

30 minutes after Vaccination 2

Notes:

[32] - 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: Only descriptive analysis was planned for this endpoint.

End point values	Stage 1: Groups 2+4 Combined			
Subject group type	Subject analysis set			
Number of subjects analysed	946			
Units: Percentage of subjects				
number (confidence interval 95%)	0.3 (0.1 to 0.9)			

Statistical analyses

No statistical analyses for this end point

Primary: Stage2: Percentage of Subjects With Local Reactions Within 7 Days After Booster Vaccination: Group 1 Through Group 4

End point title	Stage2: Percentage of Subjects With Local Reactions Within 7 Days After Booster Vaccination: Group 1 Through Group 4[33]

End point description:

Local reactions (redness, swelling, and pain) at the site of investigational product administration were recorded in e-diary. Redness and swelling were measured and recorded in caliper units. Each caliper unit represented 0.5 cm. Redness and swelling were graded as mild (>2.0 to 5.0 cm), moderate (>5.0 to 10.0 cm) and severe (>10.0 cm). Pain at injection site was graded as mild (did not interfere with activity), moderate (interfered with activity), and severe (prevented daily activity). The safety

population for Stage 2 included subjects who received the booster vaccination and for whom safety data were available. Here, 'Number of subjects Analysed' signifies number of subjects with known values. Analysis was planned for Group 1 through Group 4.

End point type	Primary

End point timeframe:

7 days after booster vaccination

Notes:

[33] - 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: Only descriptive analysis was planned for this endpoint.

End point values	Group 1: MenABCWY + Saline (ACWY-Naive)	Group 2: Bivalent rLP2086 + MenACWY-CRM (ACWY-Naive)	Group 3: MenABCWY + Saline (ACWY-Experienced)	Group 4: Bivalent rLP2086 + MenACWY-CRM (ACWY-Experienced)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	59	35	74	55
Units: Percentage of subjects				
number (confidence interval 95%)				
Redness: Mild	5.1 (1.1 to 14.1)	11.4 (3.2 to 26.7)	9.5 (3.9 to 18.5)	14.5 (6.5 to 26.7)
Redness: Moderate	3.4 (0.4 to 11.7)	11.4 (3.2 to 26.7)	8.1 (3.0 to 16.8)	9.1 (3.0 to 20.0)
Redness: Severe	5.1 (1.1 to 14.1)	5.7 (0.7 to 19.2)	4.1 (0.8 to 11.4)	1.8 (0.0 to 9.7)
Swelling: Mild	10.2 (3.8 to 20.8)	11.4 (3.2 to 26.7)	6.8 (2.2 to 15.1)	9.1 (3.0 to 20.0)
Swelling: Moderate	8.5 (2.8 to 18.7)	11.4 (3.2 to 26.7)	12.2 (5.7 to 21.8)	7.3 (2.0 to 17.6)
Swelling: Severe	0.0 (0.0 to 6.1)	2.9 (0.1 to 14.9)	0.0 (0.0 to 4.9)	1.8 (0.0 to 9.7)
Pain at injection site: Mild	41.4 (28.6 to 55.1)	25.7 (12.5 to 43.3)	36.5 (25.6 to 48.5)	47.3 (33.7 to 61.2)
Pain at injection site: Moderate	36.2 (24.0 to 49.9)	45.7 (28.8 to 63.4)	47.3 (35.6 to 59.3)	38.2 (25.4 to 52.3)
Pain at injection site: Severe	1.7 (0.0 to 9.2)	14.3 (4.8 to 30.3)	1.4 (0.0 to 7.3)	0.0 (0.0 to 6.5)

Statistical analyses

No statistical analyses for this end point

Primary: Stage1: Number of Subjects who Missed School/Work due to AE During the Vaccination Phase (Group 2 and 4 Combined)

End point title	Stage1: Number of Subjects who Missed School/Work due to AE During the Vaccination Phase (Group 2 and 4 Combined)[34]

End point description:

Stage 1 Safety population: subjects who had received at least 1 dose of investigational product during Stage 1 and for whom safety data were available. Analysis was planned for combined Group 2 and 4.

End point type	Primary

End point timeframe:

Stage 1 Vaccination Phase: From Vaccination 1 through 1 month after Vaccination 2 (7 Months)

Notes:

[34] - 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: Only descriptive analysis was planned for this endpoint.

End point values	Stage 1: Groups 2+4 Combined			
Subject group type	Subject analysis set			
Number of subjects analysed	1057			
Units: Subjects	171			

Statistical analyses

No statistical analyses for this end point

Primary: Stage2: Percentage of Subjects With Systemic Events Within 7 Days After Booster Vaccination: Group 1 Through Group 4

End point title	Stage2: Percentage of Subjects With Systemic Events Within 7 Days After Booster Vaccination: Group 1 Through Group 4[35]

End point description:

Systemic events fever, vomiting, diarrhea, headache, fatigue, chills, muscle pain and joint pain were recorded in an e-diary. Fever was defined as >=38.0 degree Celsius (C) and categorized to 38.0 to 38.4 degree C, 38.5 to 38.9 degree C, 39.0 to 40.0 degree C and >40.0 degree C. Headache, fatigue, chills, muscle pain and joint pain were graded as mild (did not interfere with activity), moderate (some interference with activity) and severe (prevented daily activity). Vomiting was graded as mild (1-2 times in 24 hours), moderate (>2 times in 24 hours) and severe (required IV hydration). Diarrhea was graded as mild (2-3 loose stools in 24 hours), moderate (4-5 loose stools in 24 hours) and severe (>=6 in 24 hours). Stage 2 safety population: subjects who received the booster vaccination and for whom safety data were available. Here, 'Number of subjects Analysed' signifies number of subjects with known values. Analysis was planned for Group 1 through Group 4.

End point type	Primary

End point timeframe:

7 days after booster vaccination

Notes:

[35] - 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: Only descriptive analysis was planned for this endpoint.

End point values	Group 1: MenABCWY + Saline (ACWY-Naive)	Group 2: Bivalent rLP2086 + MenACWY-CRM (ACWY-Naive)	Group 3: MenABCWY + Saline (ACWY-Experienced)	Group 4: Bivalent rLP2086 + MenACWY-CRM (ACWY-Experienced)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	60	39	76	56
Units: Percentage of subjects				
number (confidence interval 95%)				
Fever: 38.0 to 38.4 degree C	1.7 (0.0 to 8.9)	0.0 (0.0 to 9.0)	0.0 (0.0 to 4.7)	1.8 (0.0 to 9.6)
Fever: 38.4 to 38.9 degree C	0.0 (0.0 to 6.0)	2.6 (0.1 to 13.5)	0.0 (0.0 to 4.7)	0.0 (0.0 to 6.4)
Fever: 38.9 to 40.0 degree C	3.3 (0.4 to 11.5)	0.0 (0.0 to 9.0)	0.0 (0.0 to 4.7)	0.0 (0.0 to 6.4)
Fever: > 40.0 degree C	0.0 (0.0 to 6.0)	0.0 (0.0 to 9.0)	0.0 (0.0 to 4.7)	0.0 (0.0 to 6.4)

Fatigue: Mild	25.0 (14.7 to 37.9)	25.6 (13.0 to 42.1)	50.0 (38.3 to 61.7)	37.5 (24.9 to 51.5)
Fatigue: Moderate	21.7 (12.1 to 34.2)	30.8 (17.0 to 47.6)	10.5 (4.7 to 19.7)	23.2 (13.0 to 36.4)
Fatigue: Severe	0.0 (0.0 to 6.0)	5.1 (0.6 to 17.3)	1.3 (0.0 to 7.1)	5.4 (1.1 to 14.9)
Headache: Mild	25.0 (14.7 to 37.9)	20.5 (9.3 to 36.5)	34.2 (23.7 to 46.0)	39.3 (26.5 to 53.2)
Headache: Moderate	8.3 (2.8 to 18.4)	28.2 (15.0 to 44.9)	10.5 (4.7 to 19.7)	14.3 (6.4 to 26.2)
Headache: Severe	3.3 (0.4 to 11.5)	5.1 (0.6 to 17.3)	1.3 (0.0 to 7.1)	1.8 (0.0 to 9.6)
Chills: Mild	10.0 (3.8 to 20.5)	12.8 (4.3 to 27.4)	15.8 (8.4 to 26.0)	12.5 (5.2 to 24.1)
Chills: Moderate	0.0 (0.0 to 6.0)	5.1 (0.6 to 17.3)	2.6 (0.3 to 9.2)	0.0 (0.0 to 6.4)
Chills: Severe	0.0 (0.0 to 6.0)	0.0 (0.0 to 9.0)	0.0 (0.0 to 4.7)	1.8 (0.0 to 9.6)
Vomiting: Mild	1.7 (0.0 to 8.9)	0.0 (0.0 to 9.0)	1.3 (0.0 to 7.1)	1.8 (0.0 to 9.6)
Vomiting: Moderate	1.7 (0.0 to 8.9)	0.0 (0.0 to 9.0)	1.3 (0.0 to 7.1)	0.0 (0.0 to 6.4)
Vomiting: severe	0.0 (0.0 to 6.0)	0.0 (0.0 to 9.0)	0.0 (0.0 to 4.7)	0.0 (0.0 to 6.4)
Diarrhea: Mild	5.0 (1.0 to 13.9)	7.7 (1.6 to 20.9)	7.9 (3.0 to 16.4)	7.1 (2.0 to 17.3)
Diarrhea: Moderate	0.0 (0.0 to 6.0)	2.6 (0.1 to 13.5)	1.3 (0.0 to 7.1)	5.4 (1.1 to 14.9)
Diarrhea: Severe	0.0 (0.0 to 6.0)	0.0 (0.0 to 9.0)	0.0 (0.0 to 4.7)	0.0 (0.0 to 6.4)
Muscle pain: Mild	13.3 (5.9 to 24.6)	10.3 (2.9 to 24.2)	22.4 (13.6 to 33.4)	19.6 (10.2 to 32.4)
Muscle pain: Moderate	5.0 (1.0 to 13.9)	12.8 (4.3 to 27.4)	7.9 (3.0 to 16.4)	3.6 (0.4 to 12.3)
Muscle pain: Severe	0.0 (0.0 to 6.0)	7.7 (1.6 to 20.9)	1.3 (0.0 to 7.1)	0.0 (0.0 to 6.4)
Joint pain: Mild	15.0 (7.1 to 26.6)	12.8 (4.3 to 27.4)	11.8 (5.6 to 21.3)	12.5 (5.2 to 24.1)
Joint pain: Moderate	3.3 (0.4 to 11.5)	10.3 (2.9 to 24.2)	9.2 (3.8 to 18.1)	3.6 (0.4 to 12.3)
Joint pain: Severe	0.0 (0.0 to 6.0)	2.6 (0.1 to 13.5)	0.0 (0.0 to 4.7)	0.0 (0.0 to 6.4)

Statistical analyses

No statistical analyses for this end point

Primary: Stage2: Percentage of Subjects With Antipyretic Medication use Within 7 Days After Booster Vaccination: Group 1 Through Group 4

End point title	Stage2: Percentage of Subjects With Antipyretic Medication use Within 7 Days After Booster Vaccination: Group 1 Through Group 4[36]

End point description:

The safety population for Stage 2 included subjects who received the booster vaccination and for whom safety data were available. Here, 'Number of subjects Analysed' signifies number of subjects with known values. Analysis was planned for Group 1 through Group 4.

End point type	Primary

End point timeframe:

7 days after booster vaccination

Notes:

[36] - 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: Only descriptive analysis was planned for this endpoint.

End point values	Group 1: MenABCWY + Saline (ACWY-Naive)	Group 2: Bivalent rLP2086 + MenACWY-CRM (ACWY-Naive)	Group 3: MenABCWY + Saline (ACWY-Experienced)	Group 4: Bivalent rLP2086 + MenACWY-CRM (ACWY-Experienced)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	60	39	76	56
Units: Percentage of subjects				
number (confidence interval 95%)	16.7 (8.3 to 28.5)	20.5 (9.3 to 36.5)	13.2 (6.5 to 22.9)	10.7 (4.0 to 21.9)

Statistical analyses

No statistical analyses for this end point

Primary: Stage2: Percentage of Subjects With at Least 1 SAE During Booster Phase: Group 1 Through Group 4

End point title	Stage2: Percentage of Subjects With at Least 1 SAE During Booster Phase: Group 1 Through Group 4[37]

End point description:

An AE was any untoward medical occurrence in a subject who received study drug without regard to possibility of causal relationship. SAE was any untoward medical occurrence at any dose that: resulted in death, was life threatening (immediate risk of death), required hospitalization or prolongation of existing hospitalization, resulted in persistent or significant disability/incapacity (substantial disruption of the ability to conduct normal life functions), resulted in congenital anomaly/birth defect. Or that was considered to be an important medical event. The safety population for Stage 2 included subjects who received the booster vaccination and for whom safety data were available. Here, 'Number of subjects Analysed' signifies subjects evaluable for this endpoint. Analysis was planned for Group 1 through Group 4.

End point type	Primary

End point timeframe:

Booster vaccination phase: From booster vaccination through 1 month after booster vaccination

Notes:

[37] - 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: Only descriptive analysis was planned for this endpoint.

End point values	Group 1: MenABCWY + Saline (ACWY-Naive)	Group 2: Bivalent rLP2086 + MenACWY-CRM (ACWY-Naive)	Group 3: MenABCWY + Saline (ACWY-Experienced)	Group 4: Bivalent rLP2086 + MenACWY-CRM (ACWY-Experienced)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	67	40	77	56
Units: Percentage of subjects				
number (confidence interval 95%)	0.0 (0.0 to 5.4)	0.0 (0.0 to 8.8)	0.0 (0.0 to 4.7)	1.8 (0.0 to 9.6)

Statistical analyses

No statistical analyses for this end point

Primary: Stage2: Percentage of Subjects With at Least 1 SAE During the Booster Follow-up Phase: Group 1 Through Group 4

End point title	Stage2: Percentage of Subjects With at Least 1 SAE During the Booster Follow-up Phase: Group 1 Through Group 4[38]

End point description:

An AE was any untoward medical occurrence in a subject who received study drug without regard to possibility of causal relationship. SAE was any untoward medical occurrence at any dose that: resulted in death, was life threatening (immediate risk of death), required hospitalization or prolongation of existing hospitalization, resulted in persistent or significant disability/incapacity (substantial disruption of the ability to conduct normal life functions), resulted in congenital anomaly/birth defect. Or that was considered to be an important medical event. The safety population for Stage 2 included subjects who received the booster vaccination and for whom safety data were available. Here, 'Number of subjects Analysed' signifies subjects evaluable for this endpoint. Analysis was planned for Group 1 through Group 4.

End point type	Primary

End point timeframe:

Booster follow-up phase: From 1 month after booster vaccination through 6 months after booster vaccination

Notes:

[38] - 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: Only descriptive analysis was planned for this endpoint.

End point values	Group 1: MenABCWY + Saline (ACWY-Naive)	Group 2: Bivalent rLP2086 + MenACWY-CRM (ACWY-Naive)	Group 3: MenABCWY + Saline (ACWY-Experienced)	Group 4: Bivalent rLP2086 + MenACWY-CRM (ACWY-Experienced)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	67	38	77	56
Units: Percentage of subjects				
number (confidence interval 95%)	0.0 (0.0 to 5.4)	0.0 (0.0 to 9.3)	2.6 (0.3 to 9.1)	0.0 (0.0 to 6.4)

Statistical analyses

No statistical analyses for this end point

Primary: Stage2: Percentage of Subjects With at Least 1 SAE Throughout Booster Phase: Group 1 Through Group 4

End point title	Stage2: Percentage of Subjects With at Least 1 SAE Throughout Booster Phase: Group 1 Through Group 4[39]

End point description:

An AE was any untoward medical occurrence in a subject who received study drug without regard to

possibility of causal relationship. SAE was any untoward medical occurrence at any dose that: resulted in death, was life threatening (immediate risk of death), required hospitalization or prolongation of existing hospitalization, resulted in persistent or significant disability/incapacity (substantial disruption of the ability to conduct normal life functions), resulted in congenital anomaly/birth defect. Or that was considered to be an important medical event. The safety population for Stage 2 included subjects who received the booster vaccination and for whom safety data were available. Here, 'Number of subjects Analysed' signifies subjects evaluable for this endpoint. Analysis was planned for Group 1 through Group 4.

End point type	Primary

End point timeframe:

Booster vaccination phase: From booster vaccination through 6 months after booster vaccination

Notes:

[39] - 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: Only descriptive analysis was planned for this endpoint.

End point values	Group 1: MenABCWY + Saline (ACWY-Naive)	Group 2: Bivalent rLP2086 + MenACWY-CRM (ACWY-Naive)	Group 3: MenABCWY + Saline (ACWY-Experienced)	Group 4: Bivalent rLP2086 + MenACWY-CRM (ACWY-Experienced)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	67	40	77	56
Units: Percentage of subjects				
number (confidence interval 95%)	0.0 (0.0 to 5.4)	0.0 (0.0 to 8.8)	2.6 (0.3 to 9.1)	0.0 (0.0 to 6.4)

Statistical analyses

No statistical analyses for this end point

Primary: Stage2: Percentage of Subjects With at Least 1 Medically Attended AE During Booster Phase: Group 1 Through Group 4

End point title	Stage2: Percentage of Subjects With at Least 1 Medically Attended AE During Booster Phase: Group 1 Through Group 4[40]

End point description:

Medically attended AE was defined as a nonserious AE that resulted in an evaluation at a medical facility. The safety population for Stage 2 included subjects who received the booster vaccination and for whom safety data were available. Here, 'Number of subjects Analysed' signifies subjects evaluable for this endpoint. Analysis was planned for Group 1 through Group 4.

End point type	Primary

End point timeframe:

Booster vaccination phase: From booster vaccination through 1 month after booster vaccination

Notes:

[40] - 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: Only descriptive analysis was planned for this endpoint.

End point values	Group 1: MenABCWY + Saline (ACWY-Naive)	Group 2: Bivalent rLP2086 + MenACWY-CRM (ACWY-Naive)	Group 3: MenABCWY + Saline (ACWY-Experienced)	Group 4: Bivalent rLP2086 + MenACWY-CRM (ACWY-Experienced)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	67	40	77	56
Units: Percentage of subjects				
number (confidence interval 95%)	9.0 (3.4 to 18.5)	5.0 (0.6 to 16.9)	2.6 (0.3 to 9.1)	7.1 (2.0 to 17.3)

Statistical analyses

No statistical analyses for this end point

Primary: Stage2: Percentage of Subjects With at Least 1 Medically Attended AE During the Booster Follow-up Phase: Group 1 Through Group 4

End point title	Stage2: Percentage of Subjects With at Least 1 Medically Attended AE During the Booster Follow-up Phase: Group 1 Through Group 4[41]

End point description:

Medically attended AE was defined as a nonserious AE that resulted in an evaluation at a medical facility. The safety population for Stage 2 included subjects who received the booster vaccination and for whom safety data were available. Here, 'Number of subjects Analysed' signifies subjects evaluable for this endpoint. Analysis was planned for Group 1 through Group 4.

End point type	Primary

End point timeframe:

Booster Follow-up Phase: From 1 month after booster vaccination through 6 months after booster vaccination

Notes:

[41] - 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: Only descriptive analysis was planned for this endpoint.

End point values	Group 1: MenABCWY + Saline (ACWY-Naive)	Group 2: Bivalent rLP2086 + MenACWY-CRM (ACWY-Naive)	Group 3: MenABCWY + Saline (ACWY-Experienced)	Group 4: Bivalent rLP2086 + MenACWY-CRM (ACWY-Experienced)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	67	38	77	56
Units: Percentage of subjects				
number (confidence interval 95%)	3.0 (0.4 to 10.4)	13.2 (4.4 to 28.1)	6.5 (2.1 to 14.5)	7.1 (2.0 to 17.3)

Statistical analyses

No statistical analyses for this end point

Primary: Stage2: Percentage of Subjects With at Least 1 Medically Attended AE Throughout Booster Phase: Group 1 Through Group 4

End point title	Stage2: Percentage of Subjects With at Least 1 Medically Attended AE Throughout Booster Phase: Group 1 Through Group 4[42]

End point description:

Medically attended AE was defined as a nonserious AE that resulted in an evaluation at a medical facility. The safety population for Stage 2 included subjects who received the booster vaccination and for whom safety data were available. Here, 'Number of subjects Analysed' signifies subjects evaluable for this endpoint. Analysis was planned for Group 1 through Group 4.

End point type	Primary

End point timeframe:

Booster Vaccination Phase: From booster vaccination through 6 months after booster vaccination

Notes:

[42] - 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: Only descriptive analysis was planned for this endpoint.

End point values	Group 1: MenABCWY + Saline (ACWY-Naive)	Group 2: Bivalent rLP2086 + MenACWY-CRM (ACWY-Naive)	Group 3: MenABCWY + Saline (ACWY-Experienced)	Group 4: Bivalent rLP2086 + MenACWY-CRM (ACWY-Experienced)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	67	40	77	56
Units: Percentage of subjects				
number (confidence interval 95%)	10.4 (4.3 to 20.3)	15.0 (5.7 to 29.8)	7.8 (2.9 to 16.2)	14.3 (6.4 to 26.2)

Statistical analyses

No statistical analyses for this end point

Primary: Stage2: Percentage of Subjects With at Least 1 NDCMC During Booster Phase: Group 1 Through Group 4

End point title	Stage2: Percentage of Subjects With at Least 1 NDCMC During Booster Phase: Group 1 Through Group 4[43]

End point description:

A NDCMC was defined as a disease or medical condition, not previously identified, that was expected to be persistent or otherwise long-lasting in its effects. The safety population for Stage 2 included subjects who received the booster vaccination and for whom safety data were available. Here, 'Number of subjects Analysed' signifies subjects evaluable for this endpoint. Analysis was planned for Group 1 through Group 4.

End point type	Primary

End point timeframe:

Booster Vaccination Phase: From booster vaccination through 1 month after booster vaccination

Notes:

[43] - 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: Only descriptive analysis was planned for this endpoint.

End point values	Group 1: MenABCWY + Saline (ACWY-Naive)	Group 2: Bivalent rLP2086 + MenACWY-CRM (ACWY-Naive)	Group 3: MenABCWY + Saline (ACWY-Experienced)	Group 4: Bivalent rLP2086 + MenACWY-CRM (ACWY-Experienced)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	67	40	77	56
Units: Percentage of subjects				
number (confidence interval 95%)	0.0 (0.0 to 5.4)	0.0 (0.0 to 8.8)	0.0 (0.0 to 4.7)	0.0 (0.0 to 6.4)

Statistical analyses

No statistical analyses for this end point

Primary: Stage2: Percentage of Subjects With at Least 1 NDCMC Throughout Booster Phase: Group 1 Through Group 4

End point title	Stage2: Percentage of Subjects With at Least 1 NDCMC Throughout Booster Phase: Group 1 Through Group 4[44]

End point description:

A NDCMC was defined as a disease or medical condition, not previously identified, that was expected to be persistent or otherwise long-lasting in its effects. The safety population for Stage 2 included subjects who received the booster vaccination and for whom safety data were available. Here, 'Number of subjects Analysed' signifies subjects evaluable for this endpoint. Analysis was planned for Group 1 through Group 4.

End point type	Primary

End point timeframe:

Booster Vaccination Phase: From booster vaccination through 6 months after booster vaccination

Notes:

[44] - 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: Only descriptive analysis was planned for this endpoint.

End point values	Group 1: MenABCWY + Saline (ACWY-Naive)	Group 2: Bivalent rLP2086 + MenACWY-CRM (ACWY-Naive)	Group 3: MenABCWY + Saline (ACWY-Experienced)	Group 4: Bivalent rLP2086 + MenACWY-CRM (ACWY-Experienced)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	67	40	77	56
Units: Percentage of subjects				
number (confidence interval 95%)	0.0 (0.0 to 5.4)	0.0 (0.0 to 8.8)	2.6 (0.3 to 9.1)	0.0 (0.0 to 6.4)

Statistical analyses

No statistical analyses for this end point

Primary: Stage2: Percentage of Subjects With at Least 1 NDCMC During the Booster Follow-up Phase: Group 1 Through Group 4

End point title	Stage2: Percentage of Subjects With at Least 1 NDCMC During the Booster Follow-up Phase: Group 1 Through Group 4[45]

End point description:

A NDCMC was defined as a disease or medical condition, not previously identified, that was expected to be persistent or otherwise long-lasting in its effects. The safety population for Stage 2 included subjects who received the booster vaccination and for whom safety data were available. Here, 'Number of subjects Analysed' signifies subjects evaluable for this endpoint. Analysis was planned for Group 1 through Group 4.

End point type	Primary

End point timeframe:

Booster Follow-up Phase: From 1 month after booster vaccination through 6 months after booster vaccination

Notes:

[45] - 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: Only descriptive analysis was planned for this endpoint.

End point values	Group 1: MenABCWY + Saline (ACWY-Naive)	Group 2: Bivalent rLP2086 + MenACWY-CRM (ACWY-Naive)	Group 3: MenABCWY + Saline (ACWY-Experienced)	Group 4: Bivalent rLP2086 + MenACWY-CRM (ACWY-Experienced)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	67	38	77	56
Units: Percentage of subjects				
number (confidence interval 95%)	0.0 (0.0 to 5.4)	0.0 (0.0 to 9.3)	2.6 (0.3 to 9.1)	0.0 (0.0 to 6.4)

Statistical analyses

No statistical analyses for this end point

Primary: Stage2: Percentage of Subjects With at Least 1 AE During Booster Phase: Group 1 Through Group 4

End point title	Stage2: Percentage of Subjects With at Least 1 AE During Booster Phase: Group 1 Through Group 4[46]

End point description:

An AE was any untoward medical occurrence in a subject who received study drug without regard to possibility of causal relationship. The safety population for Stage 2 included subjects who received the booster vaccination and for whom safety data were available. Here, 'Number of subjects Analysed' signifies subjects evaluable for this endpoint. Analysis was planned for Group 1 through Group 4.

End point type	Primary

End point timeframe:

Booster Vaccination Phase: From booster vaccination through 1 month after booster vaccination

Notes:

[46] - 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: Only descriptive analysis was planned for this endpoint.

End point values	Group 1: MenABCWY + Saline (ACWY-Naive)	Group 2: Bivalent rLP2086 + MenACWY-CRM (ACWY-Naive)	Group 3: MenABCWY + Saline (ACWY-Experienced)	Group 4: Bivalent rLP2086 + MenACWY-CRM (ACWY-Experienced)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	67	40	77	56

Units: Percentage of subjects				
number (confidence interval 95%)	13.4 (6.3 to 24.0)	10.0 (2.8 to 23.7)	10.4 (4.6 to 19.4)	17.9 (8.9 to 30.4)

Statistical analyses

No statistical analyses for this end point

Primary: Stage2: Percentage of Subjects With at Least 1 Immediate AE After Booster Vaccination: Group 1 Through Group 4

End point title	Stage2: Percentage of Subjects With at Least 1 Immediate AE After Booster Vaccination: Group 1 Through Group 4[47]

End point description:

Immediate AE was defined as AE occurring within the first 30 minutes after investigational product administration. The safety population for Stage 2 included subjects who received the booster vaccination and for whom safety data were available. Analysis was planned for Group 1 through Group 4.

End point type	Primary

End point timeframe:

30 minutes after booster vaccination

Notes:

[47] - 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: Only descriptive analysis was planned for this endpoint.

End point values	Group 1: MenABCWY + Saline (ACWY-Naive)	Group 2: Bivalent rLP2086 + MenACWY-CRM (ACWY-Naive)	Group 3: MenABCWY + Saline (ACWY-Experienced)	Group 4: Bivalent rLP2086 + MenACWY-CRM (ACWY-Experienced)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	67	40	77	56
Units: Percentage of subjects				
number (confidence interval 95%)	0.0 (0.0 to 0.0)	0.0 (0.0 to 0.0)	0.0 (0.0 to 0.0)	0.0 (0.0 to 0.0)

Statistical analyses

No statistical analyses for this end point

Primary: Stage2: Number of Subjects who Missed School/Work due to AE After Booster Vaccination: Group 1 Through Group 4

End point title	Stage2: Number of Subjects who Missed School/Work due to AE After Booster Vaccination: Group 1 Through Group 4[48]

End point description:

The safety population for Stage 2 included subjects who received the booster vaccination and for whom safety data were available. Here, 'Number of subjects Analysed' signifies subjects evaluable for this endpoint. Analysis was planned for Group 1 through Group 4.

End point type	Primary

End point timeframe:

Booster Vaccination Phase: From booster vaccination through 1 month after booster vaccination

Notes:

[48] - 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: Only descriptive analysis was planned for this endpoint.

End point values	Group 1: MenABCWY + Saline (ACWY-Naive)	Group 2: Bivalent rLP2086 + MenACWY-CRM (ACWY-Naive)	Group 3: MenABCWY + Saline (ACWY-Experienced)	Group 4: Bivalent rLP2086 + MenACWY-CRM (ACWY-Experienced)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	67	40	77	56
Units: Subjects	3	0	3	2

Statistical analyses

No statistical analyses for this end point

Secondary: Stage1: Percentage of Subjects With hSBA Titer Level >= LLOQ for all 4 Primary MenB Test Strains Combined Before Vaccination 1 and 1 Month After Vaccination 2 (Group 2 and 4 Combined)

End point title	Stage1: Percentage of Subjects With hSBA Titer Level >= LLOQ for all 4 Primary MenB Test Strains Combined Before Vaccination 1 and 1 Month After Vaccination 2 (Group 2 and 4 Combined)

End point description:

Percentage of subjects who achieved an hSBA titer >= LLOQ for all 4 primary MenB test strains combined (LLOQ was 1:16 for A22 and 1:8 for A56, B24, and B44) was reported in this endpoint. Stage 1 EIP, included all eligible subjects who were randomised to the study group of interest, received all investigational products as randomised, had blood drawn for assay testing within the required time frames at Months 0 and 7, had valid and determinate assay results, had received no prohibited vaccines or treatment, and had no other major protocol violations as determined by the sponsor's global medical monitor. Here, 'n' signifies number of subjects with valid and determinate hSBA results on all 4 strains at the given time point. Analysis was planned for combined Group 2 and 4.

End point type	Secondary

End point timeframe:

Before Vaccination 1, 1 month after Vaccination 2

End point values	Stage 1: Groups 2+4 Combined			
Subject group type	Subject analysis set			
Number of subjects analysed	864			
Units: Percentage of subjects				
number (confidence interval 95%)				
PMB80 (A22) Before Vaccination 1, (n=839)	25.1 (22.2 to 28.2)			
PMB80 (A22) 1 month after Vaccination 2, (n=852)	91.0 (88.8 to 92.8)			
PMB2001 (A56) Before Vaccination 1, (n=833)	12.8 (10.6 to 15.3)			

PMB2001 (A56) 1 month after Vaccination 2, (n=854)	99.4 (98.6 to 99.8)			
PMB2948 (B24) Before Vaccination 1, (n=855)	11.9 (9.8 to 14.3)			
PMB2948 (B24) 1 month after Vaccination 2,(n=842)	79.3 (76.4 to 82.0)			
PMB2707 (B44) Before Vaccination 1, (n=861)	4.5 (3.2 to 6.1)			
PMB2707 (B44) 1 month after Vaccination 2,(n=853)	94.5 (92.7 to 95.9)			

Statistical analyses

No statistical analyses for this end point

Secondary: Stage1: Percentage of Subjects With hSBA Titer Level >= 1:4, >= 1:8, >= 1:16, >= 1:32, >= 1:64, >= 1:128 for all 4 Primary MenB Test Strains Before Vaccination 1 and 1 Month After Vaccination 2 (Group 2 and 4 Combined)

End point title	Stage1: Percentage of Subjects With hSBA Titer Level >= 1:4, >= 1:8, >= 1:16, >= 1:32, >= 1:64, >= 1:128 for all 4 Primary MenB Test Strains Before Vaccination 1 and 1 Month After Vaccination 2 (Group 2 and 4 Combined)

End point description:

Percentage of subjects who achieved an hSBA titer >= 1:4, >= 1:8, >= 1:16, >= 1:32, >= 1:64, >= 1:128 for all 4 primary MenB test strains was reported in this endpoint. Stage 1 EIP, included all eligible subjects who were randomised to the study group of interest, received all investigational products as randomised, had blood drawn for assay testing within the required time frames at Months 0 and 7, had valid and determinate assay results, had received no prohibited vaccines or treatment, and had no other major protocol violations as determined by the sponsor’s global medical monitor. Here, 'n’ signifies number of subjects with valid and determinate hSBA results on all 4 strains at the given time point. Analysis was planned for combined Group 2 and 4.

End point type	Secondary

End point timeframe:

Before Vaccination 1 (Vacc 1), 1 month after Vaccination 2 (Vacc 2)

End point values	Stage 1: Groups 2+4 Combined			
Subject group type	Subject analysis set			
Number of subjects analysed	864			
Units: Percentage of subjects				
number (confidence interval 95%)				
PMB80 (A22) Before Vacc 1 >=1:4,(n=839)	36.6 (33.3 to 40.0)			
PMB80 (A22) Before Vacc 1 >=1:8,(n=839)	31.8 (28.7 to 35.1)			
PMB80 (A22) Before Vacc 1 >=1:16,(n=839)	25.1 (22.2 to 28.2)			
PMB80 (A22) Before Vacc 1 >=1:32,(n=839)	11.4 (9.4 to 13.8)			
PMB80 (A22) Before Vacc 1 >=1:64, (n=839)	4.4 (3.1 to 6.0)			
PMB80 (A22) Before Vacc 1 >=1:128,(n=839)	0.8 (0.3 to 1.7)			

PMB80 (A22) 1 Month after Vacc 2 >=1:4,(n=852)	91.7 (89.6 to 93.4)			
PMB80 (A22) 1 Month after Vacc 2 >=1:8,n=852)	91.5 (89.5 to 93.3)			
PMB80 (A22) 1 Month after Vacc 2 >=1:16,(n=852)	91.0 (88.8 to 92.8)			
PMB80 (A22) 1 Month after Vacc 2 >=1:32,(n=852)	80.2 (77.3 to 82.8)			
PMB80 (A22) 1 Month after Vacc 2 >=1:64,(n=852)	54.9 (51.5 to 58.3)			
PMB80 (A22) 1 Month after Vacc 2 >=1:128,(n=852)	27.3 (24.4 to 30.5)			
PMB2001 (A56) Before Vacc 1 >=1:4,(n=833)	17.5 (15.0 to 20.3)			
PMB2001 (A56) Before Vacc 1 >=1:8,(n=833)	12.8 (10.6 to 15.3)			
PMB2001 (A56) Before Vacc 1 >=1:16,(n=833)	11.0 (9.0 to 13.4)			
PMB2001 (A56) Before Vacc 1 >=1:32,(n=833)	7.6 (5.9 to 9.6)			
PMB2001 (A56) Before Vacc 1 >=1:64,(n=833)	4.3 (3.0 to 5.9)			
PMB2001 (A56) Before Vacc 1 >=1:128,(n=833)	2.4 (1.5 to 3.7)			
PMB2001 (A56) 1 Month after Vacc 2 >=1:4,(n=854)	99.5 (98.8 to 99.9)			
PMB2001 (A56) 1 Month after Vacc 2 >=1:8,(n=854)	99.4 (98.6 to 99.8)			
PMB2001 (A56) 1 Month after Vacc 2 >=1:16,(n=854)	99.1 (98.2 to 99.6)			
PMB2001 (A56) 1 Month after Vacc 2 >=1:32,(n=854)	97.0 (95.6 to 98.0)			
PMB2001 (A56) 1 Month after Vacc 2 >=1:64,(n=854)	87.7 (85.3 to 89.8)			
PMB2001 (A56) 1 Month after Vacc 2 >=1:128,(n=854)	69.2 (66.0 to 72.3)			
PMB2948 (B24) Before Vacc 1 >=1:4,(n=855)	14.6 (12.3 to 17.2)			
PMB2948 (B24) Before Vacc 1 >=1:8,(n=855)	11.9 (9.8 to 14.3)			
PMB2948 (B24) Before Vacc 1 >=1:16,(n=855)	8.2 (6.4 to 10.2)			
PMB2948 (B24) Before Vacc 1 >=1:32,(n=855)	4.2 (3.0 to 5.8)			
PMB2948 (B24) Before Vacc 1 >=1:64,(n=855)	2.3 (1.4 to 3.6)			
PMB2948 (B24) Before Vacc 1 >=1:128,(n=855)	1.1 (0.5 to 2.0)			
PMB2948 (B24) 1 Month after Vacc 2 >=1:4,(n=842)	81.2 (78.4 to 83.8)			
PMB2948 (B24) 1 Month after Vacc 2 >=1:8,(n=842)	79.3 (76.4 to 82.0)			
PMB2948 (B24) 1 Month after Vacc 2 >=1:16,(n=842)	74.0 (70.9 to 76.9)			
PMB2948 (B24) 1 Month after Vacc 2 >=1:32,(n=842)	47.9 (44.4 to 51.3)			
PMB2948 (B24) 1 Month after Vacc 2 >=1:64,(n=842)	24.9 (22.1 to 28.0)			
PMB2948 (B24) 1 Month after Vacc 2 >=1:128,(n=842)	9.6 (7.7 to 11.8)			
PMB2707 (B44) Before Vacc 1 >=1:4,(n=861)	7.2 (5.6 to 9.1)			

PMB2707 (B44) Before Vacc 1 >=1:8,(n=861)	4.5 (3.2 to 6.1)			
PMB2707 (B44) Before Vacc 1 >=1:16,(n=861)	3.3 (2.2 to 4.7)			
PMB2707 (B44) Before Vacc 1 >=1:32,(n=861)	2.1 (1.2 to 3.3)			
PMB2707 (B44) Before Vacc 1 >=1:64,(n=861)	1.2 (0.6 to 2.1)			
PMB2707 (B44) Before Vacc 1 >=1:128,(n=861)	0.3 (0.1 to 1.0)			
PMB2707 (B44) 1 Month after Vacc 2 >=1:4,(n=853)	96.2 (94.7 to 97.4)			
PMB2707 (B44) 1 Month after Vacc 2 >=1:8,(n=853)	94.5 (92.7 to 95.9)			
PMB2707 (B44) 1 Month after Vacc 2 >=1:16,(n=853)	89.0 (86.7 to 91.0)			
PMB2707 (B44) 1 Month after Vacc 2 >=1:32,(n=853)	68.6 (65.3 to 71.7)			
PMB2707 (B44) 1 Month after Vacc 2 >=1:64,(n=853)	41.0 (37.7 to 44.4)			
PMB2707 (B44) 1 Month after Vacc 2 >=1:128,(n=853)	19.2 (16.6 to 22.0)			

Statistical analyses

No statistical analyses for this end point

Secondary: Stage1: hSBA Geometric Mean Titers (GMTs) for all 4 Primary MenB Test Strains Combined Before Vaccination 1 and 1 Month After Vaccination 2 (Group 2 and 4 Combined)

End point title	Stage1: hSBA Geometric Mean Titers (GMTs) for all 4 Primary MenB Test Strains Combined Before Vaccination 1 and 1 Month After Vaccination 2 (Group 2 and 4 Combined)

End point description:

GMTs were calculated using all subjects with valid and determinate hSBA titers at the given time point. LLOQ = 1:16 for A22; 1:8 for A56, B24, and B44. Titers below the LLOQ were set to 0.5 * LLOQ for analysis. Stage 1 EIP, included all eligible subjects who were randomised to the study group of interest, received all investigational products as randomised, had blood drawn for assay testing within the required time frames at Months 0 and 7, had valid and determinate assay results, had received no prohibited vaccines or treatment, and had no other major protocol violations as determined by the sponsor's global medical monitor. Here, 'n' signifies number of subjects with valid and determinate hSBA results on all 4 strains at the given time point. Analysis was planned for combined Group 2 and 4.

End point type	Secondary

End point timeframe:

Before Vaccination 1 (Vacc 1), 1 month after Vaccination 2 (Vacc 2)

End point values	Stage 1: Groups 2+4 Combined			
Subject group type	Subject analysis set			
Number of subjects analysed	864			
Units: Titers				
geometric mean (confidence interval 95%)				

PMB80 (A22) Before Vacc 1,(n=839)	10.7 (10.3 to 11.1)			
PMB80 (A22) 1 month after Vacc 2,(n=852)	49.3 (46.2 to 52.6)			
PMB2001 (A56) Before Vacc 1,(n=833)	5.3 (5.0 to 5.6)			
PMB2001 (A56) 1 month after Vacc 2,(n=854)	139.5 (130.6 to 149.1)			
PMB2948 (B24) Before Vacc 1,(n=855)	4.9 (4.7 to 5.1)			
PMB2948 (B24) 1 month after Vacc 2,(n=842)	21.2 (19.6 to 22.9)			
PMB2707 (B44) Before Vacc 1,(n=861)	4.3 (4.2 to 4.5)			
PMB2707 (B44) 1 month after Vacc 2,(n=853)	37.8 (35.1 to 40.8)			

Statistical analyses

No statistical analyses for this end point

Secondary: Stage1: Percentage of Subjects With hSBA Titer Level >= LLOQ for 10 Secondary MenB Test Strains Before Vaccination 1 and 1 Month After Vaccination 2 (Group 2 and 4 Combined)

End point title	Stage1: Percentage of Subjects With hSBA Titer Level >= LLOQ for 10 Secondary MenB Test Strains Before Vaccination 1 and 1 Month After Vaccination 2 (Group 2 and 4 Combined)

End point description:

Percentage of subjects who achieved an hSBA titer greater than or equal to LLOQ for for 10 Secondary MenB test strains combined (LLOQ = 1:16 for A06, A12, and A19; 1:8 for A07, A15, A29, B03, B09, B15, and B16) was reported in this endpoint. Stage 1 EIP, included all eligible subjects who were randomised to the study group of interest, received all investigational products as randomised, had blood drawn for assay testing within the required time frames at Months 0 and 7, had valid and determinate assay results, had received no prohibited vaccines or treatment, and had no other major protocol violations as determined by the sponsor's global medical monitor. Here, 'n' signifies number of subjects with valid and determinate hSBA results on all 10 strains at the given time point. Analysis was planned for combined Group 2 and 4.

End point type	Secondary

End point timeframe:

Before Vaccination 1 (Vacc 1), 1 month after Vaccination 2 (Vacc 2)

End point values	Stage 1: Groups 2+4 Combined			
Subject group type	Subject analysis set			
Number of subjects analysed	864			
Units: Percentage of subjects				
number (confidence interval 95%)				
PMB3175 (A29) Before Vacc 1,(n=166)	4.8 (2.1 to 9.3)			
PMB3175 (A29) 1 month after Vacc 2,(n=166)	95.2 (90.7 to 97.9)			
PMB3010 (A06) Before Vacc 1,(n=157)	5.7 (2.7 to 10.6)			
PMB3010 (A06) 1 month after Vacc 2,(n=159)	89.3 (83.4 to 93.6)			

PMB824 (A12) Before Vacc 1,(n=154)	5.2 (2.3 to 10.0)			
PMB824 (A12) 1 month after Vacc 2,(n=157)	83.4 (76.7 to 88.9)			
PMB3040 (A07) Before Vacc 1,(n=150)	32.0 (24.6 to 40.1)			
PMB3040 (A07) 1 month after Vacc 2,(n=157)	96.8 (92.7 to 99.0)			
PMB1672 (A15) Before Vacc 1,(n=166)	22.9 (16.7 to 30.0)			
PMB1672 (A15) 1 month after Vacc 2,(n=165)	89.1 (83.3 to 93.4)			
PMB1989 (A19) Before Vacc 1,(n=167)	5.4 (2.5 to 10.0)			
PMB1989 (A19) 1 month after Vacc 2,(n=167)	90.4 (84.9 to 94.4)			
PMB648 (B16) Before Vacc 1,(n=172)	8.1 (4.5 to 13.3)			
PMB648 (B16) 1 month after Vacc 2,(n=164)	77.4 (70.3 to 83.6)			
PMB866 (B09) Before Vacc 1,(n=171)	9.9 (5.9 to 15.4)			
PMB866 (B09) 1 month after Vacc 2,(n=166)	71.1 (63.6 to 77.8)			
PMB1256 (B03) Before Vacc 1,(n=172)	3.5 (1.3 to 7.4)			
PMB1256 (B03) 1 month after Vacc 2,(n=164)	74.4 (67.0 to 80.9)			
PMB431 (B15) Before Vacc 1,(n=172)	6.4 (3.2 to 11.2)			
PMB431 (B15) 1 month after Vacc 2,(n=167)	85.0 (78.7 to 90.1)			

Statistical analyses

No statistical analyses for this end point

Secondary: Stage1: Percentage of Subjects With hSBA Titer Level >= 1:4, >= 1:8, >= 1:16, >= 1:32, >= 1:64, >= 1:128 for Each of the 10 Secondary MenB Test Strains Before Vaccination 1 and 1 Month After Vaccination 2 (Group 2 and 4 Combined)

End point title	Stage1: Percentage of Subjects With hSBA Titer Level >= 1:4, >= 1:8, >= 1:16, >= 1:32, >= 1:64, >= 1:128 for Each of the 10 Secondary MenB Test Strains Before Vaccination 1 and 1 Month After Vaccination 2 (Group 2 and 4 Combined)

End point description:

Percentage of subjects who achieved an hSBA titer >= 1:4, >= 1:8, >= 1:16, >= 1:32, >= 1:64, >= 1:128 for each of the 10 secondary MenB test strains was reported in this endpoint. Stage 1 EIP, included all eligible subjects who were randomised to the study group of interest, received all investigational products as randomised, had blood drawn for assay testing within the required time frames at Months 0 and 7, had valid and determinate assay results, had received no prohibited vaccines or treatment, and had no other major protocol violations as determined by the sponsor's global medical monitor. Here, 'n' signifies number of subjects with valid and determinate hSBA results on each of the 10 Secondary strains at the given time point. Analysis was planned for combined Group 2 and 4.

End point type	Secondary

End point timeframe:

Before Vaccination 1 (Vacc 1), 1 month after Vaccination 2 (Vacc 2)

End point values	Stage 1: Groups 2+4 Combined			
Subject group type	Subject analysis set			
Number of subjects analysed	864			
Units: Percentage of subjects				
number (confidence interval 95%)				
PMB3175 (A29) Before Vacc 1 >=1:4,(n=166)	6.6 (3.4 to 11.5)			
PMB3175 (A29) Before Vacc 1 >=1:8,(n=166)	4.8 (2.1 to 9.3)			
PMB3175 (A29) Before Vacc 1 >=1:16,(n=166)	3.6 (1.3 to 7.7)			
PMB3175 (A29) Before Vacc 1 >=1:32,(n=166)	1.2 (0.1 to 4.3)			
PMB3175 (A29) Before Vacc 1 >=1:64,(n=166)	0.0 (0.0 to 2.2)			
PMB3175 (A29) Before Vacc 1 >=1:128,(n=166)	0.0 (0.0 to 2.2)			
PMB3175 (A29) 1 Month after Vacc 2 >=1:4,(n=166)	95.8 (91.5 to 98.3)			
PMB3175 (A29) 1 Month after Vacc 2 >=1:8,(n=166)	95.2 (90.7 to 97.9)			
PMB3175 (A29) 1 Month after Vacc 2 >=1:16,(n=166)	92.2 (87.0 to 95.8)			
PMB3175 (A29) 1 Month after Vacc 2 >=1:32,(n=166)	71.7 (64.2 to 78.4)			
PMB3175 (A29) 1 Month after Vacc 2 >=1:64,(n=166)	38.0 (30.5 to 45.8)			
PMB3175 (A29) 1 Month after Vacc 2 >=1:128,(n=166)	13.9 (9.0 to 20.1)			
PMB3010 (A06) Before Vacc 1 >=1:4,(n=157)	7.0 (3.5 to 12.2)			
PMB3010 (A06) Before Vacc 1 >=1:8,(n=157)	6.4 (3.1 to 11.4)			
PMB3010 (A06) Before Vacc 1 >=1:16,(n=157)	5.7 (2.7 to 10.6)			
PMB3010 (A06) Before Vacc 1 >=1:32,(n=157)	3.8 (1.4 to 8.1)			
PMB3010 (A06) Before Vacc 1 >=1:64,(n=157)	3.2 (1.0 to 7.3)			
PMB3010 (A06) Before Vacc 1 >=1:128,(n=157)	1.9 (0.4 to 5.5)			
PMB3010 (A06) 1 Month after Vacc 2 >=1:4,(n=159)	89.9 (84.2 to 94.1)			
PMB3010 (A06) 1 Month after Vacc 2 >=1:8,(n=159)	89.3 (83.4 to 93.6)			
PMB3010 (A06) 1 Month after Vacc 2 >=1:16,(n=159)	89.3 (83.4 to 93.6)			
PMB3010 (A06) 1 Month after Vacc 2 >=1:32,(n=159)	79.9 (72.8 to 85.8)			
PMB3010 (A06) 1 Month after Vacc 2 >=1:64,(n=159)	54.7 (46.6 to 62.6)			
PMB3010 (A06) 1 Month after Vacc 2 >=1:128,(n=159)	22.0 (15.8 to 29.3)			
PMB824 (A12) Before Vacc 1 >=1:4,(n=154)	9.7 (5.6 to 15.6)			

PMB824 (A12) Before Vacc 1 >=1:8,(n=154)	9.1 (5.1 to 14.8)			
PMB824 (A12) Before Vacc 1 >=1:16,(n=154)	5.2 (2.3 to 10.0)			
PMB824 (A12) Before Vacc 1 >=1:32,(n=154)	2.6 (0.7 to 6.5)			
PMB824 (A12) Before Vacc 1 >=1:64,(n=154)	0.0 (0.0 to 2.4)			
PMB824 (A12) Before Vacc 1 >=1:128,(n=154)	0.0 (0.0 to 2.4)			
PMB824 (A12) 1 Month after Vacc 2 >=1:4,(n=157)	89.2 (83.2 to 93.6)			
PMB824 (A12) 1 Month after Vacc 2 >=1:8,(n=157)	87.9 (81.7 to 92.6)			
PMB824 (A12) 1 Month after Vacc 2 >=1:16,(n=157)	83.4 (76.7 to 88.9)			
PMB824 (A12) 1 Month after Vacc 2 >=1:32,(n=157)	52.9 (44.8 to 60.9)			
PMB824 (A12) 1 Month after Vacc 2 >=1:64,(n=157)	18.5 (12.7 to 25.4)			
PMB824 (A12) 1 Month after Vacc 2 >=1:128,(n=157)	1.3 (0.2 to 4.5)			
PMB3040 (A07) Before Vacc 1 >=1:4,(n=150)	32.7 (25.2 to 40.8)			
PMB3040 (A07) Before Vacc 1 >=1:8,(n=150)	32.0 (24.6 to 40.1)			
PMB3040 (A07) Before Vacc 1 >=1:16,(n=150)	31.3 (24.0 to 39.4)			
PMB3040 (A07) Before Vacc 1 >=1:32,(n=150)	28.7 (21.6 to 36.6)			
PMB3040 (A07) Before Vacc 1 >=1:64,(n=150)	17.3 (11.6 to 24.4)			
PMB3040 (A07) Before Vacc 1 >=1:128,(n=150)	2.7 (0.7 to 6.7)			
PMB3040 (A07) 1 Month after Vacc 2 >=1:4,(n=157)	96.8 (92.7 to 99.0)			
PMB3040 (A07) 1 Month after Vacc 2 >=1:8,(n=157)	96.8 (92.7 to 99.0)			
PMB3040 (A07) 1 Month after Vacc 2 >=1:16,(n=157)	96.8 (92.7 to 99.0)			
PMB3040 (A07) 1 Month after Vacc 2 >=1:32,(n=157)	94.3 (89.4 to 97.3)			
PMB3040 (A07) 1 Month after Vacc 2 >=1:64,(n=157)	68.8 (60.9 to 75.9)			
PMB3040 (A07) 1 Month after Vacc 2 >=1:128,(n=157)	31.2 (24.1 to 39.1)			
PMB1672 (A15) Before Vacc 1 >=1:4,(n=166)	24.7 (18.3 to 32.0)			
PMB1672 (A15) Before Vacc 1 >=1:8,(n=166)	22.9 (16.7 to 30.0)			
PMB1672 (A15) Before Vacc 1 >=1:16,(n=166)	21.7 (15.7 to 28.7)			
PMB1672 (A15) Before Vacc 1 >=1:32,(n=166)	13.9 (9.0 to 20.1)			
PMB1672 (A15) Before Vacc 1 >=1:64,(n=166)	5.4 (2.5 to 10.0)			
PMB1672 (A15) Before Vacc 1 >=1:128,(n=166)	0.6 (0.0 to 3.3)			
PMB1672 (A15) 1 Month after Vacc 2 >=1:4,(n=165)	89.1 (83.3 to 93.4)			
PMB1672 (A15) 1 Month after Vacc 2 >=1:8,(n=165)	89.1 (83.3 to 93.4)			

PMB1672 (A15) 1 Month after Vacc 2 >=1:16,(n=165)	87.3 (81.2 to 91.9)			
PMB1672 (A15) 1 Month after Vacc 2 >=1:32,(n=165)	69.7 (62.1 to 76.6)			
PMB1672 (A15) 1 Month after Vacc 2 >=1:64,(n=165)	30.3 (23.4 to 37.9)			
PMB1672 (A15) 1 Month after Vacc 2 >=1:128,(n=165)	5.5 (2.5 to 10.1)			
PMB1989 (A19) Before Vacc 1 >=1:4,(n=167)	11.4 (7.0 to 17.2)			
PMB1989 (A19) Before Vacc 1 >=1:8,(n=167)	8.4 (4.7 to 13.7)			
PMB1989 (A19) Before Vacc 1 >=1:16,(n=167)	5.4 (2.5 to 10.0)			
PMB1989 (A19) Before Vacc 1 >=1:32,(n=167)	3.6 (1.3 to 7.7)			
PMB1989 (A19) Before Vacc 1 >=1:64,(n=167)	1.2 (0.1 to 4.3)			
PMB1989 (A19) Before Vacc 1 >=1:128,(n=167)	0.6 (0.0 to 3.3)			
PMB1989 (A19) 1 Month after Vacc 2 >=1:4,(n=167)	92.2 (87.1 to 95.8)			
PMB1989 (A19) 1 Month after Vacc 2 >=1:8,(n=167)	92.2 (87.1 to 95.8)			
PMB1989 (A19) 1 Month after Vacc 2 >=1:16,(n=167)	90.4 (84.9 to 94.4)			
PMB1989 (A19) 1 Month after Vacc 2 >=1:32,(n=167)	84.4 (78.0 to 89.6)			
PMB1989 (A19) 1 Month after Vacc 2 >=1:64,(n=167)	61.1 (53.2 to 68.5)			
PMB1989 (A19) 1 Month after Vacc 2 >=1:128,(n=167)	28.7 (22.0 to 36.2)			
PMB648 (B16) Before Vacc 1 >=1:4,(n=172)	9.9 (5.9 to 15.4)			
PMB648 (B16) Before Vacc 1 >=1:8,(n=172)	8.1 (4.5 to 13.3)			
PMB648 (B16) Before Vacc 1 >=1:16,(n=172)	8.1 (4.5 to 13.3)			
PMB648 (B16) Before Vacc 1 >=1:32,(n=172)	7.6 (4.1 to 12.6)			
PMB648 (B16) Before Vacc 1 >=1:64,(n=172)	2.3 (0.6 to 5.8)			
PMB648 (B16) Before Vacc 1 >=1:128,(n=172)	0.6 (0.0 to 3.2)			
PMB648 (B16) 1 Month after Vacc 2 >=1:4,(n=164)	79.3 (72.3 to 85.2)			
PMB648 (B16) 1 Month after Vacc 2 >=1:8,(n=164)	77.4 (70.3 to 83.6)			
PMB648 (B16) 1 Month after Vacc 2 >=1:16,(n=164)	73.8 (66.4 to 80.3)			
PMB648 (B16) 1 Month after Vacc 2 >=1:32,(n=164)	51.2 (43.3 to 59.1)			
PMB648 (B16) 1 Month after Vacc 2 >=1:64,(n=164)	28.7 (21.9 to 36.2)			
PMB648 (B16) 1 Month after Vacc 2 >=1:128,(n=164)	6.1 (3.0 to 10.9)			
PMB866 (B09) Before Vacc 1 >=1:4,(n=171)	10.5 (6.4 to 16.1)			
PMB866 (B09) Before Vacc 1 >=1:8,(n=171)	9.9 (5.9 to 15.4)			
PMB866 (B09) Before Vacc 1 >=1:16,(n=171)	9.4 (5.4 to 14.7)			

PMB866 (B09) Before Vacc 1 >=1:32,(n=171)	4.7 (2.0 to 9.0)			
PMB866 (B09) Before Vacc 1 >=1:64,(n=171)	1.2 (0.1 to 4.2)			
PMB866 (B09) Before Vacc 1 >=1:128,(n=171)	0.0 (0.0 to 2.1)			
PMB866 (B09) 1 Month after Vacc 2 >=1:4,(n=166)	74.7 (67.4 to 81.1)			
PMB866 (B09) 1 Month after Vacc 2 >=1:8,(n=166)	71.1 (63.6 to 77.8)			
PMB866 (B09) 1 Month after Vacc 2 >=1:16,(n=166)	63.3 (55.4 to 70.6)			
PMB866 (B09) 1 Month after Vacc 2 >=1:32,(n=166)	34.3 (27.2 to 42.1)			
PMB866 (B09) 1 Month after Vacc 2 >=1:64,(n=166)	8.4 (4.7 to 13.7)			
PMB866 (B09) 1 Month after Vacc 2 >=1:128,(n=166)	2.4 (0.7 to 6.1)			
PMB1256 (B03) Before Vacc 1 >=1:4,(n=172)	3.5 (1.3 to 7.4)			
PMB1256 (B03) Before Vacc 1 >=1:8,(n=172)	3.5 (1.3 to 7.4)			
PMB1256 (B03) Before Vacc 1 >=1:16,(n=172)	3.5 (1.3 to 7.4)			
PMB1256 (B03) Before Vacc 1 >=1:32,(n=172)	1.7 (0.4 to 5.0)			
PMB1256 (B03) Before Vacc 1 >=1:64,(n=172)	0.6 (0.0 to 3.2)			
PMB1256 (B03) Before Vacc 1 >=1:128,(n=172)	0.6 (0.0 to 3.2)			
PMB1256 (B03) 1 Month after Vacc 2 >=1:4,(n=164)	77.4 (70.3 to 83.6)			
PMB1256 (B03) 1 Month after Vacc 2 >=1:8,(n=164)	74.4 (67.0 to 80.9)			
PMB1256 (B03) 1 Month after Vacc 2 >=1:16,(n=164)	64.0 (56.2 to 71.4)			
PMB1256 (B03) 1 Month after Vacc 2 >=1:32,(n=164)	42.1 (34.4 to 50.0)			
PMB1256 (B03) 1 Month after Vacc 2 >=1:64,(n=164)	23.2 (16.9 to 30.4)			
PMB1256 (B03) 1 Month after Vacc 2 >=1:128,(n=164)	7.3 (3.8 to 12.4)			
PMB431 (B15) Before Vacc 1 >=1:4,(n=172)	8.1 (4.5 to 13.3)			
PMB431 (B15) Before Vacc 1 >=1:8,(n=172)	6.4 (3.2 to 11.2)			
PMB431 (B15) Before Vacc 1 >=1:16,(n=172)	5.8 (2.8 to 10.4)			
PMB431 (B15) Before Vacc 1 >=1:32,(n=172)	4.1 (1.7 to 8.2)			
PMB431 (B15) Before Vacc 1 >=1:64,(n=172)	2.3 (0.6 to 5.8)			
PMB431 (B15) Before Vacc 1 >=1:128,(n=172)	0.0 (0.0 to 2.1)			
PMB431 (B15) 1 Month after Vacc 2 >=1:4,(n=167)	87.4 (81.4 to 92.0)			
PMB431 (B15) 1 Month after Vacc 2 >=1:8,(n=167)	85.0 (78.7 to 90.1)			
PMB431 (B15) 1 Month after Vacc 2 >=1:16,(n=167)	72.5 (65.0 to 79.1)			
PMB431 (B15) 1 Month after Vacc 2 >=1:32,(n=167)	36.5 (29.2 to 44.3)			

PMB431 (B15) 1 Month after Vacc 2 >=1:64,(n=167)	15.0 (9.9 to 21.3)			
PMB431 (B15) 1 Month after Vacc 2 >=1:128,(n=167)	2.4 (0.7 to 6.0)			

Statistical analyses

No statistical analyses for this end point

Secondary: Stage1: hSBA Geometric Mean Titers (GMTs) for Each of the 10 Secondary MenB Test Strains Before Vaccination 1 and 1 Month After Vaccination 2 (Group 2 and 4 Combined)

End point title	Stage1: hSBA Geometric Mean Titers (GMTs) for Each of the 10 Secondary MenB Test Strains Before Vaccination 1 and 1 Month After Vaccination 2 (Group 2 and 4 Combined)

End point description:

GMTs were calculated using all subjects with valid and determinate hSBA titers at the given time point. LLOQ = 1:16 for A06, A12, and A19; 1:8 for A07, A15, A29, B03, B09, B15, and B16. Titers below the LLOQ were set to 0.5*LLOQ for analysis. Stage 1 EIP, included all eligible subjects who were randomised to the study group of interest, received all investigational products as randomised, had blood drawn for assay testing within the required time frames at Months 0 and 7, had valid and determinate assay results, had received no prohibited vaccines or treatment, and had no other major protocol violations as determined by the sponsor's global medical monitor. Here, 'n' signifies number of subjects with valid and determinate hSBA results on each of the 10 secondary MenB strains at the given time point. Analysis was planned for combined Group 2 and 4.

End point type	Secondary

End point timeframe:

Before Vaccination 1 (Vacc 1), 1 month after Vaccination 2 (Vacc 2)

End point values	Stage 1: Groups 2+4 Combined			
Subject group type	Subject analysis set			
Number of subjects analysed	864			
Units: Titers				
geometric mean (confidence interval 95%)				
PMB3175 (A29) Before Vacc 1, (n=166)	4.3 (4.1 to 4.5)			
PMB3175 (A29) 1 month after Vacc 2, (n=166)	35.7 (30.9 to 41.2)			
PMB3010 (A06) Before Vacc 1, (n=157)	8.9 (8.2 to 9.6)			
PMB3010 (A06) 1 month after Vacc 2, (n=159)	46.0 (39.7 to 53.1)			
PMB824 (A12) Before Vacc 1, (n=154)	8.4 (8.1 to 8.8)			
PMB824 (A12) 1 month after Vacc 2, (n=157)	23.7 (21.2 to 26.5)			
PMB3040 (A07) Before Vacc 1, (n=150)	8.7 (7.2 to 10.6)			
PMB3040 (A07) 1 month after Vacc 2, (n=157)	60.7 (53.6 to 68.8)			
PMB1672 (A15) Before Vacc 1, (n=166)	6.3 (5.5 to 7.3)			
PMB1672 (A15) 1 month after Vacc 2, (n=165)	28.4 (24.7 to 32.7)			

PMB1989 (A19) Before Vacc 1, (n=167)	8.6 (8.2 to 9.1)			
PMB1989 (A19) 1 month after Vacc 2, (n=167)	53.5 (46.3 to 61.9)			
PMB648 (B16) Before Vacc 1, (n=172)	4.8 (4.4 to 5.3)			
PMB648 (B16) 1 month after Vacc 2, (n=164)	20.8 (17.5 to 24.6)			
PMB866 (B09) Before Vacc 1, (n=171)	4.8 (4.4 to 5.2)			
PMB866 (B09) 1 month after Vacc 2, (n=166)	13.9 (12.0 to 16.2)			
PMB1256 (B03) Before Vacc 1, (n=172)	4.3 (4.0 to 4.5)			
PMB1256 (B03) 1 month after Vacc 2, (n=164)	17.7 (14.8 to 21.3)			
PMB431 (B15) Before Vacc 1, (n=172)	4.6 (4.2 to 4.9)			
PMB431 (B15) 1 month after Vacc 2, (n=167)	17.3 (15.1 to 19.8)			

Statistical analyses

No statistical analyses for this end point

Secondary: Stage1: Percentage of Subjects With hSBA-MenA, hSBA-MenC, hSBA-MenW, and hSBA-MenY Titers >=LLOQ for ACWY Test Strains 1 Month After the Vaccination 1: Groups 1, 2, 3 and 4

End point title	Stage1: Percentage of Subjects With hSBA-MenA, hSBA-MenC, hSBA-MenW, and hSBA-MenY Titers >=LLOQ for ACWY Test Strains 1 Month After the Vaccination 1: Groups 1, 2, 3 and 4

End point description:

Percentage of subjects who achieved an hSBA-MenA, hSBA-MenC, hSBA-MenW, and hSBA-MenY titer >=LLOQ for ACWY test strains (LLOQ = 1:8 for all MenA, MenC, MenW, and MenY strains) was reported in this endpoint. Stage 1 modified intent-to-treat (mITT) population included all randomised subjects who have received at least 1 study vaccination and who had at least 1 valid and determinate primary strain MenB or MenA/C/W/Y assay result available at any time point from Month 0 to 7. Here, 'n' signifies number of subjects with valid and determinate hSBA results for ACWY test strains at the given time point.

End point type	Secondary

End point timeframe:

1 month after Vaccination 1

End point values	Group 1: MenABCWY + Saline (ACWY-Naive)	Group 2: Bivalent rLP2086 + MenACWY-CRM (ACWY-Naive)	Group 3: MenABCWY + Saline (ACWY-Experienced)	Group 4: Bivalent rLP2086 + MenACWY-CRM (ACWY-Experienced)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	272	534	271	523
Units: Percentage of subjects				
number (confidence interval 95%)				
MenA (n=264,510,218,411)	99.2 (97.3 to 99.9)	98.4 (96.9 to 99.3)	100.0 (98.3 to 100.0)	99.3 (97.9 to 99.8)
MenC (n=262,509,264,506)	92.4 (88.5 to 95.3)	88.6 (85.5 to 91.2)	100.0 (98.6 to 100.0)	99.4 (98.3 to 99.9)

MenW (n=264,512,219,414)	98.5 (96.2 to 99.6)	95.5 (93.3 to 97.1)	99.5 (97.5 to 100.0)	99.5 (98.3 to 99.9)
MenY (n=263,510,218,413)	99.6 (97.9 to 100.0)	96.9 (95.0 to 98.2)	99.5 (97.5 to 100.0)	99.8 (98.7 to 100.0)

Statistical analyses

No statistical analyses for this end point

Secondary: Stage1: Percentage of Subjects With hSBA-MenA, hSBA-MenC, hSBA-MenW, and hSBA-MenY Titers >=1:4, >=1:8, >=1:16, >=1:32, >=1:64, and >=1:128 for ACWY Test Strains 1 Month After the Vaccination 1: Groups 1, 2, 3 and

End point title	Stage1: Percentage of Subjects With hSBA-MenA, hSBA-MenC, hSBA-MenW, and hSBA-MenY Titers >=1:4, >=1:8, >=1:16, >=1:32, >=1:64, and >=1:128 for ACWY Test Strains 1 Month After the Vaccination 1: Groups 1, 2, 3 and 4

End point description:

Percentage of subjects who achieved an hSBA-MenA, hSBA-MenC, hSBA-MenW, and hSBA-MenY titer >=1:4, >=1:8, >=1:16, >=1:32, >=1:64, >=1:128 for ACWY test strains was reported in this endpoint. Stage 1 mITT population included all randomised subjects who had received at least 1 study vaccination and who had at least 1 valid and determinate primary strain MenB or MenA/C/W/Y assay result available at any time point from 0 to 7 months. Here, 'n' signifies number of subjects with valid and determinate hSBA results for ACWY test strains at the given time point. Analysis was planned for combined Group 1 through Group 4.

End point type	Secondary

End point timeframe:

1 month after Vaccination 1

End point values	Group 1: MenABCWY + Saline (ACWY-Naive)	Group 2: Bivalent rLP2086 + MenACWY-CRM (ACWY-Naive)	Group 3: MenABCWY + Saline (ACWY-Experienced)	Group 4: Bivalent rLP2086 + MenACWY-CRM (ACWY-Experienced)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	272	534	271	523
Units: Percentage of subjects				
number (confidence interval 95%)				
MenA >=1:4, (n=264,510,218,411)	99.6 (97.9 to 100.0)	98.4 (96.9 to 99.3)	100.0 (98.3 to 100.0)	99.3 (97.9 to 99.8)
MenA >=1:8, (n=264,510,218,411)	99.2 (97.3 to 99.9)	98.4 (96.9 to 99.3)	100.0 (98.3 to 100.0)	99.3 (97.9 to 99.8)
MenA >=1:16, (n=264,510,218,411)	98.5 (96.2 to 99.6)	98.0 (96.4 to 99.1)	100.0 (98.3 to 100.0)	99.3 (97.9 to 99.8)
MenA >=31:2, (n=264,510,218,411)	97.7 (95.1 to 99.2)	93.9 (91.5 to 95.8)	99.5 (97.5 to 100.0)	99.0 (97.5 to 99.7)
MenA >=1:64, (n=264,510,218,411)	90.9 (86.8 to 94.1)	86.3 (83.0 to 89.1)	99.1 (96.7 to 99.9)	98.3 (96.5 to 99.3)
MenA >= 1:128, (n=264,510,218,411)	75.0 (69.3 to 80.1)	71.2 (67.0 to 75.1)	95.4 (91.7 to 97.8)	96.4 (94.1 to 97.9)
MenC >=1:4 (n=262,509,264,506)	95.4 (92.1 to 97.6)	93.3 (90.8 to 95.3)	100.0 (98.6 to 100.0)	99.4 (98.3 to 99.9)
MenC >=1:8, (n=262,509,264,506)	92.4 (88.5 to 95.3)	88.6 (85.5 to 91.2)	100.0 (98.6 to 100.0)	99.4 (98.3 to 99.9)

MenC >=1:16, (n=262,509,264,506)	88.2 (83.6 to 91.8)	80.9 (77.3 to 84.3)	100.0 (98.6 to 100.0)	99.2 (98.0 to 99.8)
MenC >=1:32, (262,509,264,506)	76.3 (70.7 to 81.3)	67.8 (63.5 to 71.8)	98.9 (96.7 to 99.8)	98.2 (96.7 to 99.2)
MenC >=1:64, (n=262,509,264,506)	61.8 (55.7 to 67.7)	55.0 (50.6 to 59.4)	97.3 (94.6 to 98.9)	97.2 (95.4 to 98.5)
MenC >=1:128, (n=262,509,264,506)	50.8 (44.5 to 57.0)	45.6 (41.2 to 50.0)	95.5 (92.2 to 97.6)	94.1 (91.6 to 96.0)
MenW >=1:4, (n=264,512,219,414)	99.6 (97.9 to 100.0)	97.7 (95.9 to 98.8)	100.0 (98.3 to 100.0)	99.5 (98.3 to 99.9)
MenW >=1:8, (n=264,512,219,414)	98.5 (96.2 to 99.6)	95.5 (93.3 to 97.1)	99.5 (97.5 to 100.0)	99.5 (98.3 to 99.9)
MenW >=1:16, (n=264,512,219,414)	96.2 (93.1 to 98.2)	89.3 (86.2 to 91.8)	99.5 (97.5 to 100.0)	99.3 (97.9 to 99.9)
MenW >=1:32, (n=264,512,219,414)	82.2 (77.0 to 86.6)	75.0 (71.0 to 78.7)	99.5 (97.5 to 100.0)	98.1 (96.2 to 99.2)
MenW >=1:64, (n=264,512,219,414)	65.9 (59.8 to 71.6)	56.1 (51.6 to 60.4)	99.1 (96.7 to 99.9)	96.6 (94.4 to 98.1)
MenW >=1:128, (n=264,512,219,414)	43.9 (37.9 to 50.2)	38.1 (33.9 to 42.4)	98.6 (96.0 to 99.7)	94.0 (91.2 to 96.1)
MenY >=1:4, (n=263,510,218,413)	100.0 (98.6 to 100.0)	99.2 (98.0 to 99.8)	99.5 (97.5 to 100.0)	100.0 (99.1 to 100.0)
MenY >=1:8, (n=263,510,218,413)	99.6 (97.9 to 100.0)	96.9 (95.0 to 98.2)	99.5 (97.5 to 100.0)	99.8 (98.7 to 100.0)
MenY >=1:16, (n=263,510,218,413)	98.9 (96.7 to 99.8)	92.9 (90.4 to 95.0)	99.5 (97.5 to 100.0)	99.3 (97.9 to 99.8)
MenY >=1:32, (n=263,510,218,413)	92.4 (88.5 to 95.3)	82.4 (78.8 to 85.6)	99.1 (96.7 to 99.9)	99.0 (97.5 to 99.7)
MenY >=1:64, (n=263,510,218,413)	78.3 (72.9 to 83.2)	66.9 (62.6 to 70.9)	99.1 (96.7 to 99.9)	97.1 (95.0 to 98.5)
MenY >=1:128, (n=263,510,218,413)	62.0 (55.8 to 67.9)	48.6 (44.2 to 53.1)	98.6 (96.0 to 99.7)	94.9 (92.3 to 96.8)

Statistical analyses

No statistical analyses for this end point

Secondary: Stage1: hSBA Geometric Mean Titers (GMTs) for ACWY Test Strains 1 Month After Vaccination 1: Groups 1, 2, 3 and 4

End point title	Stage1: hSBA Geometric Mean Titers (GMTs) for ACWY Test Strains 1 Month After Vaccination 1: Groups 1, 2, 3 and 4

End point description:

GMTs were calculated using all subjects with valid and determinate hSBA titers at the given time point. LLOQ = 1:8 for all MenA, MenC, MenW, and MenY. Titers below the LLOQ were set to 0.5*LLOQ for analysis. Stage 1 mITT population included all randomized subjects who had received at least 1 study vaccination and who had at least 1 valid and determinate primary strain MenB or MenA/C/W/Y assay result available at any time point from Visit 1 to Visit 4. Here, 'n' signifies number of subjects with valid and determinate hSBA results for ACWY test strains at the given time point. Analysis was planned for combined Group 1 through Group 4.

End point type	Secondary

End point timeframe:

1 month after Vaccination 1

End point values	Group 1: MenABCWY + Saline (ACWY-Naive)	Group 2: Bivalent rLP2086 + MenACWY-CRM (ACWY-Naive)	Group 3: MenABCWY + Saline (ACWY-Experienced)	Group 4: Bivalent rLP2086 + MenACWY-CRM (ACWY-Experienced)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	272	534	271	523
Units: Titers				
geometric mean (confidence interval 95%)				
MenA (n=264,510,218,411)	215.8 (184.6 to 252.4)	203.2 (178.7 to 231.0)	568.6 (492.9 to 656.0)	916.1 (809.1 to 1037.3)
MenC, (n=262,509,264,506)	111.5 (87.2 to 142.6)	81.4 (68.1 to 97.4)	814.9 (689.4 to 963.2)	827.0 (722.5 to 946.6)
MenW, (n=264,512,219,414)	98.4 (80.7 to 120.0)	71.2 (61.5 to 82.4)	1214.9 (1032.0 to 1430.1)	1176.7 (1017.9 to 1360.2)
MenY, (n=263,510,218,413)	141.9 (118.8 to 169.4)	96.6 (83.9 to 111.2)	1174.0 (990.3 to 1391.9)	1000.2 (872.1 to 1147.1)

Statistical analyses

No statistical analyses for this end point

Secondary: Stage1: Percentage of Subjects With hSBA-MenA, hSBA-MenC, hSBA-MenW, and hSBA-MenY Titers >=1:8 (or LLOQ, Whichever is Higher) for ACWY Test Strains 1 Month After the Vaccination 1 in Groups 2 and 4, and 1 Month After Vaccination 2 in Groups 1 and 3

End point title	Stage1: Percentage of Subjects With hSBA-MenA, hSBA-MenC, hSBA-MenW, and hSBA-MenY Titers >=1:8 (or LLOQ, Whichever is Higher) for ACWY Test Strains 1 Month After the Vaccination 1 in Groups 2 and 4, and 1 Month After Vaccination 2 in Groups 1 and 3

End point description:

Percentage of subjects who achieved an hSBA-MenA, hSBA-MenC, hSBA-MenW, and hSBA-MenY titer greater than or equal to LLOQ for ACWY test strains (LLOQ = 1:8 for all MenA, MenC, MenW, and MenY strains) was reported in this endpoint. Stage 1 mITT population included all randomised subjects who had received at least 1 study vaccination and who had at least 1 valid and determinate primary strain MenB or MenA/C/W/Y assay result available at any time point from 0 to 7 months. Here, 'n' signifies number of subjects with valid and determinate hSBA results for ACWY test strains at the given time point.

End point type	Secondary

End point timeframe:

For Group 2 and 4: 1 month after Vaccination 1; For Group 1 and 3: 1 month after Vaccination 2

End point values	Group 1: MenABCWY + Saline (ACWY-Naive)	Group 2: Bivalent rLP2086 + MenACWY-CRM (ACWY-Naive)	Group 3: MenABCWY + Saline (ACWY-Experienced)	Group 4: Bivalent rLP2086 + MenACWY-CRM (ACWY-Experienced)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	272	534	271	523

Units: Percentage of subjects				
number (confidence interval 95%)				
MenA, (n=510,411,232,191)	100.0 (98.4 to 100.0)	98.4 (96.9 to 99.3)	99.5 (97.1 to 100.0)	99.3 (97.9 to 99.8)
MenC, (n=509,506,231,237)	100.0 (98.4 to 100.0)	88.6 (85.5 to 91.2)	99.6 (97.7 to 100.0)	99.4 (98.3 to 99.9)
MenW, (n=512,414,233,191)	100.0 (98.4 to 100.0)	95.5 (93.3 to 97.1)	99.5 (97.1 to 100.0)	99.5 (98.3 to 99.9)
MenY, (n=510,413,233,191)	100.0 (98.4 to 100.0)	96.9 (95.0 to 98.2)	99.5 (97.1 to 100.0)	99.8 (98.7 to 100.0)

Statistical analyses

No statistical analyses for this end point

Secondary: Stage1: Percentage of Subjects With hSBA Titers >=1:4, >=1:8, >=1:16, >=1:32, >=1:64, and, >=1:128 for ACWY Test Strains 1 Month After the Vaccination 1 in Groups 2 and 4, and 1 Month After Vaccination 2 in Groups 1 and 3

End point title	Stage1: Percentage of Subjects With hSBA Titers >=1:4, >=1:8, >=1:16, >=1:32, >=1:64, and, >=1:128 for ACWY Test Strains 1 Month After the Vaccination 1 in Groups 2 and 4, and 1 Month After Vaccination 2 in Groups 1 and 3

End point description:

Percentage of subjects who achieved an hSBA-MenA, hSBA-MenC, hSBA-MenW, and hSBA-MenY titer >=1:4, >=1:8, >=1:16, >=1:32, >=1:64, >=1:128 for ACWY test strains was reported in this endpoint. Stage 1 mITT population included all randomised subjects who had received at least 1 study vaccination and who had at least 1 valid and determinate primary strain MenB or MenA/C/W/Y assay result available at any time point from 0 to 7 months. Here, 'n' signifies number of subjects with valid and determinate hSBA results for ACWY test strains at the given time point.

End point type	Secondary

End point timeframe:

For Group 2 and 4: 1 month after Vaccination 1; For Group 1 and 3: 1 month after Vaccination 2

End point values	Group 1: MenABCWY + Saline (ACWY-Naive)	Group 2: Bivalent rLP2086 + MenACWY-CRM (ACWY-Naive)	Group 3: MenABCWY + Saline (ACWY-Experienced)	Group 4: Bivalent rLP2086 + MenACWY-CRM (ACWY-Experienced)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	272	534	271	523
Units: Percentage of subjects				
number (confidence interval 95%)				
MenA >=1:4, (n=510,411,232,191)	100.0 (98.4 to 100.0)	98.4 (96.9 to 99.3)	99.5 (97.1 to 100.0)	99.3 (97.9 to 99.8)
MenA >=1:8, (n=510,411,232,191)	100.0 (98.4 to 100.0)	98.4 (96.9 to 99.3)	99.5 (97.1 to 100.0)	99.3 (97.9 to 99.8)
MenA >=1:16, (n=510,411,232,191)	100.0 (98.4 to 100.0)	98.0 (96.4 to 99.1)	99.5 (97.1 to 100.0)	99.3 (97.9 to 99.8)
MenA >=1:32, (n=510,411,232,191)	97.8 (95.0 to 99.3)	93.9 (91.5 to 95.8)	99.5 (97.1 to 100.0)	99.0 (97.5 to 99.7)
MenA >=1:64, (n=510,411,232,191)	92.2 (88.0 to 95.3)	86.3 (83.0 to 89.1)	97.4 (94.0 to 99.1)	98.3 (96.5 to 99.3)

MenA >=1:128, (n=510,411,232,191)	69.4 (63.0 to 75.3)	71.2 (67.0 to 75.1)	92.7 (88.0 to 95.9)	96.4 (94.1 to 97.9)
MenC >=1:4, (n=509,506,231,237)	100.0 (98.4 to 100.0)	93.3 (90.8 to 95.3)	99.6 (97.7 to 100.0)	99.4 (98.3 to 99.9)
MenC >=1:8, (509,506,231,237)	100.0 (98.4 to 100.0)	88.6 (85.5 to 91.2)	99.6 (97.7 to 100.0)	99.4 (98.3 to 99.9)
MenC >=1:16, (509,506,231,237)	99.6 (97.6 to 100.0)	80.9 (77.3 to 84.3)	99.6 (97.7 to 100.0)	99.2 (98.0 to 99.8)
MenC >=1:32, (n=509,506,231,237)	97.4 (94.4 to 99.0)	67.8 (63.5 to 71.8)	99.6 (97.7 to 100.0)	98.2 (96.7 to 99.2)
MenC >=1:64, (n=509,506,231,237)	90.9 (86.4 to 94.3)	55.0 (50.6 to 59.4)	98.3 (95.7 to 99.5)	97.2 (95.4 to 98.5)
MenC >=1:128, (n=509,506,231,237)	78.8 (72.9 to 83.9)	45.6 (41.2 to 50.0)	92.8 (88.8 to 95.8)	94.1 (91.6 to 96.0)
MenW >=1:4, (n=512,414,233,191)	100.0 (98.4 to 100.0)	97.7 (95.9 to 98.8)	100.0 (98.1 to 100.0)	99.5 (98.3 to 99.9)
MenW >=1:8, (n=512,414,233,191)	100.0 (98.4 to 100.0)	95.5 (93.3 to 97.1)	99.5 (97.1 to 100.0)	99.5 (98.3 to 99.9)
MenW >=1:16, (n=512,414,233,191)	100.0 (98.4 to 100.0)	89.3 (86.2 to 91.8)	99.5 (97.1 to 100.0)	99.3 (97.9 to 99.9)
MenW >=1:32, (512,414,233,191)	99.6 (97.6 to 100.0)	75.0 (71.0 to 78.7)	99.5 (97.1 to 100.0)	98.1 (96.2 to 99.2)
MenW >=1:64, (n=512,414,233,191)	97.0 (93.9 to 98.8)	56.1 (51.6 to 60.4)	99.0 (96.3 to 99.9)	96.6 (94.4 to 98.1)
MenW >=1:128, (n=512,414,233,191)	89.7 (85.1 to 93.3)	38.1 (33.9 to 42.4)	97.9 (94.7 to 99.4)	94.0 (91.2 to 96.1)
MenY >=1:4, (n=510,413,233,191)	100.0 (98.4 to 100.0)	99.2 (98.0 to 99.8)	99.5 (97.1 to 100.0)	100.0 (99.1 to 100.0)
MenY >=1:8, (n=510,413,233,191)	100.0 (98.4 to 100.0)	96.9 (95.0 to 98.2)	99.5 (97.1 to 100.0)	99.8 (98.7 to 100.0)
MenY >=1:16, (n=510,413,233,191)	100.0 (98.4 to 100.0)	92.9 (90.4 to 95.0)	99.5 (97.1 to 100.0)	99.3 (97.9 to 99.8)
MenY >=1:32, (n=510,413,233,191)	100.0 (98.4 to 100.0)	82.4 (78.8 to 85.6)	99.5 (97.1 to 100.0)	99.0 (97.5 to 99.7)
MenY >=1:64, (n=510,413,233,191)	97.4 (94.5 to 99.0)	66.9 (62.6 to 70.9)	99.5 (97.1 to 100.0)	97.1 (95.0 to 98.5)
MenY >=1:128, (n=510,413,233,191)	89.7 (85.1 to 93.3)	48.6 (44.2 to 53.1)	95.3 (91.2 to 97.8)	94.9 (92.3 to 96.8)

Statistical analyses

No statistical analyses for this end point

Secondary: Stage1: hSBA GMTs for ACWY Test Strains 1 Month After Vaccination 1 in Groups 2 and 4 and 1 Month After Vaccination 2 in Groups 1 and 3

End point title	Stage1: hSBA GMTs for ACWY Test Strains 1 Month After Vaccination 1 in Groups 2 and 4 and 1 Month After Vaccination 2 in Groups 1 and 3

End point description:

GMTs were calculated using all subjects with valid and determinate hSBA titers at the given time point. LLOQ = 1:8 for all MenA, MenC, MenW, and MenY. Titers below the LLOQ were set to 0.5*LLOQ for analysis. Stage 1 mITT population included all randomised subjects who had received at least 1 study vaccination and who had at least 1 valid and determinate primary strain MenB or MenA/C/W/Y assay result available at any time point from 0 to 7 months. Here, 'n' signifies number of subjects with valid and determinate hSBA results for ACWY test strains at the given time point.

End point type	Secondary

End point timeframe:

For Group 2 and 4: 1 month after Vaccination 1; For Group 1 and 3: 1 month after Vaccination 2

End point values	Group 1: MenABCWY + Saline (ACWY-Naive)	Group 2: Bivalent rLP2086 + MenACWY-CRM (ACWY-Naive)	Group 3: MenABCWY + Saline (ACWY-Experienced)	Group 4: Bivalent rLP2086 + MenACWY-CRM (ACWY-Experienced)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	272	534	271	523
Units: Titers				
geometric mean (confidence interval 95%)				
MenA, (n=510,411,232,191)	151.3 (134.1 to 170.7)	203.2 (178.7 to 231.0)	337.3 (291.7 to 390.0)	916.1 (809.1 to 1037.3)
MenC, (n=509,506,231,237)	229.1 (194.7 to 269.5)	81.4 (68.1 to 97.4)	498.7 (429.1 to 579.6)	827.0 (722.5 to 946.6)
MenW, (n=512,414,233,191)	274.1 (242.7 to 309.7)	71.2 (61.5 to 82.4)	570.9 (484.3 to 673.0)	1176.7 (1017.9 to 1360.2)
MenY, (n=510,413,233,191)	301.5 (266.6 to 341.0)	96.6 (83.9 to 111.2)	558.6 (470.0 to 663.9)	1000.2 (872.1 to 1147.1)

Statistical analyses

No statistical analyses for this end point

Secondary: Stage1: Percentage of Subjects With hSBA Titer Level >= LLOQ for 4 Primary MenB Test Strains Before Vaccination 1 and 1 Month After Vaccination 2 (Group 1 and 3 Combined; Group 2 and 4 Combined)

End point title	Stage1: Percentage of Subjects With hSBA Titer Level >= LLOQ for 4 Primary MenB Test Strains Before Vaccination 1 and 1 Month After Vaccination 2 (Group 1 and 3 Combined; Group 2 and 4 Combined)

End point description:

Percentage of subjects who achieved an hSBA titer >=LLOQ for all 4 primary MenB test strains combined (LLOQ was 1:16 for A22 and 1:8 for A56, B24, and B44) was reported in this endpoint. Stage 1 EIP, included all eligible subjects who were randomised to the study group of interest, received all investigational products as randomised, had blood drawn for assay testing within the required time frames at Months 0 and 7, had valid and determinate assay results, had received no prohibited vaccines or treatment, and had no other major protocol violations as determined by the sponsor's global medical monitor. Here, 'n' signifies number of subjects with valid and determinate hSBA results on all 4 strains at the given time point. Analysis was planned for combined Group 2 and 4 and combined Group 1 and 3.

End point type	Secondary

End point timeframe:

Before Vaccination 1 (Vacc 1), 1 month after Vaccination 2 (Vacc 2)

End point values	Stage 1: Groups 2+4 Combined	Stage 1: Group 1+3 Combined		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	864	438		
Units: Percentage of subjects				
number (confidence interval 95%)				
PMB80 (A22) Before Vacc 1, (n=427,839)	25.1 (22.2 to 28.2)	25.3 (21.2 to 29.7)		
PMB80 (A22) 1 month after Vacc 2, (n=433,852)	91.0 (88.8 to 92.8)	91.0 (87.9 to 93.5)		
PMB2001 (A56) Before Vacc 1, (n=421,833)	12.8 (10.6 to 15.3)	13.8 (10.6 to 17.4)		
PMB2001 (A56) 1 month after Vacc 2, (n=435,854)	99.4 (98.6 to 99.8)	98.6 (97.0 to 99.5)		
PMB2948 (B24) Before Vacc 1, (434,855)	11.9 (9.8 to 14.3)	10.4 (7.7 to 13.6)		
PMB2948 (B24) 1 month after Vacc 2, (n=426,842)	79.3 (76.4 to 82.0)	84.3 (80.5 to 87.6)		
PMB2707 (B44) Before Vacc 1, (434,861)	4.5 (3.2 to 6.1)	3.7 (2.1 to 5.9)		
PMB2707 (B44) 1 month after Vacc 2, (n=436,853)	94.5 (92.7 to 95.9)	95.4 (93.0 to 97.2)		

Statistical analyses

No statistical analyses for this end point

Secondary: Stage1: Percentage of Subjects With >=4 Fold Rise in hSBA for 4 Primary MenB Strains and Composite Response (hSBA >=LLOQ for all 4 Primary MenB Strains Combined) From Baseline to 1 Month After Vaccination 2 (Group 1 and 3 Combined; Group 2 and 4 Combined)

End point title	Stage1: Percentage of Subjects With >=4 Fold Rise in hSBA for 4 Primary MenB Strains and Composite Response (hSBA >=LLOQ for all 4 Primary MenB Strains Combined) From Baseline to 1 Month After Vaccination 2 (Group 1 and 3 Combined; Group 2 and 4 Combined)

End point description:

Percentage of subjects who achieved an hSBA titer greater than or equal to LLOQ for all 4 primary MenB test strains combined (LLOQ was 1:16 for A22 and 1:8 for A56, B24, and B44) was reported in this endpoint. Stage 1 EIP, included all eligible subjects who were randomised to the study group of interest, received all investigational products as randomised, had blood drawn for assay testing within the required time frames at Months 0 and 7, had valid and determinate assay results, had received no prohibited vaccines or treatment, and had no other major protocol violations as determined by the sponsor's global medical monitor. Here, 'n' signifies number of subjects with valid and determinate hSBA results on all 4 strains at the given time point. Analysis was planned for combined Group 2 and 4 and combined Group 1 and 3.

End point type	Secondary

End point timeframe:

Baseline to 1 month after Vaccination 2

End point values	Stage 1: Groups 2+4 Combined	Stage 1: Group 1+3 Combined		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	864	438		
Units: Percentage of subjects				
number (confidence interval 95%)				
PMB80 (A22), (n=422,827)	73.8 (70.6 to 76.7)	75.8 (71.5 to 79.8)		
PMB2001 (A56), (n=418,823)	95.0 (93.3 to 96.4)	94.7 (92.1 to 96.7)		
PMB2948 (B24), (n=422,835)	67.4 (64.1 to 70.6)	76.1 (71.7 to 80.1)		
PMB2707 (B44), (n=432,850)	86.4 (83.9 to 88.6)	91.7 (88.6 to 94.1)		
Composite hSBA response, (n=418,814)	74.3 (71.2 to 77.3)	79.9 (75.7 to 83.6)		

Statistical analyses

No statistical analyses for this end point

Secondary: Stage1: Percentage of Subjects With hSBA Titers >=1:4, >=1:8, >=1:16, >=1:32, >=1:64, and >=1:128 for Each of the 4 Primary MenB Test Strains From 1 Month After Vaccination 2 (Group 1 and 3 Combined; Group 2 and 4 Combined)

End point title	Stage1: Percentage of Subjects With hSBA Titers >=1:4, >=1:8, >=1:16, >=1:32, >=1:64, and >=1:128 for Each of the 4 Primary MenB Test Strains From 1 Month After Vaccination 2 (Group 1 and 3 Combined; Group 2 and 4

End point description:

Percentage of subjects who achieved an hSBA titer >=1:4, >=1:8, >=1:16, >=1:32, >=1:64, and >=1:128 for all 4 primary MenB test strains was reported in this endpoint. Stage 1 EIP, included all eligible subjects who were randomised to the study group of interest, received all investigational products as randomised, had blood drawn for assay testing within the required time frames at Months 0 and 7, had valid and determinate assay results, had received no prohibited vaccines or treatment, and had no other major protocol violations as determined by the sponsor's global medical monitor. Here, 'n' signifies number of subjects with valid and determinate hSBA results on all 4 strains at the given time point. Analysis was planned for combined Group 2 and 4 and combined Group 1 and 3.

End point type	Secondary

End point timeframe:

1 month after Vaccination 2

End point values	Stage 1: Groups 2+4 Combined	Stage 1: Group 1+3 Combined		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	864	438		
Units: Percentage of subjects				
number (confidence interval 95%)				
PMB80 (A22) >=1:4,(n=433,852)	91.7 (89.6 to 93.4)	91.9 (88.9 to 94.3)		
PMB80 (A22) >=1:8,(n=433,852)	91.5 (89.5 to 93.3)	91.7 (88.7 to 94.1)		

PMB80 (A22) >=1:16,(n=433,852)	91.0 (88.8 to 92.8)	91.0 (87.9 to 93.5)		
PMB80 (A22) >=1:32,(n=433,852)	80.2 (77.3 to 82.8)	82.4 (78.5 to 85.9)		
PMB80 (A22) >=1:64,(n=433,852)	54.9 (51.5 to 58.3)	58.0 (53.2 to 62.7)		
PMB80 (A22) >=1:128,(n=433,852)	27.3 (24.4 to 30.5)	27.9 (23.8 to 32.4)		
PMB2001 (A56) >=1:4,(n=435,854)	99.5 (98.8 to 99.9)	98.9 (97.3 to 99.6)		
PMB2001 (A56) >=1:8,(n=435,854)	99.4 (98.6 to 99.8)	98.6 (97.0 to 99.5)		
PMB2001 (A56) >=1:16,(n=435,854)	99.1 (98.2 to 99.6)	98.6 (97.0 to 99.5)		
PMB2001 (A56) >=1:32,(n=435,854)	97.0 (95.6 to 98.0)	96.8 (94.7 to 98.2)		
PMB2001 (A56) >=1:64,(n=435,854)	87.7 (85.3 to 89.8)	90.1 (86.9 to 92.8)		
PMB2001 (A56) >=1:128,(n=435,854)	69.2 (66.0 to 72.3)	74.0 (69.6 to 78.1)		
PMB2948 (B24) >=1:4,(n=426,842)	81.2 (78.4 to 83.8)	86.9 (83.3 to 89.9)		
PMB2948 (B24) >=1:8,(n=426,842)	79.3 (76.4 to 82.0)	84.3 (80.5 to 87.6)		
PMB2948 (B24) >=1:16,(n=426,842)	74.0 (70.9 to 76.9)	80.8 (76.7 to 84.4)		
PMB2948 (B24) >=1:32,(n=426,842)	47.9 (44.4 to 51.3)	58.5 (53.6 to 63.2)		
PMB2948 (B24) >=1:64,(n=426,842)	24.9 (22.1 to 28.0)	31.0 (26.6 to 35.6)		
PMB2948 (B24) >=1:128,(n=426,842)	9.6 (7.7 to 11.8)	13.4 (10.3 to 17.0)		
PMB2707 (B44) >=1:4,(n=436,853)	96.2 (94.7 to 97.4)	97.2 (95.2 to 98.6)		
PMB2707 (B44) >=1:8,(n=436,853)	94.5 (92.7 to 95.9)	95.4 (93.0 to 97.2)		
PMB2707 (B44) >=1:16,(n=436,853)	89.0 (86.7 to 91.0)	92.4 (89.5 to 94.7)		
PMB2707 (B44) >=1:32,(n=436,853)	68.6 (65.3 to 71.7)	72.9 (68.5 to 77.1)		
PMB2707 (B44) >=1:64,(n=436,853)	41.0 (37.7 to 44.4)	48.9 (44.1 to 53.7)		
PMB2707 (B44) >=1:128,(n=436,853)	19.2 (16.6 to 22.0)	22.0 (18.2 to 26.2)		

Statistical analyses

No statistical analyses for this end point

Secondary: Stage1: Percentage of Subjects With hSBA-MenA, hSBA-MenC, hSBA-MenW, and hSBA-MenY Titers >=1:8 (or LLOQ) for ACWY Test Strains Before Vaccination 1 and 1 Month After Vaccination 2: Groups 1, 2, 3 and 4

End point title	Stage1: Percentage of Subjects With hSBA-MenA, hSBA-MenC, hSBA-MenW, and hSBA-MenY Titers >=1:8 (or LLOQ) for ACWY Test Strains Before Vaccination 1 and 1 Month After Vaccination 2: Groups 1, 2, 3 and 4

End point description:

Percentage of subjects who achieved an hSBA-MenA, hSBA-MenC, hSBA-MenW, and hSBA-MenY titer

>=LLOQ for ACWY test strains (LLOQ = 1:8 for all MenA, MenC, MenW, and MenY strains) was reported in this endpoint. Stage 1 mITT population included all randomised subjects who had received at least 1 study vaccination and who had at least 1 valid and determinate primary strain MenB or MenA/C/W/Y assay result available at any time point from 0 to 7 months. Here, 'n' signifies number of subjects with valid and determinate hSBA results for ACWY test strains at the given time point. Analysis was planned for Group 1 through Group 4.

End point type	Secondary

End point timeframe:

Before Vaccination 1 (Vacc 1), 1 month after Vaccination 2 (Vacc 2)

End point values	Group 1: MenABCWY + Saline (ACWY-Naive)	Group 2: Bivalent rLP2086 + MenACWY-CRM (ACWY-Naive)	Group 3: MenABCWY + Saline (ACWY-Experienced)	Group 4: Bivalent rLP2086 + MenACWY-CRM (ACWY-Experienced)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	272	534	271	523
Units: Percentage of subjects				
number (confidence interval 95%)				
MenA Before Vacc 1, (n=270,528,219,418)	15.9 (11.8 to 20.8)	22.9 (19.4 to 26.7)	53.9 (47.0 to 60.6)	52.6 (47.7 to 57.5)
MenA 1 Month after Vacc 2, (n=232,463,191,376)	100.0 (98.4 to 100.0)	95.7 (93.4 to 97.3)	99.5 (97.1 to 100.0)	99.5 (98.1 to 99.9)
MenC Before Vacc 1, (n=267,526,264,511)	38.6 (32.7 to 44.7)	39.0 (34.8 to 43.3)	59.5 (53.3 to 65.4)	61.1 (56.7 to 65.3)
MenC 1 Month after Vacc 2, (n=231,454,237,466)	100.0 (98.4 to 100.0)	94.1 (91.5 to 96.0)	99.6 (97.7 to 100.0)	99.8 (98.8 to 100.0)
MenW Before Vacc 1, (268,527,218,418)	32.1 (26.5 to 38.0)	34.5 (30.5 to 38.8)	61.9 (55.1 to 68.4)	60.8 (55.9 to 65.5)
MenW 1 Month after Vacc 2, (n=233,464,191,376)	100.0 (98.4 to 100.0)	99.1 (97.8 to 99.8)	99.5 (97.1 to 100.0)	100.0 (99.0 to 100.0)
MenY Before Vacc 1, (n=265,528,219,421)	54.0 (47.8 to 60.1)	58.1 (53.8 to 62.4)	79.9 (74.0 to 85.0)	77.9 (73.6 to 81.8)
MenY 1 Month after Vacc 2, (n=233,461,191,374)	100.0 (98.4 to 100.0)	97.8 (96.0 to 99.0)	99.5 (97.1 to 100.0)	100.0 (99.0 to 100.0)

Statistical analyses

No statistical analyses for this end point

Secondary: Stage1: hSBA GMTs for Each of the 4 Primary MenB Test Strains 1 Month After Vaccination 2 (Group 1 and 3 Combined; Group 2 and 4 Combined)

End point title	Stage1: hSBA GMTs for Each of the 4 Primary MenB Test Strains 1 Month After Vaccination 2 (Group 1 and 3 Combined; Group 2 and 4 Combined)

End point description:

GMTs were calculated using all subjects with valid and determinate hSBA titers at the given time point. LLOQ =1:16 for A22; 1:8 for A56, B24, and B44. Titers below the LLOQ were set to 0.5 × LLOQ for analysis. Stage 1 EIP, included all eligible subjects who were randomised to the study group of interest, received all investigational products as randomised, had blood drawn for assay testing within the required time frames at Months 0 and 7, had valid and determinate assay results, had received no prohibited vaccines or treatment, and had no other major protocol violations as determined by the sponsor's global medical monitor. Here, 'n' signifies number of subjects with valid and determinate

hSBA results on all 4 strains at the given time point. Analysis was planned for combined Group 2 and 4 and combined Group 1 and 3.

End point type	Secondary

End point timeframe:

1 month after Vaccination 2

End point values	Stage 1: Groups 2+4 Combined	Stage 1: Group 1+3 Combined		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	864	438		
Units: Titers				
geometric mean (confidence interval 95%)				
PMB80 (A22), (n=433,852)	49.3 (46.2 to 52.6)	51.0 (46.7 to 55.7)		
PMB2001 (A56), (n=435,854)	139.5 (130.6 to 149.1)	152.3 (138.5 to 167.5)		
PMB2948 (B24), (n=426,842)	21.2 (19.6 to 22.9)	26.6 (23.9 to 29.7)		
PMB2707 (B44), (n=436,853)	37.8 (35.1 to 40.8)	43.3 (39.1 to 47.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: Stage1: Percentage of Subjects With hSBA-MenA, hSBA-MenC, hSBA-MenW, and hSBA-MenY Titers >=1:4, >=1:8, >=1:16, >=1:32, >=1:64, and >=1:128 for ACWY Test Strains Before Vaccination 1 and 1 Month After Vaccination 2: Groups 1, 2, 3 and 4

End point title	Stage1: Percentage of Subjects With hSBA-MenA, hSBA-MenC, hSBA-MenW, and hSBA-MenY Titers >=1:4, >=1:8, >=1:16, >=1:32, >=1:64, and >=1:128 for ACWY Test Strains Before Vaccination 1 and 1 Month After Vaccination 2: Groups 1, 2, 3 and 4

End point description:

Percentage of subjects who achieved an hSBA-MenA, hSBA-MenC, hSBA-MenW, and hSBA-MenY titer >=1:4, >= :8, >=1:16, >=1:32, >=1:64, >=1:128 for ACWY test strains was reported in this endpoint. Stage 1 mITT population included all randomised subjects who had received at least 1 study vaccination and who had at least 1 valid and determinate primary strain MenB or MenA/C/W/Y assay result available at any time point from 0 to 7 months. Here, 'n' signifies number of subjects with valid and determinate hSBA results for ACWY test strains at the given time point. Analysis was planned for combined Group 1 through Group 4.

End point type	Secondary

End point timeframe:

Before Vaccination 1 (Vacc 1), 1 month after Vaccination 2 (Vacc 2)

End point values	Group 1: MenABCWY + Saline (ACWY-Naive)	Group 2: Bivalent rLP2086 + MenACWY-CRM (ACWY-Naive)	Group 3: MenABCWY + Saline (ACWY-Experienced)	Group 4: Bivalent rLP2086 + MenACWY-CRM (ACWY-Experienced)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	272	534	271	523
Units: Percentage of subjects				
number (confidence interval 95%)				
MenA Before Vacc 1 >=1:4(n=270,528,219,418)	26.3 (21.1 to 32.0)	33.3 (29.3 to 37.5)	64.4 (57.7 to 70.7)	65.8 (61.0 to 70.3)
MenA Before Vacc 1 >=1:8(270,528,219,418)	15.9 (11.8 to 20.8)	22.9 (19.4 to 26.7)	53.9 (47.0 to 60.6)	52.6 (47.7 to 57.5)
MenA Before Vacc 1 >=1:16(n=270,528,219,418)	14.4 (10.5 to 19.2)	18.0 (14.8 to 21.5)	40.2 (33.6 to 47.0)	41.6 (36.9 to 46.5)
MenA Before Vacc 1 >=1:32(n=270,528,219,418)	8.5 (5.5 to 12.5)	10.6 (8.1 to 13.6)	24.2 (18.7 to 30.4)	22.0 (18.1 to 26.3)
MenA Before Vacc 1 >=1:64(n=270,528,219,418)	5.2 (2.9 to 8.5)	5.5 (3.7 to 7.8)	12.8 (8.7 to 17.9)	15.1 (11.8 to 18.9)
MenA Before Vacc 1 >=1:128(n=270,528,219,418)	3.0 (1.3 to 5.8)	4.0 (2.5 to 6.0)	7.8 (4.6 to 12.1)	6.2 (4.1 to 9.0)
MenA 1Month post Vacc 2 >=1:4(n=232,463,191,376)	100.0 (98.4 to 100.0)	97.0 (95.0 to 98.3)	99.5 (97.1 to 100.0)	99.7 (98.5 to 100.0)
MenA 1Month post Vacc 2 >=1:8(n=232,463,191,376)	100.0 (98.4 to 100.0)	95.7 (93.4 to 97.3)	99.5 (97.1 to 100.0)	99.5 (98.1 to 99.9)
MenA 1Month post Vacc 2 >=1:16(n=232,463,191,376)	100.0 (98.4 to 100.0)	90.7 (87.7 to 93.2)	99.5 (97.1 to 100.0)	99.5 (98.1 to 99.9)
MenA 1Month post Vacc 2 >=1:32(232,463,191,376)	97.8 (95.0 to 99.3)	74.3 (70.1 to 78.2)	99.5 (97.1 to 100.0)	98.2 (96.7 to 99.2)
MenA 1Month post Vacc 2 >=1:64(n=232,463,191,376)	92.2 (88.0 to 95.3)	51.4 (46.7 to 56.0)	97.4 (94.0 to 99.1)	92.8 (89.7 to 95.2)
MenA 1Month post Vacc 2 >=1:128(n=232,463,191,376)	69.4 (63.0 to 75.3)	33.9 (29.6 to 38.4)	92.7 (88.0 to 95.9)	75.5 (70.9 to 79.8)
MenC Before Vacc 1 >=1:4(n=267,526,264,511)	63.7 (57.6 to 69.4)	59.7 (55.4 to 63.9)	76.1 (70.5 to 81.1)	78.3 (74.4 to 81.8)
MenC Before Vacc 1 >=1:8(n=267,526,264,511)	38.6 (32.7 to 44.7)	39.0 (34.8 to 43.3)	59.5 (53.3 to 65.4)	61.1 (56.7 to 65.3)
MenC Before Vacc 1 >=1:16(n=267,526,264,511)	24.3 (19.3 to 29.9)	24.5 (20.9 to 28.4)	42.0 (36.0 to 48.3)	44.4 (40.1 to 48.9)
MenC Before Vacc 1 >=1:32(n=267,526,264,511)	12.0 (8.3 to 16.5)	12.5 (9.8 to 15.7)	26.9 (21.6 to 32.7)	29.7 (25.8 to 33.9)
MenC Before Vacc 1 >=1:64(n=267,526,264,511)	5.2 (2.9 to 8.6)	6.8 (4.8 to 9.3)	15.9 (11.7 to 20.9)	18.2 (14.9 to 21.8)
MenC Before Vacc 1 >=1:128(n=267,526,264,511)	4.5 (2.3 to 7.7)	4.0 (2.5 to 6.0)	6.8 (4.1 to 10.6)	9.2 (6.8 to 12.0)
MenC 1Month post Vacc 2 >=1:4(n=231,454,237,466)	100.0 (98.4 to 100.0)	95.8 (93.5 to 97.5)	99.6 (97.7 to 100.0)	99.8 (98.8 to 100.0)
MenC 1Month post Vacc 2 >=1:8(n=231,454,237,466)	100.0 (98.4 to 100.0)	94.1 (91.5 to 96.0)	99.6 (97.7 to 100.0)	99.8 (98.8 to 100.0)
MenC 1Month post Vacc 2 >=1:16(n=231,454,237,466)	99.6 (97.6 to 100.0)	90.5 (87.5 to 93.1)	99.6 (97.7 to 100.0)	98.9 (97.5 to 99.7)
MenC 1Month post Vacc 2 >=1:32(n=231,454,237,466)	97.4 (94.4 to 99.0)	74.7 (70.4 to 78.6)	99.6 (97.7 to 100.0)	95.5 (93.2 to 97.2)
MenC 1Month post Vacc 2 >=1:64(n=231,454,237,466)	90.9 (86.4 to 94.3)	50.4 (45.7 to 55.1)	98.3 (95.7 to 99.5)	86.9 (83.5 to 89.8)
MenC 1Month post Vacc 2 >=1:128(n=231,454,237,466)	78.8 (72.9 to 83.9)	35.0 (30.6 to 39.6)	92.8 (88.8 to 95.8)	71.7 (67.3 to 75.7)
MenW Before Vacc 1 >=1:4(n=268,527,218,418)	47.8 (41.6 to 53.9)	50.5 (46.1 to 54.8)	83.0 (77.4 to 87.8)	76.3 (71.9 to 80.3)
MenW Before Vacc 1 >=1:8(n=268,527,218,418)	32.1 (26.5 to 38.0)	34.5 (30.5 to 38.8)	61.9 (55.1 to 68.4)	60.8 (55.9 to 65.5)

MenW Before Vacc 1 >=1:16(n=268,527,218,418)	23.9 (18.9 to 29.4)	22.8 (19.3 to 26.6)	37.6 (31.2 to 44.4)	39.7 (35.0 to 44.6)
MenW Before Vacc 1 >=1:32(n=268,527,218,418)	10.8 (7.4 to 15.2)	13.7 (10.8 to 16.9)	20.2 (15.1 to 26.1)	21.8 (17.9 to 26.0)
MenW Before Vacc 1 >=1:64(n=268,527,218,418)	7.5 (4.6 to 11.3)	6.3 (4.3 to 8.7)	9.2 (5.7 to 13.8)	11.2 (8.4 to 14.7)
MenW Before Vacc 1 >=1:128(n=268,527,218,418)	4.5 (2.3 to 7.7)	1.5 (0.7 to 3.0)	5.5 (2.9 to 9.4)	6.2 (4.1 to 9.0)
MenW 1Month post Vacc 2 >=1:4(n=233,464,191,376)	100.0 (98.4 to 100.0)	99.4 (98.1 to 99.9)	100.0 (98.1 to 100.0)	100.0 (99.0 to 100.0)
MenW 1Month post Vacc 2 >=1:8(n=233,464,191,376)	100.0 (98.4 to 100.0)	99.1 (97.8 to 99.8)	99.5 (97.1 to 100.0)	100.0 (99.0 to 100.0)
MenW 1Month post Vacc 2 >=1:16(n=233,464,191,376)	100.0 (98.4 to 100.0)	98.3 (96.6 to 99.3)	99.5 (97.1 to 100.0)	99.7 (98.5 to 100.0)
MenW 1Month post Vacc 2 >=1:32(n=233,464,191,376)	99.6 (97.6 to 100.0)	89.9 (86.8 to 92.5)	99.5 (97.1 to 100.0)	98.4 (96.6 to 99.4)
MenW 1Month post Vacc 2 >=1:64(n=233,464,191,376)	97.0 (93.9 to 98.8)	72.2 (67.9 to 76.2)	99.0 (96.3 to 99.9)	95.7 (93.2 to 97.5)
MenW 1Month post Vacc 2 >=1:128(n=233,464,191,376)	89.7 (85.1 to 93.3)	42.9 (38.3 to 47.5)	97.9 (94.7 to 99.4)	83.5 (79.4 to 87.1)
MenY Before Vacc 1 >=1:4(n=265,528,219,421)	67.2 (61.2 to 72.8)	70.3 (66.2 to 74.1)	87.7 (82.6 to 91.7)	89.5 (86.2 to 92.3)
MenY Before Vacc 1 >=1:8(n=265,528,219,421)	54.0 (47.8 to 60.1)	58.1 (53.8 to 62.4)	79.9 (74.0 to 85.0)	77.9 (73.6 to 81.8)
MenY Before Vacc 1 >=1:16(n=265,528,219,421)	44.2 (38.1 to 50.4)	46.6 (42.3 to 50.9)	67.1 (60.5 to 73.3)	65.8 (61.0 to 70.3)
MenY Before Vacc 1 >=1:32(n=265,528,219,421)	21.1 (16.4 to 26.5)	26.7 (23.0 to 30.7)	38.4 (31.9 to 45.1)	40.9 (36.1 to 45.7)
MenY Before Vacc 1 >=1:64(n=265,528,219,421)	10.9 (7.5 to 15.3)	11.2 (8.6 to 14.2)	21.9 (16.6 to 28.0)	20.2 (16.5 to 24.3)
MenY Before Vacc 1 >=1:128(n=265,528,219,421)	4.9 (2.6 to 8.2)	6.3 (4.3 to 8.7)	10.0 (6.4 to 14.8)	10.5 (7.7 to 13.8)
MenY 1Month post Vacc 2 >=1:4(n=233,461.191,374)	100.0 (98.4 to 100.0)	99.8 (98.8 to 100.0)	99.5 (97.1 to 100.0)	100.0 (99.0 to 100.0)
MenY 1Month post Vacc 2 >=1:8(n=233,461,191,374)	100.0 (98.4 to 100.0)	97.8 (96.0 to 99.0)	99.5 (97.1 to 100.0)	100.0 (99.0 to 100.0)
MenY 1Month post Vacc 2 >=1:16(n=233,461,191,374)	100.0 (98.4 to 100.0)	97.2 (95.2 to 98.5)	99.5 (97.1 to 100.0)	100.0 (99.0 to 100.0)
MenY 1Month post Vacc 2 >=1:32(n=233,461,191,374)	100.0 (98.4 to 100.0)	87.4 (84.0 to 90.3)	99.5 (97.1 to 100.0)	97.9 (95.8 to 99.1)
MenY 1Month post Vacc 2 >=1:64(n=233,461,191,374)	97.4 (94.5 to 99.0)	65.1 (60.5 to 69.4)	99.5 (97.1 to 100.0)	92.0 (88.7 to 94.5)
MenY 1Month post Vacc 2 >=1:128(n=233,461,191,374)	89.7 (85.1 to 93.3)	37.5 (33.1 to 42.1)	95.3 (91.2 to 97.8)	79.9 (75.5 to 83.9)

Statistical analyses

No statistical analyses for this end point

Secondary: Stage1: hSBA GMTs for ACWY Test Strains Before Vaccination 1 and 1 Month After Vaccination 2: Groups 1, 2, 3 and 4

End point title	Stage1: hSBA GMTs for ACWY Test Strains Before Vaccination 1 and 1 Month After Vaccination 2: Groups 1, 2, 3 and 4

End point description:

GMTs were calculated using all subjects with valid and determinate hSBA titers at the given time point. LLOQ = 1:8 for all MenA, MenC, MenW, and MenY strains. Titers below the LLOQ were set to 0.5*LLOQ for analysis. Stage 1 mITT population included all randomised subjects who had received at least 1 study vaccination and who had at least 1 valid and determinate primary strain MenB or MenA/C/W/Y

assay result available at any time point from 0 to 7 months. Here, 'n' signifies number of subjects with valid and determinate hSBA results for ACWY test strains at the given time point. Analysis was planned for Group 1 through Group 4.

End point type	Secondary

End point timeframe:

Before Vaccination 1 (Vacc 1), 1 month after Vaccination 2 (Vacc 2)

End point values	Group 1: MenABCWY + Saline (ACWY-Naive)	Group 2: Bivalent rLP2086 + MenACWY-CRM (ACWY-Naive)	Group 3: MenABCWY + Saline (ACWY-Experienced)	Group 4: Bivalent rLP2086 + MenACWY-CRM (ACWY-Experienced)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	272	534	271	523
Units: Titers				
geometric mean (confidence interval 95%)				
MenA Before Vacc 1, (n=270,528,219,418)	5.7 (5.1 to 6.3)	6.3 (5.7 to 6.8)	11.0 (9.3 to 13.0)	10.7 (9.6 to 12.0)
MenA 1 Month after Vacc 2, (n=232,463,191,376)	151.3 (134.1 to 170.7)	54.9 (48.5 to 62.0)	337.3 (291.7 to 390.0)	224.2 (197.9 to 253.9)
MenC Before Vacc 1, (n=267,526,264,511)	7.5 (6.6 to 8.5)	7.5 (6.8 to 8.2)	11.9 (10.2 to 13.8)	13.4 (11.9 to 15.1)
MenC 1 Month after Vacc 2, (n=231,454,237,466)	229.1 (194.7 to 269.5)	58.0 (50.7 to 66.5)	498.7 (429.1 to 579.6)	222.6 (195.3 to 253.8)
MenW Before Vacc 1, (268,527,218,418)	7.0 (6.2 to 7.9)	7.0 (6.4 to 7.5)	10.5 (9.1 to 12.2)	11.0 (9.8 to 12.3)
MenW 1 Month after Vacc 2, (n=233,464,191,376)	274.1 (242.7 to 309.7)	80.9 (73.5 to 89.1)	570.9 (484.3 to 673.0)	291.3 (256.8 to 330.4)
MenY Before Vacc 1, (n=265,528,219,421)	10.5 (9.1 to 12.1)	11.5 (10.4 to 12.7)	19.2 (16.3 to 22.5)	19.0 (16.8 to 21.4)
MenY 1 Month after Vacc 2, (n=233,461,191,374)	301.5 (266.6 to 341.0)	69.8 (63.1 to 77.3)	558.6 (470.0 to 663.9)	268.6 (235.0 to 307.1)

Statistical analyses

No statistical analyses for this end point

Secondary: Stage1: Percentage of Subjects With hSBA Titer Level >=LLOQ for 4 Primary MenB Test Strains Before Vaccination 1 and 1 Month After Vaccination 2 (Group 1 and 3 Combined; Group 2 and 4 Combined)

End point title	Stage1: Percentage of Subjects With hSBA Titer Level >=LLOQ for 4 Primary MenB Test Strains Before Vaccination 1 and 1 Month After Vaccination 2 (Group 1 and 3 Combined; Group 2 and 4 Combined)

End point description:

Percentage of subjects who achieved an hSBA titer >=LLOQ for all 4 primary MenB test strains (LLOQ was 1:16 for A22 and 1:8 for A56, B24, and B44) was reported in this endpoint. Stage 1 EIP, included all eligible subjects who were randomised to the study group of interest, received all investigational products as randomised, had blood drawn for assay testing within the required time frames at Months 0 and 7, had valid and determinate assay results, had received no prohibited vaccines or treatment, and had no other major protocol violations as determined by the sponsor's global medical monitor. Here, 'n' signifies number of subjects with valid and determinate hSBA results on all 4 strains at the given time

point. Analysis was planned for combined Group 2 and 4 and combined Group 1 and 3.

End point type	Secondary

End point timeframe:

Before Vaccination 1 (Vacc 1), 1 Month After Vaccination 2 (Vacc 2)

End point values	Stage 1: Groups 2+4 Combined	Stage 1: Group 1+3 Combined		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	864	438		
Units: Percentage of subjects				
number (confidence interval 95%)				
PMB80 (A22) Before Vacc 1, (n=427,839)	25.1 (22.2 to 28.2)	25.3 (21.2 to 29.7)		
PMB80 (A22) 1 month after Vacc 2, (n=433,852)	91.0 (88.8 to 92.8)	91.0 (87.9 to 93.5)		
PMB2001 (A56) Before Vacc 1, (n=421,833)	12.8 (10.6 to 15.3)	13.8 (10.6 to 17.4)		
PMB2001 (A56) 1 month after Vacc 2, (n=435,854)	99.4 (98.6 to 99.8)	98.6 (97.0 to 99.5)		
PMB2948 (B24) Before Vacc 1, (434,855)	11.9 (9.8 to 14.3)	10.4 (7.7 to 13.6)		
PMB2948 (B24) 1 month after Vacc 2, (n=426,842)	79.3 (76.4 to 82.0)	84.3 (80.5 to 87.6)		
PMB2707 (B44) Before Vacc 1, (434,861)	4.5 (3.2 to 6.1)	3.7 (2.1 to 5.9)		
PMB2707 (B44) 1 month after Vacc 2, (n=436,853)	94.5 (92.7 to 95.9)	95.4 (93.0 to 97.2)		

Statistical analyses

No statistical analyses for this end point

Secondary: Stage1: Percentage of Subjects With hSBA Titers >=1:4, >=1:8, >=1:16, >=1:32, >=1:64, and >=1:128 for Each of the 4 Primary MenB Test Strains Before Vaccination 1 and 1 Month After Vaccination 2 (Group 1 and 3 Combined; Group 2 and 4 Combined)

End point title	Stage1: Percentage of Subjects With hSBA Titers >=1:4, >=1:8, >=1:16, >=1:32, >=1:64, and >=1:128 for Each of the 4 Primary MenB Test Strains Before Vaccination 1 and 1 Month After Vaccination 2 (Group 1 and 3 Combined; Group 2 and 4 Combined)

End point description:

Percentage of subjects who achieved an hSBA titer >=1:4, >=1:8, >=1:16, >=1:32, >=1:64, and >=1:128 for all 4 primary MenB test strains was reported in this endpoint. Stage 1 EIP, included all eligible subjects who were randomised to the study group of interest, received all investigational products as randomised, had blood drawn for assay testing within the required time frames at Months 0 and 7, had valid and determinate assay results, had received no prohibited vaccines or treatment, and had no other major protocol violations as determined by the sponsor's global medical monitor. Here, 'n' signifies number of subjects with valid and determinate hSBA results on all 4 strains at the given time point. Analysis was planned for combined Group 2 and 4 and combined Group 1 and 3.

End point type	Secondary

End point timeframe:
Before Vaccination 1 (Vacc 1), 1 Month After Vaccination 2 (Vacc 2)

End point values	Stage 1: Groups 2+4 Combined	Stage 1: Group 1+3 Combined		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	864	438		
Units: Percentage of subjects				
number (confidence interval 95%)				
PMB80 (A22) Before Vacc 1 >=1:4(n=427,839)	36.6 (33.3 to 40.0)	34.7 (30.1 to 39.4)		
PMB80 (A22) Before Vacc 1 >=1:8(n=427,839)	31.8 (28.7 to 35.1)	31.9 (27.5 to 36.5)		
PMB80 (A22) Before Vacc 1 >=1:16(n=427,839)	25.1 (22.2 to 28.2)	25.3 (21.2 to 29.7)		
PMB80 (A22) Before Vacc 1 >=1:32(n=427,839)	11.4 (9.4 to 13.8)	11.0 (8.2 to 14.4)		
PMB80 (A22) Before Vacc 1 >=1:64(n=427,839)	4.4 (3.1 to 6.0)	4.7 (2.9 to 7.1)		
PMB80 (A22) Before Vacc 1 >=1:128(n=427,839)	0.8 (0.3 to 1.7)	1.4 (0.5 to 3.0)		
PMB80 (A22) 1 month post Vacc 2>=1:4(n=433,852)	91.7 (89.6 to 93.4)	91.9 (88.9 to 94.3)		
PMB80 (A22) 1 month post Vacc 2>=1:8(n=433,852)	91.5 (89.5 to 93.3)	91.7 (88.7 to 94.1)		
PMB80 (A22) 1 month post Vacc 2>=1:16(n=433,852)	91.0 (88.8 to 92.8)	91.0 (87.9 to 93.5)		
PMB80 (A22) 1 month post Vacc 2>=1:32(n=433,852)	80.2 (77.3 to 82.8)	82.4 (78.5 to 85.9)		
PMB80 (A22) 1 month post Vacc 2>=1:64(n=433,852)	54.9 (51.5 to 58.3)	58.0 (53.2 to 62.7)		
PMB80 (A22) 1 month postVacc 2>=1:128(n=433,852)	27.3 (24.4 to 30.5)	27.9 (23.8 to 32.4)		
PMB2001 (A56) Before Vacc 1 >=1:4(n=421,833)	17.5 (15.0 to 20.3)	19.5 (15.8 to 23.6)		
PMB2001 (A56) Before Vacc 1 >=1:8(n=421,833)	12.8 (10.6 to 15.3)	13.8 (10.6 to 17.4)		
PMB2001 (A56) Before Vacc 1 >=1:16(n=421,833)	11.0 (9.0 to 13.4)	10.7 (7.9 to 14.0)		
PMB2001 (A56) Before Vacc 1 >=1:32(n=421,833)	7.6 (5.9 to 9.6)	6.7 (4.5 to 9.5)		
PMB2001 (A56) Before Vacc 1 >=1:64(n=421,833)	4.3 (3.0 to 5.9)	3.8 (2.2 to 6.1)		
PMB2001 (A56) Before Vacc 1 >=1:128(n=421,833)	2.4 (1.5 to 3.7)	2.9 (1.5 to 4.9)		
PMB2001 (A56) 1 month post Vacc 2>=1:4(n=435,854)	99.5 (98.8 to 99.9)	98.9 (97.3 to 99.6)		
PMB2001 (A56) 1 month post Vacc 2>=1:8(n=435,854)	99.4 (98.6 to 99.8)	98.6 (97.0 to 99.5)		
PMB2001 (A56) 1 month post Vacc 2>=1:16(n=435,854)	99.1 (98.2 to 99.6)	98.6 (97.0 to 99.5)		
PMB2001 (A56) 1 month post Vacc 2>=1:32(n=435,854)	97.0 (95.6 to 98.0)	96.8 (94.7 to 98.2)		
PMB2001 (A56) 1 month post Vacc 2>=1:64(n=435,854)	87.7 (85.3 to 89.8)	90.1 (86.9 to 92.8)		

PMB2001 (A56) 1 month postVacc 2>=1:128(n=435,854)	69.2 (66.0 to 72.3)	74.0 (69.6 to 78.1)		
PMB2948 (B24) Before Vacc 1 >=1:4(n=434,855)	14.6 (12.3 to 17.2)	14.1 (10.9 to 17.7)		
PMB2948 (B24) Before Vacc 1 >=1:8(n=434,855)	11.9 (9.8 to 14.3)	10.4 (7.7 to 13.6)		
PMB2948 (B24) Before Vacc 1 >=1:16(n=434,855)	8.2 (6.4 to 10.2)	6.2 (4.1 to 8.9)		
PMB2948 (B24) Before Vacc 1 >=1:32(n=434,855)	4.2 (3.0 to 5.8)	3.7 (2.1 to 5.9)		
PMB2948 (B24) Before Vacc 1 >=1:64(n=434,855)	2.3 (1.4 to 3.6)	0.9 (0.3 to 2.3)		
PMB2948 (B24) Before Vacc 1 >=1:128(n=434,855)	1.1 (0.5 to 2.0)	0.2 (0.0 to 1.3)		
PMB2948 (B24) 1 month post Vacc 2>=1:4(n=426,842)	81.2 (78.4 to 83.8)	86.9 (83.3 to 89.9)		
PMB2948 (B24) 1 month post Vacc 2>=1:8(n=426,842)	79.3 (76.4 to 82.0)	84.3 (80.5 to 87.6)		
PMB2948 (B24) 1 month post Vacc 2>=1:16(n=426,842)	74.0 (70.9 to 76.9)	80.8 (76.7 to 84.4)		
PMB2948 (B24) 1 month post Vacc 2>=1:32(n=426,842)	47.9 (44.4 to 51.3)	58.5 (53.6 to 63.2)		
PMB2948 (B24) 1 month post Vacc 2>=1:64(n=426,842)	24.9 (22.1 to 28.0)	31.0 (26.6 to 35.6)		
PMB2948 (B24) 1 month postVacc 2>=1:128(n=426,842)	9.6 (7.7 to 11.8)	13.4 (10.3 to 17.0)		
PMB2707 (B44) Before Vacc 1 >=1:4(n=434,861)	7.2 (5.6 to 9.1)	7.1 (4.9 to 10.0)		
PMB2707 (B44) Before Vacc 1 >=1:8(n=434,861)	4.5 (3.2 to 6.1)	3.7 (2.1 to 5.9)		
PMB2707 (B44) Before Vacc 1 >=1:16(n=434,861)	3.3 (2.2 to 4.7)	2.1 (1.0 to 3.9)		
PMB2707 (B44) Before Vacc 1 >=1:32(n=434,861)	2.1 (1.2 to 3.3)	0.9 (0.3 to 2.3)		
PMB2707 (B44) Before Vacc 1 >=1:64(n=434,861)	1.2 (0.6 to 2.1)	0.7 (0.1 to 2.0)		
PMB2707 (B44) Before Vacc 1 >=1:128(n=434,861)	0.3 (0.1 to 1.0)	0.5 (0.1 to 1.7)		
PMB2707 (B44) 1 month post Vacc 2>=1:4(n=436,853)	96.2 (94.7 to 97.4)	97.2 (95.2 to 98.6)		
PMB2707 (B44) 1 month post Vacc 2>=1:8(n=436,853)	94.5 (92.7 to 95.9)	95.4 (93.0 to 97.2)		
PMB2707 (B44) 1 month post Vacc 2>=1:16(n=436,853)	89.0 (86.7 to 91.0)	92.4 (89.5 to 94.7)		
PMB2707 (B44) 1 month post Vacc 2>=1:32(n=436,853)	68.6 (65.3 to 71.7)	72.9 (68.5 to 77.1)		
PMB2707 (B44) 1 month post Vacc 2>=1:64(n=436,853)	41.0 (37.7 to 44.4)	48.9 (44.1 to 53.7)		
PMB2707 (B44) 1 month postVacc 2>=1:128(n=436,853)	19.2 (16.6 to 22.0)	22.0 (18.2 to 26.2)		

Statistical analyses

No statistical analyses for this end point

Secondary: Stage1: hSBA GMTs for Each of the 4 Primary MenB Test Strains Before Vaccination 1 and 1 Month After Vaccination 2 (Group 1 and 3 Combined; Group 2 and 4 Combined)

End point title	Stage1: hSBA GMTs for Each of the 4 Primary MenB Test Strains Before Vaccination 1 and 1 Month After Vaccination 2 (Group 1 and 3 Combined; Group 2 and 4 Combined)

End point description:

GMTs were calculated using all subjects with valid and determinate hSBA titers at the given time point. LLOQ =1:16 for A22; 1:8 for A56, B24, and B44. Titers below the LLOQ were set to 0.5*LLOQ for analysis. Stage 1 EIP, included all eligible subjects who were randomised to the study group of interest, received all investigational products as randomised, had blood drawn for assay testing within the required time frames at Months 0 and 7, had valid and determinate assay results, had received no prohibited vaccines or treatment, and had no other major protocol violations as determined by the sponsor's global medical monitor. Here, 'n' signifies number of subjects with valid and determinate hSBA results on all 4 strains at the given time point. Analysis was planned for combined Group 2 and 4 and combined Group 1 and 3.

End point type	Secondary

End point timeframe:

Before Vaccination 1 (Vacc 1), 1 Month After Vaccination 2 (Vacc 2)

End point values	Stage 1: Groups 2+4 Combined	Stage 1: Group 1+3 Combined		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	864	438		
Units: Titers				
geometric mean (confidence interval 95%)				
PMB80 (A22), Before vacc 1, (n=427,839)	10.7 (10.3 to 11.1)	10.8 (10.2 to 11.5)		
PMB80 (A22), 1 month after vacc 2, (n=433,852)	49.3 (46.2 to 52.6)	51.0 (46.7 to 55.7)		
PMB2001 (A56), Before vacc 1, (n=421,833)	5.3 (5.0 to 5.6)	5.2 (4.9 to 5.7)		
PMB2001 (A56), 1 month after vacc 2, (n=435,854)	139.5 (130.6 to 149.1)	152.3 (138.5 to 167.5)		
PMB2948 (B24), Before vacc 1, (n=434,855)	4.9 (4.7 to 5.1)	4.6 (4.4 to 4.9)		
PMB2948 (B24), 1 month after vacc 2, (n=426,842)	21.2 (19.6 to 22.9)	26.6 (23.9 to 29.7)		
PMB2707 (B44), Before vacc 1, (n=434,861)	4.3 (4.2 to 4.5)	4.2 (4.1 to 4.4)		
PMB2707 (B44), 1 month after vacc 2, (n=436,853)	37.8 (35.1 to 40.8)	43.3 (39.1 to 47.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: Stage2: Percentage of Subjects With hSBA-MenA, hSBA-MenC, hSBA-MenW, and hSBA-MenY Titers >=1:8 (or LLOQ if Higher) for ACWY Test Strains During Persistence Phase: Groups 1, 2, 3 and 4

End point title	Stage2: Percentage of Subjects With hSBA-MenA, hSBA-MenC, hSBA-MenW, and hSBA-MenY Titers >=1:8 (or LLOQ if Higher) for ACWY Test Strains During Persistence Phase: Groups 1, 2, 3 and 4

End point description:

Percentage of subjects who achieved an hSBA-MenA, hSBA-MenC, hSBA-MenW, and hSBA-MenY titer >=LLOQ for ACWY Test Strains (LLOQ = 1:8 for all MenA, MenC, MenW, and MenY strains) was reported in this endpoint. Stage 2 mITT population included all subjects who signed the ICD at Month 18 and who had at least 1 valid and determinate primary strain MenB or MenA/C/W/Y assay result available in Stage 2. Here, 'n' signifies number of subjects with valid and determinate hSBA results for ACWY test strains at the given time point. Analysis was planned for Group 1 through Group 4.

End point type	Secondary

End point timeframe:

Persistence Phase: 12, 24, 36 and 48 months after Vaccination 2 (Vacc 2)

End point values	Group 1: MenABCWY + Saline (ACWY-Naive)	Group 2: Bivalent rLP2086 + MenACWY-CRM (ACWY-Naive)	Group 3: MenABCWY + Saline (ACWY-Experienced)	Group 4: Bivalent rLP2086 + MenACWY-CRM (ACWY-Experienced)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	112	64	101	73
Units: Percentage of subjects				
number (confidence interval 95%)				
MenA 12 Months after Vacc 2, (n=112,59,48,22)	91.1 (84.2 to 95.6)	71.2 (57.9 to 82.2)	97.9 (88.9 to 99.9)	100.0 (84.6 to 100.0)
MenA 24 Months after Vacc 2, (n=101,60,61,37)	88.1 (80.2 to 93.7)	70.0 (56.8 to 81.2)	100.0 (94.1 to 100.0)	100.0 (90.5 to 100.0)
MenA 36 Months after Vacc 2, (n=95,54,57,33)	88.4 (80.2 to 94.1)	72.2 (58.4 to 83.5)	100.0 (93.7 to 100.0)	97.0 (84.2 to 99.9)
MenA 48 Months after Vacc 2, (n=71,41,40,23)	81.7 (70.7 to 89.9)	63.4 (46.9 to 77.9)	100.0 (91.2 to 100.0)	100.0 (85.2 to 100.0)
MenC 12 Months after Vacc 2, (n=112,62,54,23)	76.8 (67.9 to 84.2)	51.6 (38.6 to 64.5)	96.3 (87.3 to 99.5)	91.3 (72.0 to 98.9)
MenC 24 Months after Vacc 2, (n=101,61,97,71)	75.2 (65.7 to 83.3)	47.5 (34.6 to 60.7)	96.9 (91.2 to 99.4)	94.4 (86.2 to 98.4)
MenC 36 Months after Vacc 2, (n=95,54,96,67)	67.4 (57.0 to 76.6)	44.4 (30.9 to 58.6)	96.9 (91.1 to 99.4)	95.5 (87.5 to 99.1)
MenC 48 Months after Vacc 2, (n=71,42,76,58)	62.0 (49.7 to 73.2)	38.1 (23.6 to 54.4)	98.7 (92.9 to 100.0)	89.7 (78.8 to 96.1)
MenW 12 Months after Vacc 2, (n=112,62,48,22)	99.1 (95.1 to 100.0)	83.9 (72.3 to 92.0)	100.0 (92.6 to 100.0)	95.5 (77.2 to 99.9)
MenW 24 Months after Vacc 2, (n=103,61,61,37)	99.0 (94.7 to 100.0)	78.7 (66.3 to 88.1)	100.0 (94.1 to 100.0)	94.6 (81.8 to 99.3)
MenW 36 Months after Vacc 2, (n=97,54,57,33)	94.8 (88.4 to 98.3)	77.8 (64.4 to 88.0)	100.0 (93.7 to 100.0)	97.0 (84.2 to 99.9)
MenW 48 Months after Vacc 2, (n=70,41,40,23)	91.4 (82.3 to 96.8)	70.7 (54.5 to 83.9)	100.0 (91.2 to 100.0)	91.3 (72.0 to 98.9)
MenY 12 Months after Vacc 2, (n=112,62,48,22)	100.0 (96.8 to 100.0)	98.4 (91.3 to 100.0)	100.0 (92.6 to 100.0)	100.0 (84.6 to 100.0)
MenY 24 Months after Vacc 2, (n=102,61,61,37)	100.0 (96.4 to 100.0)	93.4 (84.1 to 98.2)	100.0 (94.1 to 100.0)	100.0 (90.5 to 100.0)
MenY 36 Months after Vacc 2, (n=97,54,57,33)	100.0 (96.3 to 100.0)	90.7 (79.7 to 96.9)	100.0 (93.7 to 100.0)	100.0 (84.2 to 100.0)
MenY 48 Months after Vacc 2, (n=71,42,40,22)	100.0 (94.9 to 100.0)	95.2 (83.8 to 99.4)	100.0 (91.2 to 100.0)	100.0 (84.6 to 100.0)

Statistical analyses

No statistical analyses for this end point

Secondary: Stage2: Percentage of Subjects With hSBA Titer Level >=LLOQ for 4 Primary MenB Test Strains During Persistence Phase (Group 1 and 3 Combined; Group 2 and 4 Combined)

End point title	Stage2: Percentage of Subjects With hSBA Titer Level >=LLOQ for 4 Primary MenB Test Strains During Persistence Phase (Group 1 and 3 Combined; Group 2 and 4 Combined)

End point description:

Percentage of subjects who achieved an hSBA titer >=LLOQ for all 4 primary MenB test strains (LLOQ was 1:16 for A22 and 1:8 for A56, B24, and B44) was reported in this endpoint. Stage 2 mITT population included all subjects who signed the ICD at Month 18 and who had at least 1 valid and determinate primary strain MenB or MenA/C/W/Y assay result available in Stage 2. Here, 'n' signifies number of subjects with valid and determinate hSBA results on all 4 strains at the given time point. Analysis was planned for combined Group 2 and 4 and combined Group 1 and 3.

End point type	Secondary

End point timeframe:

Persistence Phase: 12, 24, 36 and 48 months after Vaccination 2 (Vacc 2)

End point values	Stage 2: Group 1+3 Combined	Stage 2: Groups 2+4 Combined		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	213	137		
Units: Percentage of subjects				
number (confidence interval 95%)				
PMB80 (A22) 12 months after Vacc 2,(n=162,83)	32.7 (25.6 to 40.5)	26.5 (17.4 to 37.3)		
PMB80 (A22) 24 months after Vacc 2,(n=196,128)	36.7 (30.0 to 43.9)	28.9 (21.2 to 37.6)		
PMB80 (A22) 36 months after Vacc 2,(n=185,116)	29.2 (22.8 to 36.3)	25.9 (18.2 to 34.8)		
PMB80 (A22) 48 months after Vacc 2,(n=139,94)	28.1 (20.8 to 36.3)	31.9 (22.7 to 42.3)		
PMB2001 (A56) 12 months after Vacc 2,(n=162,84)	33.3 (26.1 to 41.2)	32.1 (22.4 to 43.2)		
PMB2001 (A56) 24 months after Vacc 2,(n=196,131)	34.7 (28.1 to 41.8)	33.6 (25.6 to 42.4)		
PMB2001 (A56) 36 months after Vacc 2,(n=186,118)	29.0 (22.6 to 36.1)	33.9 (25.4 to 43.2)		
PMB2001 (A56) 48 months after Vacc 2,(n=145,98)	34.5 (26.8 to 42.8)	29.6 (20.8 to 39.7)		
PMB2948 (B24) 12 months after Vacc 2,(n=165,85)	30.9 (24.0 to 38.6)	28.2 (19.0 to 39.0)		
PMB2948 (B24) 24 months after Vacc 2,(n=196,131)	33.2 (26.6 to 40.2)	27.5 (20.0 to 36.0)		
PMB2948 (B24) 36 months after Vacc 2,(n=192,120)	35.4 (28.7 to 42.6)	28.3 (20.5 to 37.3)		
PMB2948 (B24) 48 months after Vacc 2,(n=145,98)	36.6 (28.7 to 44.9)	26.5 (18.1 to 36.4)		
PMB2707 (B44) 12 months after Vacc 2,(n=166,85)	18.7 (13.1 to 25.4)	15.3 (8.4 to 24.7)		
PMB2707 (B44) 24 months after Vacc 2,(n=200,132)	18.0 (12.9 to 24.0)	18.2 (12.0 to 25.8)		

PMB2707 (B44) 36 months after Vacc 2,(n=193,121)	20.2 (14.8 to 26.6)	19.8 (13.1 to 28.1)		
PMB2707 (B44) 48 months after Vacc 2,(n=148,99)	18.2 (12.4 to 25.4)	16.2 (9.5 to 24.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: Stage2: Percentage of Subjects With hSBA-MenA, hSBA-MenC, hSBA-MenW, and hSBA-MenY Titers >=1:8 (or >=LLOQ if higher) for ACWY Test Strains 1 Month After Booster Vaccination: Groups 1 and 3 (Separately)

End point title	Stage2: Percentage of Subjects With hSBA-MenA, hSBA-MenC, hSBA-MenW, and hSBA-MenY Titers >=1:8 (or >=LLOQ if higher) for ACWY Test Strains 1 Month After Booster Vaccination: Groups 1 and 3 (Separately)

End point description:

Percentage of subjects who achieved an hSBA-MenA, hSBA-MenC, hSBA-MenW, and hSBA-MenY titer >=LLOQ for ACWY test strains (LLOQ = 1:8 for all MenA, MenC, MenW, and MenY strains) was reported in this endpoint. The booster EIP included subjects who were eligible for the study (ie, met all Stage 1 eligibility criteria as well as continually met Stage 2 eligibility criteria), received a booster dose as intended (the same vaccine as they received in Stage 1), had blood drawn for assay testing within the required time frame at Month 55 (Visit 11), and had a valid and determinate MenB or MenA/C/W/Y assay result after the booster dose, as well as no major protocol violations as determined by the sponsor's global medical monitor. Here, 'n' signifies number of subjects with valid and determinate hSBA results for ACWY test strains at the given time point. Analysis was planned for Group 1 and Group 3 separately.

End point type	Secondary

End point timeframe:

1 month after booster vaccination

End point values	Group 1: MenABCWY + Saline (ACWY-Naive)	Group 3: MenABCWY + Saline (ACWY-Experienced)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	60	70		
Units: Percentage of subjects				
number (confidence interval 95%)				
MenA (n=60,33)	100.0 (94.0 to 100.0)	100.0 (89.4 to 100.0)		
MenC (n=60,70)	100.0 (94.0 to 100.0)	100.0 (94.9 to 100.0)		
MenW (n=60,33)	100.0 (94.0 to 100.0)	100.0 (89.4 to 100.0)		
MenY (n=60,33)	100.0 (94.0 to 100.0)	100.0 (89.4 to 100.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: Stage2: Percentage of Subjects With hSBA Titer Level >=LLOQ for 4 Primary MenB Test Strains 1 Month After Booster Vaccination (Group 1 and 3 Combined; Group 2 and 4 Combined)

End point title	Stage2: Percentage of Subjects With hSBA Titer Level >=LLOQ for 4 Primary MenB Test Strains 1 Month After Booster Vaccination (Group 1 and 3 Combined; Group 2 and 4 Combined)

End point description:

Percentage of subjects who achieved an hSBA titer >=LLOQ for all 4 primary MenB test strains (LLOQ was 1:16 for A22 and 1:8 for A56, B24, and B44) was reported in this endpoint. The booster EIP included subjects who were eligible for the study (ie, met all Stage 1 eligibility criteria as well as continually met Stage 2 eligibility criteria), received a booster dose as intended (the same vaccine as they received in Stage 1), had blood drawn for assay testing within the required time frame at Month 55 (Visit 11), and had a valid and determinate MenB or MenA/C/W/Y assay result after the booster dose, as well as no major protocol violations as determined by the sponsor's global medical monitor. Here, 'n' signifies number of subjects with valid and determinate hSBA results for ACWY test strains at the given time point. Analysis was planned for combined Group 1 and Group 3 and Combined Group 2 and 4.

End point type	Secondary

End point timeframe:

1 month after booster vaccination

End point values	Stage 2: Group 1+3 Combined	Stage 2: Groups 2+4 Combined		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	130	88		
Units: Percentage of subjects				
number (confidence interval 95%)				
PMB80 (A22) (n=122,81)	95.1 (89.6 to 98.2)	93.8 (86.2 to 98.0)		
PMB2001 (A56) (n=124,86)	100.0 (97.1 to 100.0)	98.8 (93.7 to 100.0)		
PMB2948 (B24) (n=123,84)	95.1 (89.7 to 98.2)	95.2 (88.3 to 98.7)		
PMB2707 (B44) (n=128,86)	99.2 (95.7 to 100.0)	98.8 (93.7 to 100.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: Stage1: Percentage of Subjects With Local Reactions Within 7 Days After Vaccination 1 and 2: Group 1 and Group 3

End point title	Stage1: Percentage of Subjects With Local Reactions Within 7 Days After Vaccination 1 and 2: Group 1 and Group 3[49]

End point description:

Local reactions (redness, swelling, and pain) at the site of investigational product administration were recorded in e-diary. Redness and swelling were measured and recorded in caliper units. Each caliper unit represented 0.5 cm. Redness and swelling were graded as mild (>2.0 to 5.0 cm), moderate (>5.0 to 10.0 cm) and severe (>10.0 cm). Pain at injection site was graded as mild (did not interfere with activity), moderate (interfered with activity), and severe (prevented daily activity). The safety

population for Stage 1 included subjects who had received at least 1 dose of investigational product during Stage 1 and for whom safety data were available. Here, 'Number of subjects Analysed' signifies number of subjects with known values. Analysis was planned for Group 1 and Group 3.

End point type	Secondary

End point timeframe:

7 days after Vaccination 1 (Vacc 1) and Vaccination 2 (Vacc 2)

Notes:

[49] - 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: This endpoint reports data only for Group 1 and 3 not for Group 1 and 4.

End point values	Group 1: MenABCWY + Saline (ACWY-Naive)	Group 3: MenABCWY + Saline (ACWY-Experienced)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	272	270		
Units: Percentage of subjects				
number (confidence interval 95%)				
Vacc 1: Redness: Mild	7.4 (4.6 to 11.2)	5.6 (3.2 to 9.0)		
Vacc 1: Redness: Moderate	10.0 (6.7 to 14.3)	7.4 (4.6 to 11.2)		
Vacc 1: Redness: Severe	2.2 (0.8 to 4.8)	1.9 (0.6 to 4.3)		
Vacc 1: Swelling: Mild	9.3 (6.1 to 13.4)	8.6 (5.5 to 12.6)		
Vacc 1: Swelling: Moderate	10.4 (7.0 to 14.7)	8.6 (5.5 to 12.6)		
Vacc 1: Swelling: Severe	1.1 (0.2 to 3.2)	0.4 (0.0 to 2.1)		
Vacc 1: Pain at injection site: Mild	37.2 (31.4 to 43.3)	45.4 (39.3 to 51.5)		
Vacc 1: Pain at injection site: Moderate	45.7 (39.7 to 51.9)	40.1 (34.2 to 46.3)		
Vacc 1: Pain at injection site: Severe	6.3 (3.7 to 9.9)	4.8 (2.6 to 8.1)		
Vacc 2: Redness: Mild	7.0 (4.0 to 11.1)	6.9 (4.0 to 10.9)		
Vacc 2: Redness: Moderate	11.7 (7.9 to 16.6)	9.0 (5.7 to 13.4)		
Vacc 2: Redness: Severe	4.3 (2.1 to 7.9)	3.4 (1.5 to 6.7)		
Vacc 2: Swelling: Mild	8.7 (5.4 to 13.1)	5.6 (3.0 to 9.4)		
Vacc 2: Swelling: Moderate	10.0 (6.4 to 14.6)	11.2 (7.4 to 15.9)		
Vacc 2: Swelling: Severe	0.4 (0.0 to 2.4)	1.3 (0.3 to 3.7)		
Vacc 2: Pain at injection site: Mild	34.3 (28.2 to 40.9)	37.8 (31.5 to 44.3)		
Vacc 2: Pain at injection site: Moderate	47.0 (40.4 to 53.6)	38.2 (31.9 to 44.8)		
Vacc 2: Pain at injection site: Severe	3.9 (1.8 to 7.3)	7.7 (4.6 to 11.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: Stage1: Percentage of Subjects With Systemic Events Within 7 Days After Vaccination 1 and 2: Group 1 and Group 3

End point title	Stage1: Percentage of Subjects With Systemic Events Within 7 Days After Vaccination 1 and 2: Group 1 and Group 3[50]

End point description:

Systemic events fever, vomiting, diarrhea, headache, fatigue, chills, muscle pain and joint pain were recorded in an e-diary. Fever was defined as >=38.0 degree C and categorized to 38.0 to 38.4 degree C, 38.5 to 38.9 degree C, 39.0 to 40.0 degree C and >40.0 degree C. Headache, fatigue, chills, muscle pain and joint pain were graded as mild (did not interfere with activity), moderate (some interference with activity) and severe (prevented daily activity). Vomiting was graded as mild (1-2 times in 24 hours), moderate (>2 times in 24 hours) and severe (required IV hydration). Diarrhea was graded as mild (2-3 loose stools in 24 hours), moderate (4-5 loose stools in 24 hours) and severe (>=6 in 24 hours). Stage 1 safety population: subjects who received at least 1 dose of investigational product during Stage 1 and for whom safety data were available. Here, 'Number of subjects Analysed' signifies number of subjects with known values. Analysis was planned for Group 1 and Group 3.

End point type	Secondary

End point timeframe:

7 days after Vaccination 1 (Vacc 1) and Vaccination 2 (Vacc 2)

Notes:

[50] - 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: This endpoint reports data only for Group 1 and 3 not for Group 1 and 4.

End point values	Group 1: MenABCWY + Saline (ACWY-Naive)	Group 3: MenABCWY + Saline (ACWY-Experienced)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	272	270		
Units: Percentage of subjects				
number (confidence interval 95%)				
Vacc 1: Fever: 38.0 to 38.4 degree C	4.1 (2.1 to 7.2)	4.1 (2.1 to 7.2)		
Vacc 1: Fever: 38.4 to 38.9 degree C	2.2 (0.8 to 4.8)	0.7 (0.1 to 2.7)		
Vacc 1: Fever: 38.9 to 40.0 degree C	1.1 (0.2 to 3.2)	0.4 (0.0 to 2.1)		
Vacc 1: Fever: > 40.0 degree C	0.0 (0.0 to 1.4)	0.0 (0.0 to 1.4)		
Vacc 1: Fatigue: Mild	26.8 (21.6 to 32.5)	27.9 (22.6 to 33.6)		
Vacc 1: Fatigue: Moderate	25.3 (20.2 to 30.9)	17.5 (13.1 to 22.5)		
Vacc 1: Fatigue: Severe	4.5 (2.3 to 7.7)	3.7 (1.8 to 6.7)		
Vacc 1: Headache: Mild	27.1 (21.9 to 32.9)	29.4 (24.0 to 35.2)		
Vacc 1: Headache: Moderate	19.3 (14.8 to 24.6)	14.1 (10.2 to 18.9)		
Vacc 1: Headache: Severe	1.9 (0.6 to 4.3)	1.5 (0.4 to 3.8)		
Vacc 1: Chills: Mild	14.5 (10.5 to 19.3)	9.3 (6.1 to 13.4)		
Vacc 1: Chills: Moderate	4.5 (2.3 to 7.7)	4.8 (2.6 to 8.1)		
Vacc 1: Chills: Severe	1.1 (0.2 to 3.2)	0.7 (0.1 to 2.7)		
Vacc 1: Vomiting: Mild	2.2 (0.8 to 4.8)	1.9 (0.6 to 4.3)		
Vacc 1: Vomiting: Moderate	0.4 (0.0 to 2.1)	0.0 (0.0 to 1.4)		
Vacc 1: Vomiting: severe	0.0 (0.0 to 1.4)	0.0 (0.0 to 1.4)		
Vacc 1: Diarrhea: Mild	10.0 (6.7 to 14.3)	10.8 (7.3 to 15.1)		
Vacc 1: Diarrhea: Moderate	2.2 (0.8 to 4.8)	4.5 (2.3 to 7.7)		
Vacc 1: Diarrhea: Severe	0.0 (0.0 to 1.4)	0.0 (0.0 to 1.4)		

Vacc 1: Muscle pain: Mild	17.1 (12.8 to 22.1)	14.5 (10.5 to 19.3)		
Vacc 1: Muscle pain: Moderate	10.4 (7.0 to 14.7)	7.1 (4.3 to 10.8)		
Vacc 1: Muscle pain: Severe	1.5 (0.4 to 3.8)	1.1 (0.2 to 3.2)		
Vacc 1: Joint pain: Mild	13.0 (9.2 to 17.6)	10.8 (7.3 to 15.1)		
Vacc 1: Joint pain: Moderate	7.8 (4.9 to 11.7)	6.7 (4.0 to 10.4)		
Vacc 1: Joint pain: Severe	0.0 (0.0 to 1.4)	0.7 (0.1 to 2.7)		
Vacc 2: Fever: 38.0 to 38.4°C	2.2 (0.7 to 5.0)	0.9 (0.1 to 3.1)		
Vacc 2: Fever: 38.5 to 38.9°C	1.3 (0.3 to 3.8)	0.9 (0.1 to 3.1)		
Vacc 2: Fever: 39.0 to 40.0°C	0.0 (0.0 to 1.6)	0.0 (0.0 to 1.6)		
Vacc 2: Fever: > 40.0°C	0.0 (0.0 to 1.6)	0.0 (0.0 to 1.6)		
Vacc 2: Fatigue: Mild	20.9 (15.8 to 26.7)	26.2 (20.7 to 32.3)		
Vacc 2: Fatigue: Moderate	26.1 (20.5 to 32.3)	18.9 (14.1 to 24.5)		
Vacc 2: Fatigue: Severe	2.6 (1.0 to 5.6)	2.6 (1.0 to 5.5)		
Vacc 2: Headache: Mild	22.6 (17.4 to 28.6)	26.6 (21.1 to 32.8)		
Vacc 2: Headache: Moderate	17.8 (13.1 to 23.4)	13.3 (9.2 to 18.4)		
Vacc 2: Headache: Severe	1.3 (0.3 to 3.8)	3.9 (1.8 to 7.2)		
Vacc 2: Chills: Mild	16.1 (11.6 to 21.5)	11.6 (7.8 to 16.4)		
Vacc 2: Chills: Moderate	3.9 (1.8 to 7.3)	5.2 (2.7 to 8.8)		
Vacc 2: Chills: Severe	0.9 (0.1 to 3.1)	2.6 (1.0 to 5.5)		
Vacc 2: Vomiting: Mild	1.7 (0.5 to 4.4)	3.4 (1.5 to 6.7)		
Vacc 2: Vomiting: Moderate	0.0 (0.0 to 1.6)	0.4 (0.0 to 2.4)		
Vacc 2: Vomiting: Severe	0.0 (0.0 to 1.6)	0.0 (0.0 to 1.6)		
Vacc 2: Diarrhea: Mild	9.6 (6.1 to 14.1)	5.2 (2.7 to 8.8)		
Vacc 2: Diarrhea: Moderate	3.9 (1.8 to 7.3)	2.6 (1.0 to 5.5)		
Vacc 2: Diarrhea: Severe	0.0 (0.0 to 1.6)	0.4 (0.0 to 2.4)		
Vacc 2: Muscle pain: Mild	13.0 (9.0 to 18.1)	8.6 (5.3 to 12.9)		
Vacc 2: Muscle pain: Moderate	10.9 (7.2 to 15.6)	9.9 (6.4 to 14.4)		
Vacc 2: Muscle pain: Severe	0.9 (0.1 to 3.1)	0.9 (0.1 to 3.1)		
Vacc 2: Joint pain: Mild	9.1 (5.7 to 13.6)	10.7 (7.1 to 15.4)		
Vacc 2: Joint pain: Moderate	9.1 (5.7 to 13.6)	6.4 (3.6 to 10.4)		
Vacc 2: Joint pain: Severe	0.4 (0.0 to 2.4)	0.9 (0.1 to 3.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: Stage1: Percentage of Subjects With at Least 1 SAE Within 30 Days After Vaccination 1, 2, and any Vaccination: Group 1 and Group 3

End point title	Stage1: Percentage of Subjects With at Least 1 SAE Within 30 Days After Vaccination 1, 2, and any Vaccination: Group 1 and Group 3[51]

End point description:

An AE was any untoward medical occurrence in a subject who received study drug without regard to possibility of causal relationship. SAE was any untoward medical occurrence at any dose that: resulted in death, was life threatening (immediate risk of death), required hospitalization or prolongation of existing hospitalization, resulted in persistent or significant disability/incapacity (substantial disruption of the ability to conduct normal life functions), resulted in congenital anomaly/birth defect. Or that was considered to be an important medical event. Stage 1 safety population: subjects who received at least 1 dose of investigational product during Stage 1 and for whom safety data were available. Analysis was planned for Group 1 and Group 3.

End point type	Secondary

End point timeframe:

30 days after Vaccination 1, Vaccination 2 and any Vaccination

Notes:

[51] - 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: This endpoint reports data only for Group 1 and 3 not for Group 1 and 4.

End point values	Group 1: MenABCWY + Saline (ACWY-Naive)	Group 3: MenABCWY + Saline (ACWY-Experienced)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	272	271		
Units: Percentage of subjects				
number (confidence interval 95%)				
Vaccination 1	0.0 (0.0 to 1.3)	0.7 (0.1 to 2.6)		
Vaccination 2	0.4 (0.0 to 2.3)	0.0 (0.0 to 1.5)		
Any vaccination	0.4 (0.0 to 2.0)	0.7 (0.1 to 2.6)		

Statistical analyses

No statistical analyses for this end point

Secondary: Stage1: Percentage of Subjects With Antipyretic Medication use 30 Days After Vaccination 1 and 2: Group 1 and Group 3

End point title	Stage1: Percentage of Subjects With Antipyretic Medication use 30 Days After Vaccination 1 and 2: Group 1 and Group 3[52]

End point description:

Stage 1 safety population: subjects who received at least 1 dose of investigational product during Stage 1 and for whom safety data were available. Here, 'Number of subjects Analysed' signifies number of subjects with known values. Analysis was planned for Group 1 and Group 3.

End point type	Secondary

End point timeframe:

30 days after Vaccination 1 and Vaccination 2

Notes:

[52] - 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: This endpoint reports data only for Group 1 and 3 not for Group 1 and 4.

End point values	Group 1: MenABCWY + Saline (ACWY-Naive)	Group 3: MenABCWY + Saline (ACWY-Experienced)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	272	271		
Units: Percentage of subjects				
number (confidence interval 95%)				
Vaccination 1	20.8 (16.1 to 26.2)	13.8 (9.9 to 18.5)		
Vaccination 2	17.8 (13.1 to 23.4)	13.3 (9.2 to 18.4)		

Statistical analyses

No statistical analyses for this end point

Secondary: Stage1: Percentage of Subjects With at Least 1 SAE During the Vaccination Phase: Group 1 and Group 3

End point title	Stage1: Percentage of Subjects With at Least 1 SAE During the Vaccination Phase: Group 1 and Group 3[53]

End point description:

An AE was any untoward medical occurrence in a subject who received study drug without regard to possibility of causal relationship. SAE was any untoward medical occurrence at any dose that: resulted in death, was life threatening (immediate risk of death), required hospitalization or prolongation of existing hospitalization, resulted in persistent or significant disability/incapacity (substantial disruption of the ability to conduct normal life functions), resulted in congenital anomaly/birth defect. Or that was considered to be an important medical event. Stage 1 safety population: subjects who received at least 1 dose of investigational product during Stage 1 and for whom safety data were available. Analysis was planned for Group 1 and Group 3.

End point type	Secondary

End point timeframe:

Stage 1 Vaccination Phase: From Vaccination 1 through 1 month after Vaccination 2 (7 Months)

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: This endpoint reports data only for Group 1 and 3 not for Group 1 and 4.

End point values	Group 1: MenABCWY + Saline (ACWY-Naive)	Group 3: MenABCWY + Saline (ACWY-Experienced)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	272	271		
Units: Percentage of subjects				
number (confidence interval 95%)	0.4 (0.0 to 2.0)	1.8 (0.6 to 4.3)		

Statistical analyses

No statistical analyses for this end point

Secondary: Stage1: Percentage of Subjects With at Least 1 SAE Throughout the Stage 1: Group 1 and Group 3

End point title	Stage1: Percentage of Subjects With at Least 1 SAE Throughout the Stage 1: Group 1 and Group 3[54]

End point description:

An AE was any untoward medical occurrence in a subject who received study drug without regard to possibility of causal relationship. SAE was any untoward medical occurrence at any dose that: resulted in death, was life threatening (immediate risk of death), required hospitalization or prolongation of existing hospitalization, resulted in persistent or significant disability/incapacity (substantial disruption of the ability to conduct normal life functions), resulted in congenital anomaly/birth defect. Or that was considered to be an important medical event. Stage 1 safety population: subjects who received at least 1 dose of investigational product during Stage 1 and for whom safety data were available. Analysis was planned for Group 1 and Group 3.

End point type	Secondary

End point timeframe:

Throughout Stage 1: From the Vaccination 1 through 6 months after Vaccination 2 (12 Months)

Notes:

[54] - 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: This endpoint reports data only for Group 1 and 3 not for Group 1 and 4.

End point values	Group 1: MenABCWY + Saline (ACWY-Naive)	Group 3: MenABCWY + Saline (ACWY-Experienced)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	272	271		
Units: Percentage of subjects				
number (confidence interval 95%)	1.5 (0.4 to 3.7)	2.2 (0.8 to 4.8)		

Statistical analyses

No statistical analyses for this end point

Secondary: Stage1: Percentage of Subjects With at Least 1 Medically Attended AE Within 30 Days After Vaccination 1, 2, and any Vaccination: Group 1 and Group 3

End point title	Stage1: Percentage of Subjects With at Least 1 Medically Attended AE Within 30 Days After Vaccination 1, 2, and any Vaccination: Group 1 and Group 3[55]

End point description:

Medically attended AE was defined as a nonserious AE that resulted in an evaluation at a medical facility. Stage 1 safety population: subjects who received at least 1 dose of investigational product during Stage 1 and for whom safety data were available. Analysis was planned for Group 1 and Group 3.

End point type	Secondary

End point timeframe:

30 days after vaccination 1, 2, and any vaccination

Notes:

[55] - 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: This endpoint reports data only for Group 1 and 3 not for Group 1 and 4.

End point values	Group 1: MenABCWY + Saline (ACWY-Naive)	Group 3: MenABCWY + Saline (ACWY-Experienced)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	272	271		
Units: Percentage of subjects				
number (confidence interval 95%)				
Vaccination 1	4.8 (2.6 to 8.0)	5.9 (3.4 to 9.4)		
Vaccination 2	5.8 (3.2 to 9.5)	9.0 (5.7 to 13.3)		
Any vaccination	9.6 (6.3 to 13.7)	13.3 (9.5 to 17.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: Stage1: Percentage of Subjects With at Least 1 SAE During the Follow-up Phase: Group 1 and Group 3

End point title	Stage1: Percentage of Subjects With at Least 1 SAE During the Follow-up Phase: Group 1 and Group 3[56]

End point description:

An AE was any untoward medical occurrence in a subject who received study drug without regard to possibility of causal relationship. SAE was any untoward medical occurrence at any dose that: resulted in death, was life threatening (immediate risk of death), required hospitalization or prolongation of existing hospitalization, resulted in persistent or significant disability/incapacity (substantial disruption of the ability to conduct normal life functions), resulted in congenital anomaly/birth defect. Or that was considered to be an important medical event. Stage 1 safety population: subjects who received at least 1 dose of investigational product during Stage 1 and for whom safety data were available. Here, 'Number of subjects Analysed' signifies number of subjects with known values. Analysis was planned for Group 1 and Group 3.

End point type	Secondary

End point timeframe:

Stage 1 Follow-up phase: From 1 month after Vaccination 2 through 6 months after Vaccination 2 (5 Months)

Notes:

[56] - 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: This endpoint reports data only for Group 1 and 3 not for Group 1 and 4.

End point values	Group 1: MenABCWY + Saline (ACWY-Naive)	Group 3: MenABCWY + Saline (ACWY-Experienced)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	239	239		
Units: Percentage of subjects				
number (confidence interval 95%)	0.8 (0.1 to 3.0)	0.4 (0.0 to 2.3)		

Statistical analyses

No statistical analyses for this end point

Secondary: Stage1: Percentage of Subjects With at Least 1 Medically Attended AE During the Vaccination Phase: Group 1 and Group 3

End point title	Stage1: Percentage of Subjects With at Least 1 Medically Attended AE During the Vaccination Phase: Group 1 and Group 3[57]

End point description:

Medically attended AE was defined as a nonserious AE that resulted in an evaluation at a medical facility. Stage 1 safety population: subjects who received at least 1 dose of investigational product during Stage 1 and for whom safety data were available. Analysis was planned for Group 1 and Group 3.

End point type	Secondary

End point timeframe:

Stage 1 Vaccination Phase: From Vaccination 1 through 1 month after Vaccination 2 (7 Months)

Notes:

[57] - 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: This endpoint reports data only for Group 1 and 3 not for Group 1 and 4.

End point values	Group 1: MenABCWY + Saline (ACWY-Naive)	Group 3: MenABCWY + Saline (ACWY-Experienced)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	272	271		
Units: Percentage of subjects				
number (confidence interval 95%)	23.9 (19.0 to 29.4)	28.4 (23.1 to 34.2)		

Statistical analyses

No statistical analyses for this end point

Secondary: Stage1: Percentage of Subjects With at Least 1 NDCMC Within 30 Days After Vaccination 1, 2, and any Vaccination: Group 1 and Group 3

End point title	Stage1: Percentage of Subjects With at Least 1 NDCMC Within 30 Days After Vaccination 1, 2, and any Vaccination: Group 1 and Group 3[58]

End point description:

A NDCMC was defined as a disease or medical condition, not previously identified, that was expected to be persistent or otherwise long-lasting in its effects. Stage 1 safety population: subjects who received at least 1 dose of investigational product during Stage 1 and for whom safety data were available. Analysis was planned for Group 1 and Group 3.

End point type	Secondary

End point timeframe:

30 days after Vaccination 1, 2, and any Vaccination

Notes:

[58] - 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: This endpoint reports data only for Group 1 and 3 not for Group 1 and 4.

End point values	Group 1: MenABCWY + Saline (ACWY-Naive)	Group 3: MenABCWY + Saline (ACWY-Experienced)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	272	271		
Units: Percentage of subjects				
number (confidence interval 95%)				
Vaccination 1	0.0 (0.0 to 1.3)	0.0 (0.0 to 1.4)		
Vaccination 2	0.0 (0.0 to 1.5)	0.0 (0.0 to 1.5)		
Any vaccination	0.0 (0.0 to 1.3)	0.0 (0.0 to 1.4)		

Statistical analyses

No statistical analyses for this end point

Secondary: Stage1: Percentage of Subjects With at Least 1 Medically Attended AE Throughout the Stage 1: Group 1 and Group 3

End point title	Stage1: Percentage of Subjects With at Least 1 Medically Attended AE Throughout the Stage 1: Group 1 and Group 3[59]

End point description:

Medically attended AE was defined as a nonserious AE that resulted in an evaluation at a medical facility. Stage 1 safety population: subjects who received at least 1 dose of investigational product during Stage 1 and for whom safety data were available. Analysis was planned for Group 1 and Group 3.

End point type	Secondary

End point timeframe:

Throughout Stage 1: From the Vaccination 1 through 6 months after Vaccination 2 (12 Months)

Notes:

[59] - 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: This endpoint reports data only for Group 1 and 3 not for Group 1 and 4.

End point values	Group 1: MenABCWY + Saline (ACWY-Naive)	Group 3: MenABCWY + Saline (ACWY-Experienced)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	272	271		
Units: Percentage of subjects				
number (confidence interval 95%)	30.9 (25.4 to 36.7)	35.1 (29.4 to 41.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: Stage1: Percentage of Subjects With at Least 1 Medically Attended AE During the Follow-up Phase: Group 1 and Group 3

End point title	Stage1: Percentage of Subjects With at Least 1 Medically Attended AE During the Follow-up Phase: Group 1 and Group 3

	[60]

End point description:

Medically attended AE was defined as a nonserious AE that resulted in an evaluation at a medical facility. Stage 1 safety population: subjects who received at least 1 dose of investigational product during Stage 1 and for whom safety data were available. Here, 'Number of subjects Analysed' signifies number of subjects with known values. Analysis was planned for Group 1 and Group 3.

End point type	Secondary

End point timeframe:

Stage 1 Follow-up phase: From 1 month after Vaccination 2 through 6 months after Vaccination 2 (5 Months)

Notes:

[60] - 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: This endpoint reports data only for Group 1 and 3 not for Group 1 and 4.

End point values	Group 1: MenABCWY + Saline (ACWY-Naive)	Group 3: MenABCWY + Saline (ACWY-Experienced)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	239	239		
Units: Percentage of subjects				
number (confidence interval 95%)	13.8 (9.7 to 18.8)	18.8 (14.1 to 24.4)		

Statistical analyses

No statistical analyses for this end point

Secondary: Stage1: Percentage of Subjects With at Least 1 AE Within 30 Days After Vaccination 1, 2, and any Vaccination: Group 1 and Group 3

End point title	Stage1: Percentage of Subjects With at Least 1 AE Within 30 Days After Vaccination 1, 2, and any Vaccination: Group 1 and Group 3[61]

End point description:

An AE was any untoward medical occurrence in a subject who received study drug without regard to possibility of causal relationship. Stage 1 safety population: subjects who received at least 1 dose of investigational product during Stage 1 and for whom safety data were available. Here, 'Number of subjects Analysed' signifies number of subjects with known values. Analysis was planned for Group 1 and Group 3.

End point type	Secondary

End point timeframe:

30 days after Vaccination 1, 2, and any Vaccination

Notes:

[61] - 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: This endpoint reports data only for Group 1 and 3 not for Group 1 and 4.

End point values	Group 1: MenABCWY + Saline (ACWY-Naive)	Group 3: MenABCWY + Saline (ACWY-Experienced)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	272	271		
Units: Percentage of subjects				
number (confidence interval 95%)				
Vaccination 1	15.1 (11.0 to 19.9)	11.1 (7.6 to 15.4)		
Vaccination 2	16.1 (11.7 to 21.4)	12.3 (8.5 to 17.1)		
Any vaccination	25.7 (20.6 to 31.4)	19.9 (15.3 to 25.2)		

Statistical analyses

No statistical analyses for this end point

Secondary: Stage1: Percentage of Subjects With at Least 1 NDCMC During the Follow-up Phase: Group 1 and Group 3

End point title	Stage1: Percentage of Subjects With at Least 1 NDCMC During the Follow-up Phase: Group 1 and Group 3[62]

End point description:

A NDCMC was defined as a disease or medical condition, not previously identified, that was expected to be persistent or otherwise long-lasting in its effects. Stage 1 safety population: subjects who received at least 1 dose of investigational product during Stage 1 and for whom safety data were available. Here, 'Number of subjects Analysed' signifies number of subjects with known values. Analysis was planned for Group 1 and Group 3.

End point type	Secondary

End point timeframe:

Stage 1 Follow-up phase: From 1 month after Vaccination 2 through 6 months after Vaccination 2 (5 Months)

Notes:

[62] - 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: This endpoint reports data only for Group 1 and 3 not for Group 1 and 4.

End point values	Group 1: MenABCWY + Saline (ACWY-Naive)	Group 3: MenABCWY + Saline (ACWY-Experienced)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	239	239		
Units: Percentage of subjects				
number (confidence interval 95%)	0.4 (0.0 to 2.3)	0.0 (0.0 to 1.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: Stage1: Percentage of Subjects With at Least 1 NDCMC During the Vaccination Phase: Group 1 and Group 3

End point title	Stage1: Percentage of Subjects With at Least 1 NDCMC During the Vaccination Phase: Group 1 and Group 3[63]

End point description:

A NDCMC was defined as a disease or medical condition, not previously identified, that was expected to be persistent or otherwise long-lasting in its effects. Stage 1 safety population: subjects who received at least 1 dose of investigational product during Stage 1 and for whom safety data were available. Analysis was planned for Group 1 and Group 3.

End point type	Secondary

End point timeframe:

Stage 1 Vaccination Phase: From Vaccination 1 through 1 month after Vaccination 2 (7 Months)

Notes:

[63] - 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: This endpoint reports data only for Group 1 and 3 not for Group 1 and 4.

End point values	Group 1: MenABCWY + Saline (ACWY-Naive)	Group 3: MenABCWY + Saline (ACWY-Experienced)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	272	271		
Units: Percentage of subjects				
number (confidence interval 95%)	0.7 (0.1 to 2.6)	0.0 (0.0 to 1.4)		

Statistical analyses

No statistical analyses for this end point

Secondary: Stage1: Percentage of Subjects With at Least 1 NDCMC Throughout the Stage 1: Group 1 and Group 3

End point title	Stage1: Percentage of Subjects With at Least 1 NDCMC Throughout the Stage 1: Group 1 and Group 3[64]

End point description:

A NDCMC was defined as a disease or medical condition, not previously identified, that was expected to be persistent or otherwise long-lasting in its effects. Stage 1 safety population: subjects who received at least 1 dose of investigational product during Stage 1 and for whom safety data were available. Analysis was planned for Group 1 and Group 3.

End point type	Secondary

End point timeframe:

Throughout Stage 1: From the Vaccination 1 through 6 months after Vaccination 2 (12 Months)

Notes:

[64] - 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: This endpoint reports data only for Group 1 and 3 not for Group 1 and 4.

End point values	Group 1: MenABCWY + Saline (ACWY-Naive)	Group 3: MenABCWY + Saline (ACWY-Experienced)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	272	271		
Units: Percentage of subjects				
number (confidence interval 95%)	1.1 (0.2 to 3.2)	0.0 (0.0 to 1.4)		

Statistical analyses

No statistical analyses for this end point

Secondary: Stage1: Percentage of Subjects With at Least 1 AE During the Vaccination Phase: Group 1 and Group 3

End point title	Stage1: Percentage of Subjects With at Least 1 AE During the Vaccination Phase: Group 1 and Group 3[65]

End point description:

An AE was any untoward medical occurrence in a subject who received study drug without regard to possibility of causal relationship. Stage 1 safety population: subjects who received at least 1 dose of investigational product during Stage 1 and for whom safety data were available. Analysis was planned for Group 1 and Group 3.

End point type	Secondary

End point timeframe:

Stage 1 Vaccination Phase: From Vaccination 1 through 1 month after Vaccination 2 (7 Months)

Notes:

[65] - 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: This endpoint reports data only for Group 1 and 3 not for Group 1 and 4.

End point values	Group 1: MenABCWY + Saline (ACWY-Naive)	Group 3: MenABCWY + Saline (ACWY-Experienced)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	272	271		
Units: Percentage of subjects				
number (confidence interval 95%)	41.5 (35.6 to 47.6)	36.9 (31.1 to 42.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: Stage1: Number of Subjects who Missed School/Work due to AE During the Vaccination Phase: Group 1 and Group 3

End point title	Stage1: Number of Subjects who Missed School/Work due to AE During the Vaccination Phase: Group 1 and Group 3[66]

End point description:

The safety population for Stage 1 included subjects who had received at least 1 dose of investigational

product during Stage 1 and for whom safety data were available. Analysis was planned for Group 1 and Group 3.

End point type	Secondary

End point timeframe:

Stage 1 Vaccination Phase: From Vaccination 1 through 1 month after Vaccination 2 (7 Months)

Notes:

[66] - 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: This endpoint reports data only for Group 1 and 3 not for Group 1 and 4.

End point values	Group 1: MenABCWY + Saline (ACWY-Naive)	Group 3: MenABCWY + Saline (ACWY-Experienced)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	272	271		
Units: Subjects	38	46		

Statistical analyses

No statistical analyses for this end point

Secondary: Stage1: Percentage of Subjects With at Least 1 Immediate AE After Vaccination 1 and 2: Group 1 and Group 3

End point title	Stage1: Percentage of Subjects With at Least 1 Immediate AE After Vaccination 1 and 2: Group 1 and Group 3[67]

End point description:

Immediate AE was defined as AE occurring within the first 30 minutes after investigational product administration. The safety population for Stage 1 included subjects who had received at least 1 dose of investigational product during Stage 1 and for whom safety data were available. Analysis was planned for Group 1 and Group 3.

End point type	Secondary

End point timeframe:

30 minutes after Vaccination 1 and Vaccination 2

Notes:

[67] - 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: This endpoint reports data only for Group 1 and 3 not for Group 1 and 4.

End point values	Group 1: MenABCWY + Saline (ACWY-Naive)	Group 3: MenABCWY + Saline (ACWY-Experienced)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	272	271		
Units: Percentage of subjects				
number (confidence interval 95%)				
Vaccination 1	0.0 (0.0 to 1.3)	0.0 (0.0 to 1.4)		
Vaccination 2	0.0 (0.0 to 1.5)	0.0 (0.0 to 1.5)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Local reactions, systemic events within 7 days of each vacc; SAEs from Month 0 to 6 months post Vacc 2, 6 months post Booster Vacc; Non-SAEs from Month 0 to 1 month post Vacc 2; within 48 hours of blood draw at Month 18, 30, 42; 1 month post Booster Vacc.

Adverse event reporting additional description:

Same event may appear as both AE and SAE, but are distinct events. An event may be categorized as serious in 1 subject and non-serious in another, or a subject may have experienced both SAE and non-SAE.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	25.1

Reporting groups

Reporting group title	Stage 1: Group 1: MenABCWY + Saline (ACWY-Naive)

Reporting group description:

Stage 1: ACWY-naive subjects were randomized to receive an intramuscular injection of 0.5 milliliter (mL) of Neisseria meningitidis groups A, B, C, W, and Y vaccine (MenABCWY) and 0.5 mL of saline at Month 0, Subjects received 0.5 mL of MenABCWY vaccine intramuscularly at Month 6. Stage 1 was followed by Stage 2. Stage 2: Subjects received 0.5 mL of MenABCWY vaccine (booster vaccination) intramuscularly at Month 54.

Reporting group title	Stage 1:Group 2: Bivalent rLP2086 + MenACWY-CRM (ACWY-Naive)

Reporting group description:

Stage 1: ACWY-naive subjects were randomized to receive an intramuscular injection of 0.5 mL bivalent recombinant lipoprotein 2086 (rLP2086) vaccine and 0.5 mL of meningococcal group A, C, W-135, and Y conjugate vaccine (MenACWY-CRM) at Month 0. Subjects received 0.5 mL of bivalent rLP2086 vaccine at Month 6. Stage 1 was followed by Stage 2. Stage 2: Subjects received intramuscularly injection of 0.5 mL of bivalent rLP2086 vaccine and 0.5 mL of MenACWY-CRM vaccine (booster vaccination) at Month 54.

Reporting group title	Stage 1: Group 3: MenABCWY + Saline (ACWY-Experienced)

Reporting group description:

Stage 1: ACWY-experienced subjects were randomized to receive an intramuscular injection of 0.5 milliliter (mL) of Neisseria meningitidis groups A, B, C, W, and Y vaccine (MenABCWY) and 0.5 mL of saline at Month 0, Subjects received 0.5 mL of MenABCWY vaccine intramuscularly at Month 6. Stage 1 was followed by Stage 2. Stage 2: Subjects received 0.5 mL of MenABCWY vaccine (booster vaccination) intramuscularly at Month 54.

Reporting group title	Stage1:Group4: Bivalent rLP2086+MenACWY-CRM (ACWY-Experienced)

Reporting group description:

Stage 1: ACWY-experienced subjects were randomized to receive an intramuscular injection of 0.5 mL bivalent recombinant lipoprotein 2086 (rLP2086) vaccine and 0.5 mL of meningococcal group A, C, W-135, and Y conjugate vaccine (MenACWY-CRM) at Month 0. Subjects received 0.5 mL of bivalent rLP2086 vaccine at Month 6. Stage 1 was followed by Stage 2. Stage 2: Subjects received intramuscularly injection of 0.5 mL of bivalent rLP2086 vaccine and 0.5 mL of MenACWY-CRM vaccine (booster vaccination) at Month 54.

Reporting group title	Stage 2: Group 1: MenABCWY + Saline (ACWY-Naive)

Reporting group description:

Stage 1: ACWY-naive subjects were randomized to receive an intramuscular injection of 0.5 milliliter (mL) of Neisseria meningitidis groups A, B, C, W, and Y vaccine (MenABCWY) and 0.5 mL of saline at Month 0, Subjects received 0.5 mL of MenABCWY vaccine intramuscularly at Month 6. Stage 1 was followed by Stage 2. Stage 2: Subjects received 0.5 mL of MenABCWY vaccine (booster vaccination) intramuscularly at Month 54.

Reporting group title	Stage 2:Group 2: Bivalent rLP2086 + MenACWY-CRM (ACWY-Naive)

Reporting group description:

Stage 1: ACWY-naive subjects were randomized to receive an intramuscular injection of 0.5 mL bivalent recombinant lipoprotein 2086 (rLP2086) vaccine and 0.5 mL of meningococcal group A, C, W-135, and Y conjugate vaccine (MenACWY-CRM) at Month 0. Subjects received 0.5 mL of bivalent rLP2086 vaccine at Month 6. Stage 1 was followed by Stage 2. Stage 2: Subjects received intramuscularly injection of 0.5 mL of bivalent rLP2086 vaccine and 0.5 mL of MenACWY-CRM vaccine (booster vaccination) at Month 54.

Reporting group title	Stage 2: Group 3: MenABCWY + Saline (ACWY-Experienced)

Reporting group description:

Stage 1: ACWY-experienced subjects were randomized to receive an intramuscular injection of 0.5 milliliter (mL) of Neisseria meningitidis groups A, B, C, W, and Y vaccine (MenABCWY) and 0.5 mL of saline at Month 0, Subjects received 0.5 mL of MenABCWY vaccine intramuscularly at Month 6. Stage 1 was followed by Stage 2. Stage 2: Subjects received 0.5 mL of MenABCWY vaccine (booster vaccination) intramuscularly at Month 54.

Reporting group title	Stage2:Group4: Bivalent rLP2086+MenACWY-CRM (ACWY-Experienced)

Reporting group description:

Stage 1: ACWY-experienced subjects were randomized to receive an intramuscular injection of 0.5 mL bivalent recombinant lipoprotein 2086 (rLP2086) vaccine and 0.5 mL of meningococcal group A, C, W-135, and Y conjugate vaccine (MenACWY-CRM) at Month 0. Subjects received 0.5 mL of bivalent rLP2086 vaccine at Month 6. Stage 1 was followed by Stage 2. Stage 2: Subjects received intramuscularly injection of 0.5 mL of bivalent rLP2086 vaccine and 0.5 mL of MenACWY-CRM vaccine (booster vaccination) at Month 54.

Serious adverse events	Stage 1: Group 1: MenABCWY + Saline (ACWY-Naive)	Stage 1:Group 2: Bivalent rLP2086 + MenACWY-CRM (ACWY-Naive)	Stage 1: Group 3: MenABCWY + Saline (ACWY-Experienced)
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 272 (1.84%)	6 / 534 (1.12%)	6 / 271 (2.21%)
number of deaths (all causes)	1	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Glioma			
subjects affected / exposed	0 / 272 (0.00%)	0 / 534 (0.00%)	0 / 271 (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
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	1 / 272 (0.37%)	0 / 534 (0.00%)	0 / 271 (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
General disorders and administration site conditions			
Cyst			

subjects affected / exposed	1 / 272 (0.37%)	0 / 534 (0.00%)	0 / 271 (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
Reproductive system and breast disorders			
Ovarian cyst			
subjects affected / exposed	0 / 272 (0.00%)	0 / 534 (0.00%)	0 / 271 (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			
Pulmonary embolism			
subjects affected / exposed	0 / 272 (0.00%)	1 / 534 (0.19%)	0 / 271 (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
Psychiatric disorders			
Aggression			
subjects affected / exposed	0 / 272 (0.00%)	0 / 534 (0.00%)	1 / 271 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Conversion disorder			
subjects affected / exposed	0 / 272 (0.00%)	0 / 534 (0.00%)	1 / 271 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression			
subjects affected / exposed	0 / 272 (0.00%)	1 / 534 (0.19%)	0 / 271 (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
Depression suicidal			
subjects affected / exposed	0 / 272 (0.00%)	0 / 534 (0.00%)	0 / 271 (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
Major depression			

subjects affected / exposed	0 / 272 (0.00%)	0 / 534 (0.00%)	0 / 271 (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
Oppositional defiant disorder			
subjects affected / exposed	0 / 272 (0.00%)	1 / 534 (0.19%)	0 / 271 (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
Suicidal ideation			
subjects affected / exposed	0 / 272 (0.00%)	0 / 534 (0.00%)	2 / 271 (0.74%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicide attempt			
subjects affected / exposed	0 / 272 (0.00%)	0 / 534 (0.00%)	1 / 271 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychotic disorder			
subjects affected / exposed	0 / 272 (0.00%)	0 / 534 (0.00%)	0 / 271 (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
Injury, poisoning and procedural complications			
Overdose			
subjects affected / exposed	0 / 272 (0.00%)	0 / 534 (0.00%)	1 / 271 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road traffic accident			
subjects affected / exposed	1 / 272 (0.37%)	0 / 534 (0.00%)	0 / 271 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Tendon injury			
subjects affected / exposed	0 / 272 (0.00%)	0 / 534 (0.00%)	1 / 271 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			

subjects affected / exposed	0 / 272 (0.00%)	0 / 534 (0.00%)	0 / 271 (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
Cardiac disorders			
Cardiac failure chronic			
subjects affected / exposed	0 / 272 (0.00%)	1 / 534 (0.19%)	0 / 271 (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
Myocarditis			
subjects affected / exposed	0 / 272 (0.00%)	0 / 534 (0.00%)	0 / 271 (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
Cardiopulmonary failure			
subjects affected / exposed	0 / 272 (0.00%)	0 / 534 (0.00%)	0 / 271 (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
Nervous system disorders			
Migraine with aura			
subjects affected / exposed	0 / 272 (0.00%)	0 / 534 (0.00%)	1 / 271 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy			
subjects affected / exposed	1 / 272 (0.37%)	0 / 534 (0.00%)	0 / 271 (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
Dyskinesia			
subjects affected / exposed	0 / 272 (0.00%)	0 / 534 (0.00%)	1 / 271 (0.37%)
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			
Colitis ulcerative			
subjects affected / exposed	0 / 272 (0.00%)	1 / 534 (0.19%)	0 / 271 (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

Faecaloma			
subjects affected / exposed	0 / 272 (0.00%)	0 / 534 (0.00%)	0 / 271 (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
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	1 / 272 (0.37%)	0 / 534 (0.00%)	0 / 271 (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
Musculoskeletal and connective tissue disorders			
Muscular weakness			
subjects affected / exposed	0 / 272 (0.00%)	1 / 534 (0.19%)	0 / 271 (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
Infections and infestations			
Meningitis viral			
subjects affected / exposed	0 / 272 (0.00%)	1 / 534 (0.19%)	0 / 271 (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
Pharyngitis			
subjects affected / exposed	0 / 272 (0.00%)	0 / 534 (0.00%)	0 / 271 (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
Pneumonia			
subjects affected / exposed	0 / 272 (0.00%)	0 / 534 (0.00%)	0 / 271 (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			
Hyperglycaemic hyperosmolar nonketotic syndrome			
subjects affected / exposed	0 / 272 (0.00%)	1 / 534 (0.19%)	0 / 271 (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

Serious adverse events	Stage1:Group4: Bivalent	Stage 2: Group 1: MenABCWY + Saline	Stage 2:Group 2: Bivalent rLP2086 +

	rLP2086+MenACWY-CRM (ACWY-Experienced)	(ACWY-Naive)	MenACWY-CRM (ACWY-Naive)
Total subjects affected by serious adverse events			
subjects affected / exposed	9 / 523 (1.72%)	1 / 114 (0.88%)	1 / 65 (1.54%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Glioma			
subjects affected / exposed	1 / 523 (0.19%)	0 / 114 (0.00%)	0 / 65 (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
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	0 / 523 (0.00%)	1 / 114 (0.88%)	0 / 65 (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
General disorders and administration site conditions			
Cyst			
subjects affected / exposed	0 / 523 (0.00%)	0 / 114 (0.00%)	0 / 65 (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
Reproductive system and breast disorders			
Ovarian cyst			
subjects affected / exposed	1 / 523 (0.19%)	0 / 114 (0.00%)	0 / 65 (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			
Pulmonary embolism			
subjects affected / exposed	0 / 523 (0.00%)	0 / 114 (0.00%)	0 / 65 (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
Psychiatric disorders			
Aggression			

subjects affected / exposed	0 / 523 (0.00%)	0 / 114 (0.00%)	0 / 65 (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
Conversion disorder			
subjects affected / exposed	0 / 523 (0.00%)	0 / 114 (0.00%)	0 / 65 (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
Depression			
subjects affected / exposed	0 / 523 (0.00%)	0 / 114 (0.00%)	0 / 65 (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
Depression suicidal			
subjects affected / exposed	1 / 523 (0.19%)	0 / 114 (0.00%)	0 / 65 (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
Major depression			
subjects affected / exposed	1 / 523 (0.19%)	0 / 114 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oppositional defiant disorder			
subjects affected / exposed	0 / 523 (0.00%)	0 / 114 (0.00%)	0 / 65 (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
Suicidal ideation			
subjects affected / exposed	0 / 523 (0.00%)	0 / 114 (0.00%)	0 / 65 (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
Suicide attempt			
subjects affected / exposed	0 / 523 (0.00%)	0 / 114 (0.00%)	0 / 65 (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
Psychotic disorder			

subjects affected / exposed	0 / 523 (0.00%)	0 / 114 (0.00%)	0 / 65 (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
Injury, poisoning and procedural complications			
Overdose			
subjects affected / exposed	0 / 523 (0.00%)	0 / 114 (0.00%)	0 / 65 (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
Road traffic accident			
subjects affected / exposed	0 / 523 (0.00%)	0 / 114 (0.00%)	0 / 65 (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
Tendon injury			
subjects affected / exposed	0 / 523 (0.00%)	0 / 114 (0.00%)	0 / 65 (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
Femur fracture			
subjects affected / exposed	0 / 523 (0.00%)	0 / 114 (0.00%)	0 / 65 (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
Cardiac disorders			
Cardiac failure chronic			
subjects affected / exposed	0 / 523 (0.00%)	0 / 114 (0.00%)	0 / 65 (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
Myocarditis			
subjects affected / exposed	1 / 523 (0.19%)	0 / 114 (0.00%)	0 / 65 (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
Cardiopulmonary failure			
subjects affected / exposed	1 / 523 (0.19%)	0 / 114 (0.00%)	0 / 65 (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

Nervous system disorders			
Migraine with aura			
subjects affected / exposed	0 / 523 (0.00%)	0 / 114 (0.00%)	0 / 65 (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
Epilepsy			
subjects affected / exposed	0 / 523 (0.00%)	0 / 114 (0.00%)	0 / 65 (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
Dyskinesia			
subjects affected / exposed	0 / 523 (0.00%)	0 / 114 (0.00%)	0 / 65 (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			
Colitis ulcerative			
subjects affected / exposed	0 / 523 (0.00%)	0 / 114 (0.00%)	0 / 65 (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
Faecaloma			
subjects affected / exposed	1 / 523 (0.19%)	0 / 114 (0.00%)	0 / 65 (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
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 523 (0.00%)	0 / 114 (0.00%)	0 / 65 (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
Musculoskeletal and connective tissue disorders			
Muscular weakness			
subjects affected / exposed	0 / 523 (0.00%)	0 / 114 (0.00%)	0 / 65 (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			
Meningitis viral			

subjects affected / exposed	0 / 523 (0.00%)	0 / 114 (0.00%)	0 / 65 (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
Pharyngitis			
subjects affected / exposed	1 / 523 (0.19%)	0 / 114 (0.00%)	0 / 65 (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
Pneumonia			
subjects affected / exposed	1 / 523 (0.19%)	0 / 114 (0.00%)	0 / 65 (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
Metabolism and nutrition disorders			
Hyperglycaemic hyperosmolar nonketotic syndrome			
subjects affected / exposed	0 / 523 (0.00%)	0 / 114 (0.00%)	0 / 65 (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	Stage 2: Group 3: MenABCWY + Saline (ACWY-Experienced)	Stage2:Group4: Bivalent rLP2086+MenACWY-CRM (ACWY-Experienced)	
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 101 (2.97%)	2 / 73 (2.74%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Glioma			
subjects affected / exposed	0 / 101 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	1 / 101 (0.99%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

General disorders and administration site conditions			
Cyst			
subjects affected / exposed	0 / 101 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Ovarian cyst			
subjects affected / exposed	0 / 101 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Pulmonary embolism			
subjects affected / exposed	1 / 101 (0.99%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Aggression			
subjects affected / exposed	0 / 101 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Conversion disorder			
subjects affected / exposed	0 / 101 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Depression			
subjects affected / exposed	0 / 101 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Depression suicidal			
subjects affected / exposed	0 / 101 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Major depression			

subjects affected / exposed	0 / 101 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oppositional defiant disorder			
subjects affected / exposed	0 / 101 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicidal ideation			
subjects affected / exposed	0 / 101 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicide attempt			
subjects affected / exposed	0 / 101 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychotic disorder			
subjects affected / exposed	0 / 101 (0.00%)	1 / 73 (1.37%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Overdose			
subjects affected / exposed	0 / 101 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Road traffic accident			
subjects affected / exposed	0 / 101 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tendon injury			
subjects affected / exposed	0 / 101 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femur fracture			

subjects affected / exposed	2 / 101 (1.98%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Cardiac failure chronic			
subjects affected / exposed	0 / 101 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocarditis			
subjects affected / exposed	0 / 101 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiopulmonary failure			
subjects affected / exposed	0 / 101 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Migraine with aura			
subjects affected / exposed	0 / 101 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epilepsy			
subjects affected / exposed	0 / 101 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyskinesia			
subjects affected / exposed	0 / 101 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Colitis ulcerative			
subjects affected / exposed	0 / 101 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Faecaloma			
subjects affected / exposed	0 / 101 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 101 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Muscular weakness			
subjects affected / exposed	0 / 101 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Meningitis viral			
subjects affected / exposed	0 / 101 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngitis			
subjects affected / exposed	0 / 101 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	0 / 101 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Hyperglycaemic hyperosmolar nonketotic syndrome			
subjects affected / exposed	0 / 101 (0.00%)	0 / 73 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 1 %

Non-serious adverse events	Stage 1: Group 1: MenABCWY + Saline (ACWY-Naive)	Stage 1:Group 2: Bivalent rLP2086 + MenACWY-CRM (ACWY-Naive)	Stage 1: Group 3: MenABCWY + Saline (ACWY-Experienced)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	267 / 272 (98.16%)	508 / 534 (95.13%)	259 / 271 (95.57%)
Vascular disorders			
Haematoma			
subjects affected / exposed	0 / 272 (0.00%)	0 / 534 (0.00%)	0 / 271 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Pain			
subjects affected / exposed	0 / 272 (0.00%)	0 / 534 (0.00%)	0 / 271 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 272 (0.00%)	2 / 534 (0.37%)	4 / 271 (1.48%)
occurrences (all)	0	2	4
Injection site pain (PAIN AT INJECTION SITE)			
alternative assessment type: Systematic			
subjects affected / exposed	256 / 272 (94.12%)	479 / 534 (89.70%)	251 / 271 (92.62%)
occurrences (all)	445	814	438
Pyrexia (FEVER)			
alternative assessment type: Systematic			
subjects affected / exposed	29 / 272 (10.66%)	56 / 534 (10.49%)	17 / 271 (6.27%)
occurrences (all)	30	61	18
Chills (CHILLS)			
alternative assessment type: Systematic			
subjects affected / exposed	82 / 272 (30.15%)	152 / 534 (28.46%)	67 / 271 (24.72%)
occurrences (all)	103	190	86
Swelling (SWELLING)			
alternative assessment type: Systematic			
subjects affected / exposed	77 / 272 (28.31%)	123 / 534 (23.03%)	67 / 271 (24.72%)
occurrences (all)	154	242	136
Fatigue (FATIGUE)			
alternative assessment type:			

Systematic			
subjects affected / exposed	180 / 272 (66.18%)	315 / 534 (58.99%)	163 / 271 (60.15%)
occurrences (all)	270	454	243
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 272 (0.00%)	3 / 534 (0.56%)	3 / 271 (1.11%)
occurrences (all)	0	3	3
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	2 / 272 (0.74%)	2 / 534 (0.37%)	2 / 271 (0.74%)
occurrences (all)	3	2	2
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 272 (0.37%)	2 / 534 (0.37%)	1 / 271 (0.37%)
occurrences (all)	1	2	1
Oropharyngeal pain			
subjects affected / exposed	3 / 272 (1.10%)	3 / 534 (0.56%)	1 / 271 (0.37%)
occurrences (all)	3	3	1
Rhinitis allergic			
subjects affected / exposed	2 / 272 (0.74%)	1 / 534 (0.19%)	4 / 271 (1.48%)
occurrences (all)	2	1	4
Sinus congestion			
subjects affected / exposed	0 / 272 (0.00%)	0 / 534 (0.00%)	0 / 271 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	3 / 272 (1.10%)	6 / 534 (1.12%)	0 / 271 (0.00%)
occurrences (all)	3	7	0
Depression			
subjects affected / exposed	4 / 272 (1.47%)	4 / 534 (0.75%)	1 / 271 (0.37%)
occurrences (all)	4	4	1
Insomnia			
subjects affected / exposed	0 / 272 (0.00%)	0 / 534 (0.00%)	1 / 271 (0.37%)
occurrences (all)	0	0	1
Psychophysiologic insomnia			

subjects affected / exposed	0 / 272 (0.00%)	0 / 534 (0.00%)	0 / 271 (0.00%)
occurrences (all)	0	0	0
Investigations			
SARS-CoV-2 test positive			
subjects affected / exposed	0 / 272 (0.00%)	0 / 534 (0.00%)	0 / 271 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Skin laceration			
subjects affected / exposed	4 / 272 (1.47%)	3 / 534 (0.56%)	1 / 271 (0.37%)
occurrences (all)	4	3	1
Muscle strain			
subjects affected / exposed	1 / 272 (0.37%)	2 / 534 (0.37%)	2 / 271 (0.74%)
occurrences (all)	1	2	2
Ligament sprain			
subjects affected / exposed	5 / 272 (1.84%)	7 / 534 (1.31%)	8 / 271 (2.95%)
occurrences (all)	5	8	8
Eye injury			
subjects affected / exposed	0 / 272 (0.00%)	0 / 534 (0.00%)	0 / 271 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 272 (0.00%)	1 / 534 (0.19%)	5 / 271 (1.85%)
occurrences (all)	0	1	5
Congenital, familial and genetic disorders			
Pectus excavatum			
subjects affected / exposed	0 / 272 (0.00%)	0 / 534 (0.00%)	0 / 271 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Tachycardia			
subjects affected / exposed	0 / 272 (0.00%)	0 / 534 (0.00%)	0 / 271 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Syncope			
subjects affected / exposed	2 / 272 (0.74%)	7 / 534 (1.31%)	3 / 271 (1.11%)
occurrences (all)	3	7	3
Headache			

subjects affected / exposed	6 / 272 (2.21%)	11 / 534 (2.06%)	4 / 271 (1.48%)
occurrences (all)	7	16	5
Dizziness			
subjects affected / exposed	1 / 272 (0.37%)	7 / 534 (1.31%)	2 / 271 (0.74%)
occurrences (all)	1	7	2
Migraine			
subjects affected / exposed	0 / 272 (0.00%)	5 / 534 (0.94%)	3 / 271 (1.11%)
occurrences (all)	0	5	3
Headache (HEADACHE)			
alternative assessment type: Systematic			
subjects affected / exposed	163 / 272 (59.93%)	312 / 534 (58.43%)	159 / 271 (58.67%)
occurrences (all)	230	432	226
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	1 / 272 (0.37%)	1 / 534 (0.19%)	3 / 271 (1.11%)
occurrences (all)	1	1	3
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 272 (0.37%)	1 / 534 (0.19%)	0 / 271 (0.00%)
occurrences (all)	1	1	0
Nausea			
subjects affected / exposed	4 / 272 (1.47%)	9 / 534 (1.69%)	1 / 271 (0.37%)
occurrences (all)	4	9	1
Abdominal pain			
subjects affected / exposed	5 / 272 (1.84%)	1 / 534 (0.19%)	1 / 271 (0.37%)
occurrences (all)	5	1	1
Constipation			
subjects affected / exposed	4 / 272 (1.47%)	2 / 534 (0.37%)	0 / 271 (0.00%)
occurrences (all)	4	2	0
Vomiting			
subjects affected / exposed	3 / 272 (1.10%)	4 / 534 (0.75%)	1 / 271 (0.37%)
occurrences (all)	3	4	1
Diarrhoea (DIARRHEA)			
alternative assessment type: Systematic			
subjects affected / exposed	55 / 272 (20.22%)	104 / 534 (19.48%)	54 / 271 (19.93%)
occurrences (all)	66	122	61
Vomiting (VOMITING)			

alternative assessment type: Systematic			
subjects affected / exposed	13 / 272 (4.78%)	31 / 534 (5.81%)	13 / 271 (4.80%)
occurrences (all)	13	32	14
Skin and subcutaneous tissue disorders			
Dermatitis contact			
subjects affected / exposed	4 / 272 (1.47%)	0 / 534 (0.00%)	4 / 271 (1.48%)
occurrences (all)	4	0	4
Eczema			
subjects affected / exposed	3 / 272 (1.10%)	0 / 534 (0.00%)	2 / 271 (0.74%)
occurrences (all)	3	0	2
Urticaria			
subjects affected / exposed	3 / 272 (1.10%)	1 / 534 (0.19%)	1 / 271 (0.37%)
occurrences (all)	3	1	1
Erythema (REDNESS)			
alternative assessment type: Systematic			
subjects affected / exposed	73 / 272 (26.84%)	130 / 534 (24.34%)	61 / 271 (22.51%)
occurrences (all)	158	269	130
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	3 / 272 (1.10%)	3 / 534 (0.56%)	3 / 271 (1.11%)
occurrences (all)	3	4	3
Back pain			
subjects affected / exposed	1 / 272 (0.37%)	5 / 534 (0.94%)	3 / 271 (1.11%)
occurrences (all)	1	5	3
Scoliosis			
subjects affected / exposed	1 / 272 (0.37%)	0 / 534 (0.00%)	0 / 271 (0.00%)
occurrences (all)	1	0	0
Pain in extremity			
subjects affected / exposed	1 / 272 (0.37%)	3 / 534 (0.56%)	3 / 271 (1.11%)
occurrences (all)	1	3	3
Arthralgia (JOINT PAIN)			
alternative assessment type: Systematic			
subjects affected / exposed	79 / 272 (29.04%)	153 / 534 (28.65%)	78 / 271 (28.78%)
occurrences (all)	99	188	91
Myalgia (MUSCLE PAIN)			

alternative assessment type: Systematic			
subjects affected / exposed	104 / 272 (38.24%)	204 / 534 (38.20%)	87 / 271 (32.10%)
occurrences (all)	135	264	107
Infections and infestations			
COVID-19			
subjects affected / exposed	0 / 272 (0.00%)	0 / 534 (0.00%)	0 / 271 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	3 / 272 (1.10%)	6 / 534 (1.12%)	0 / 271 (0.00%)
occurrences (all)	4	6	0
Gastroenteritis			
subjects affected / exposed	6 / 272 (2.21%)	14 / 534 (2.62%)	4 / 271 (1.48%)
occurrences (all)	6	14	4
Bronchitis			
subjects affected / exposed	3 / 272 (1.10%)	6 / 534 (1.12%)	2 / 271 (0.74%)
occurrences (all)	3	6	2
Bacterial vaginosis			
subjects affected / exposed	0 / 272 (0.00%)	0 / 534 (0.00%)	3 / 271 (1.11%)
occurrences (all)	0	0	3
Acute sinusitis			
subjects affected / exposed	6 / 272 (2.21%)	5 / 534 (0.94%)	2 / 271 (0.74%)
occurrences (all)	6	5	2
Gastroenteritis viral			
subjects affected / exposed	8 / 272 (2.94%)	12 / 534 (2.25%)	4 / 271 (1.48%)
occurrences (all)	11	12	4
Pharyngitis			
subjects affected / exposed	3 / 272 (1.10%)	9 / 534 (1.69%)	8 / 271 (2.95%)
occurrences (all)	5	11	8
Otitis media acute			
subjects affected / exposed	3 / 272 (1.10%)	5 / 534 (0.94%)	1 / 271 (0.37%)
occurrences (all)	3	5	1
Otitis media			
subjects affected / exposed	1 / 272 (0.37%)	11 / 534 (2.06%)	6 / 271 (2.21%)
occurrences (all)	2	11	6
Otitis externa			

subjects affected / exposed	3 / 272 (1.10%)	2 / 534 (0.37%)	2 / 271 (0.74%)
occurrences (all)	3	2	2
Nasopharyngitis			
subjects affected / exposed	11 / 272 (4.04%)	19 / 534 (3.56%)	16 / 271 (5.90%)
occurrences (all)	12	19	20
Influenza			
subjects affected / exposed	9 / 272 (3.31%)	14 / 534 (2.62%)	4 / 271 (1.48%)
occurrences (all)	9	14	4
Impetigo			
subjects affected / exposed	1 / 272 (0.37%)	1 / 534 (0.19%)	3 / 271 (1.11%)
occurrences (all)	1	1	3
Pharyngitis streptococcal			
subjects affected / exposed	6 / 272 (2.21%)	9 / 534 (1.69%)	9 / 271 (3.32%)
occurrences (all)	7	11	9
Upper respiratory tract infection			
subjects affected / exposed	14 / 272 (5.15%)	32 / 534 (5.99%)	11 / 271 (4.06%)
occurrences (all)	15	36	12
Tonsillitis			
subjects affected / exposed	2 / 272 (0.74%)	2 / 534 (0.37%)	7 / 271 (2.58%)
occurrences (all)	2	2	8
Sinusitis			
subjects affected / exposed	5 / 272 (1.84%)	9 / 534 (1.69%)	9 / 271 (3.32%)
occurrences (all)	5	11	10
Urinary tract infection			
subjects affected / exposed	5 / 272 (1.84%)	11 / 534 (2.06%)	5 / 271 (1.85%)
occurrences (all)	6	13	5
Viral pharyngitis			
subjects affected / exposed	3 / 272 (1.10%)	3 / 534 (0.56%)	1 / 271 (0.37%)
occurrences (all)	5	3	1
Viral upper respiratory tract infection			
subjects affected / exposed	3 / 272 (1.10%)	11 / 534 (2.06%)	1 / 271 (0.37%)
occurrences (all)	3	11	1
Metabolism and nutrition disorders			
Hypercholesterolaemia			
subjects affected / exposed	0 / 272 (0.00%)	0 / 534 (0.00%)	3 / 271 (1.11%)
occurrences (all)	0	0	3

Non-serious adverse events	Stage1:Group4: Bivalent rLP2086+MenACWY-CRM (ACWY-Experienced)	Stage 2: Group 1: MenABCWY + Saline (ACWY-Naive)	Stage 2:Group 2: Bivalent rLP2086 + MenACWY-CRM (ACWY-Naive)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	502 / 523 (95.98%)	54 / 114 (47.37%)	37 / 65 (56.92%)
Vascular disorders			
Haematoma			
subjects affected / exposed	1 / 523 (0.19%)	0 / 114 (0.00%)	0 / 65 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
Pain			
subjects affected / exposed	0 / 523 (0.00%)	0 / 114 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	11 / 523 (2.10%)	0 / 114 (0.00%)	0 / 65 (0.00%)
occurrences (all)	11	0	0
Injection site pain (PAIN AT INJECTION SITE)			
alternative assessment type: Systematic			
subjects affected / exposed	480 / 523 (91.78%)	48 / 114 (42.11%)	34 / 65 (52.31%)
occurrences (all)	828	48	34
Pyrexia (FEVER)			
alternative assessment type: Systematic			
subjects affected / exposed	37 / 523 (7.07%)	3 / 114 (2.63%)	1 / 65 (1.54%)
occurrences (all)	39	3	1
Chills (CHILLS)			
alternative assessment type: Systematic			
subjects affected / exposed	141 / 523 (26.96%)	6 / 114 (5.26%)	7 / 65 (10.77%)
occurrences (all)	176	6	7
Swelling (SWELLING)			
alternative assessment type: Systematic			
subjects affected / exposed	114 / 523 (21.80%)	11 / 114 (9.65%)	9 / 65 (13.85%)
occurrences (all)	230	16	12
Fatigue (FATIGUE)			
alternative assessment type: Systematic			

subjects affected / exposed	344 / 523 (65.77%)	28 / 114 (24.56%)	24 / 65 (36.92%)
occurrences (all)	501	28	24
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	2 / 523 (0.38%)	0 / 114 (0.00%)	0 / 65 (0.00%)
occurrences (all)	2	0	0
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	2 / 523 (0.38%)	0 / 114 (0.00%)	0 / 65 (0.00%)
occurrences (all)	2	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	6 / 523 (1.15%)	0 / 114 (0.00%)	3 / 65 (4.62%)
occurrences (all)	6	0	3
Oropharyngeal pain			
subjects affected / exposed	4 / 523 (0.76%)	0 / 114 (0.00%)	0 / 65 (0.00%)
occurrences (all)	4	0	0
Rhinitis allergic			
subjects affected / exposed	3 / 523 (0.57%)	0 / 114 (0.00%)	0 / 65 (0.00%)
occurrences (all)	3	0	0
Sinus congestion			
subjects affected / exposed	0 / 523 (0.00%)	0 / 114 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Psychiatric disorders			
Anxiety			
subjects affected / exposed	5 / 523 (0.96%)	0 / 114 (0.00%)	0 / 65 (0.00%)
occurrences (all)	5	0	0
Depression			
subjects affected / exposed	4 / 523 (0.76%)	0 / 114 (0.00%)	0 / 65 (0.00%)
occurrences (all)	4	0	0
Insomnia			
subjects affected / exposed	1 / 523 (0.19%)	0 / 114 (0.00%)	1 / 65 (1.54%)
occurrences (all)	1	0	1
Psychophysiologic insomnia			
subjects affected / exposed	0 / 523 (0.00%)	0 / 114 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0

Investigations			
SARS-CoV-2 test positive			
subjects affected / exposed	0 / 523 (0.00%)	1 / 114 (0.88%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			
Skin laceration			
subjects affected / exposed	6 / 523 (1.15%)	1 / 114 (0.88%)	1 / 65 (1.54%)
occurrences (all)	6	1	1
Muscle strain			
subjects affected / exposed	7 / 523 (1.34%)	0 / 114 (0.00%)	0 / 65 (0.00%)
occurrences (all)	9	0	0
Ligament sprain			
subjects affected / exposed	7 / 523 (1.34%)	1 / 114 (0.88%)	0 / 65 (0.00%)
occurrences (all)	8	1	0
Eye injury			
subjects affected / exposed	0 / 523 (0.00%)	0 / 114 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	6 / 523 (1.15%)	0 / 114 (0.00%)	0 / 65 (0.00%)
occurrences (all)	6	0	0
Congenital, familial and genetic disorders			
Pectus excavatum			
subjects affected / exposed	0 / 523 (0.00%)	0 / 114 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Cardiac disorders			
Tachycardia			
subjects affected / exposed	0 / 523 (0.00%)	0 / 114 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Nervous system disorders			
Syncope			
subjects affected / exposed	2 / 523 (0.38%)	1 / 114 (0.88%)	0 / 65 (0.00%)
occurrences (all)	2	1	0
Headache			
subjects affected / exposed	13 / 523 (2.49%)	0 / 114 (0.00%)	0 / 65 (0.00%)
occurrences (all)	17	0	0
Dizziness			

subjects affected / exposed	2 / 523 (0.38%)	1 / 114 (0.88%)	0 / 65 (0.00%)
occurrences (all)	2	1	0
Migraine			
subjects affected / exposed	1 / 523 (0.19%)	0 / 114 (0.00%)	0 / 65 (0.00%)
occurrences (all)	2	0	0
Headache (HEADACHE)			
alternative assessment type: Systematic			
subjects affected / exposed	312 / 523 (59.66%)	23 / 114 (20.18%)	21 / 65 (32.31%)
occurrences (all)	445	23	22
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	4 / 523 (0.76%)	0 / 114 (0.00%)	0 / 65 (0.00%)
occurrences (all)	4	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	7 / 523 (1.34%)	0 / 114 (0.00%)	0 / 65 (0.00%)
occurrences (all)	7	0	0
Nausea			
subjects affected / exposed	5 / 523 (0.96%)	1 / 114 (0.88%)	0 / 65 (0.00%)
occurrences (all)	5	1	0
Abdominal pain			
subjects affected / exposed	2 / 523 (0.38%)	0 / 114 (0.00%)	0 / 65 (0.00%)
occurrences (all)	2	0	0
Constipation			
subjects affected / exposed	2 / 523 (0.38%)	0 / 114 (0.00%)	0 / 65 (0.00%)
occurrences (all)	2	0	0
Vomiting			
subjects affected / exposed	6 / 523 (1.15%)	2 / 114 (1.75%)	0 / 65 (0.00%)
occurrences (all)	6	2	0
Diarrhoea (DIARRHEA)			
alternative assessment type: Systematic			
subjects affected / exposed	105 / 523 (20.08%)	3 / 114 (2.63%)	4 / 65 (6.15%)
occurrences (all)	121	3	4
Vomiting (VOMITING)			
alternative assessment type: Systematic			

subjects affected / exposed	33 / 523 (6.31%)	2 / 114 (1.75%)	0 / 65 (0.00%)
occurrences (all)	35	2	0
Skin and subcutaneous tissue disorders			
Dermatitis contact			
subjects affected / exposed	4 / 523 (0.76%)	0 / 114 (0.00%)	0 / 65 (0.00%)
occurrences (all)	4	0	0
Eczema			
subjects affected / exposed	3 / 523 (0.57%)	1 / 114 (0.88%)	0 / 65 (0.00%)
occurrences (all)	3	1	0
Urticaria			
subjects affected / exposed	6 / 523 (1.15%)	0 / 114 (0.00%)	0 / 65 (0.00%)
occurrences (all)	6	0	0
Erythema (REDNESS)			
alternative assessment type: Systematic			
subjects affected / exposed	95 / 523 (18.16%)	8 / 114 (7.02%)	11 / 65 (16.92%)
occurrences (all)	209	12	14
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	4 / 523 (0.76%)	0 / 114 (0.00%)	1 / 65 (1.54%)
occurrences (all)	4	0	1
Back pain			
subjects affected / exposed	5 / 523 (0.96%)	0 / 114 (0.00%)	0 / 65 (0.00%)
occurrences (all)	5	0	0
Scoliosis			
subjects affected / exposed	1 / 523 (0.19%)	0 / 114 (0.00%)	0 / 65 (0.00%)
occurrences (all)	1	0	0
Pain in extremity			
subjects affected / exposed	1 / 523 (0.19%)	0 / 114 (0.00%)	0 / 65 (0.00%)
occurrences (all)	1	0	0
Arthralgia (JOINT PAIN)			
alternative assessment type: Systematic			
subjects affected / exposed	148 / 523 (28.30%)	12 / 114 (10.53%)	10 / 65 (15.38%)
occurrences (all)	187	12	10
Myalgia (MUSCLE PAIN)			
alternative assessment type: Systematic			

subjects affected / exposed	186 / 523 (35.56%)	11 / 114 (9.65%)	12 / 65 (18.46%)
occurrences (all)	230	11	12
Infections and infestations			
COVID-19			
subjects affected / exposed	0 / 523 (0.00%)	3 / 114 (2.63%)	4 / 65 (6.15%)
occurrences (all)	0	3	4
Ear infection			
subjects affected / exposed	1 / 523 (0.19%)	0 / 114 (0.00%)	0 / 65 (0.00%)
occurrences (all)	1	0	0
Gastroenteritis			
subjects affected / exposed	9 / 523 (1.72%)	0 / 114 (0.00%)	0 / 65 (0.00%)
occurrences (all)	10	0	0
Bronchitis			
subjects affected / exposed	13 / 523 (2.49%)	2 / 114 (1.75%)	0 / 65 (0.00%)
occurrences (all)	14	2	0
Bacterial vaginosis			
subjects affected / exposed	1 / 523 (0.19%)	0 / 114 (0.00%)	0 / 65 (0.00%)
occurrences (all)	1	0	0
Acute sinusitis			
subjects affected / exposed	13 / 523 (2.49%)	0 / 114 (0.00%)	0 / 65 (0.00%)
occurrences (all)	14	0	0
Gastroenteritis viral			
subjects affected / exposed	6 / 523 (1.15%)	1 / 114 (0.88%)	0 / 65 (0.00%)
occurrences (all)	6	1	0
Pharyngitis			
subjects affected / exposed	15 / 523 (2.87%)	0 / 114 (0.00%)	0 / 65 (0.00%)
occurrences (all)	15	0	0
Otitis media acute			
subjects affected / exposed	2 / 523 (0.38%)	0 / 114 (0.00%)	0 / 65 (0.00%)
occurrences (all)	2	0	0
Otitis media			
subjects affected / exposed	4 / 523 (0.76%)	0 / 114 (0.00%)	0 / 65 (0.00%)
occurrences (all)	4	0	0
Otitis externa			
subjects affected / exposed	5 / 523 (0.96%)	0 / 114 (0.00%)	0 / 65 (0.00%)
occurrences (all)	6	0	0

Nasopharyngitis			
subjects affected / exposed	21 / 523 (4.02%)	0 / 114 (0.00%)	0 / 65 (0.00%)
occurrences (all)	22	0	0
Influenza			
subjects affected / exposed	18 / 523 (3.44%)	2 / 114 (1.75%)	0 / 65 (0.00%)
occurrences (all)	19	2	0
Impetigo			
subjects affected / exposed	1 / 523 (0.19%)	1 / 114 (0.88%)	0 / 65 (0.00%)
occurrences (all)	1	1	0
Pharyngitis streptococcal			
subjects affected / exposed	13 / 523 (2.49%)	0 / 114 (0.00%)	0 / 65 (0.00%)
occurrences (all)	15	0	0
Upper respiratory tract infection			
subjects affected / exposed	28 / 523 (5.35%)	0 / 114 (0.00%)	0 / 65 (0.00%)
occurrences (all)	35	0	0
Tonsillitis			
subjects affected / exposed	6 / 523 (1.15%)	0 / 114 (0.00%)	0 / 65 (0.00%)
occurrences (all)	9	0	0
Sinusitis			
subjects affected / exposed	14 / 523 (2.68%)	0 / 114 (0.00%)	0 / 65 (0.00%)
occurrences (all)	15	0	0
Urinary tract infection			
subjects affected / exposed	10 / 523 (1.91%)	1 / 114 (0.88%)	0 / 65 (0.00%)
occurrences (all)	12	1	0
Viral pharyngitis			
subjects affected / exposed	9 / 523 (1.72%)	0 / 114 (0.00%)	0 / 65 (0.00%)
occurrences (all)	9	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	8 / 523 (1.53%)	0 / 114 (0.00%)	0 / 65 (0.00%)
occurrences (all)	11	0	0
Metabolism and nutrition disorders			
Hypercholesterolaemia			
subjects affected / exposed	3 / 523 (0.57%)	0 / 114 (0.00%)	0 / 65 (0.00%)
occurrences (all)	3	0	0

Non-serious adverse events	Stage 2: Group 3: MenABCWY + Saline (ACWY-Experienced)	Stage2:Group4: Bivalent rLP2086+MenACWY-	

		CRM (ACWY-Experienced)	
Total subjects affected by non-serious adverse events subjects affected / exposed	72 / 101 (71.29%)	57 / 73 (78.08%)	
Vascular disorders Haematoma subjects affected / exposed occurrences (all)	0 / 101 (0.00%) 0	1 / 73 (1.37%) 1	
General disorders and administration site conditions Pain subjects affected / exposed occurrences (all)	0 / 101 (0.00%) 0	1 / 73 (1.37%) 1	
Influenza like illness subjects affected / exposed occurrences (all)	0 / 101 (0.00%) 0	0 / 73 (0.00%) 0	
Injection site pain (PAIN AT INJECTION SITE) alternative assessment type: Systematic subjects affected / exposed occurrences (all)	65 / 101 (64.36%) 65	50 / 73 (68.49%) 50	
Pyrexia (FEVER) alternative assessment type: Systematic subjects affected / exposed occurrences (all)	0 / 101 (0.00%) 0	1 / 73 (1.37%) 1	
Chills (CHILLS) alternative assessment type: Systematic subjects affected / exposed occurrences (all)	14 / 101 (13.86%) 14	8 / 73 (10.96%) 8	
Swelling (SWELLING) alternative assessment type: Systematic subjects affected / exposed occurrences (all)	14 / 101 (13.86%) 22	10 / 73 (13.70%) 14	
Fatigue (FATIGUE) alternative assessment type: Systematic subjects affected / exposed occurrences (all)	47 / 101 (46.53%) 47	37 / 73 (50.68%) 37	
Immune system disorders			

Seasonal allergy			
subjects affected / exposed	0 / 101 (0.00%)	0 / 73 (0.00%)	
occurrences (all)	0	0	
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	0 / 101 (0.00%)	1 / 73 (1.37%)	
occurrences (all)	0	1	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 101 (0.00%)	0 / 73 (0.00%)	
occurrences (all)	0	0	
Oropharyngeal pain			
subjects affected / exposed	0 / 101 (0.00%)	1 / 73 (1.37%)	
occurrences (all)	0	1	
Rhinitis allergic			
subjects affected / exposed	0 / 101 (0.00%)	0 / 73 (0.00%)	
occurrences (all)	0	0	
Sinus congestion			
subjects affected / exposed	0 / 101 (0.00%)	0 / 73 (0.00%)	
occurrences (all)	0	0	
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 101 (0.99%)	0 / 73 (0.00%)	
occurrences (all)	1	0	
Depression			
subjects affected / exposed	0 / 101 (0.00%)	1 / 73 (1.37%)	
occurrences (all)	0	1	
Insomnia			
subjects affected / exposed	0 / 101 (0.00%)	0 / 73 (0.00%)	
occurrences (all)	0	0	
Psychophysiologic insomnia			
subjects affected / exposed	0 / 101 (0.00%)	1 / 73 (1.37%)	
occurrences (all)	0	1	
Investigations			
SARS-CoV-2 test positive			

subjects affected / exposed	2 / 101 (1.98%)	3 / 73 (4.11%)	
occurrences (all)	2	3	
Injury, poisoning and procedural complications			
Skin laceration			
subjects affected / exposed	0 / 101 (0.00%)	1 / 73 (1.37%)	
occurrences (all)	0	1	
Muscle strain			
subjects affected / exposed	0 / 101 (0.00%)	0 / 73 (0.00%)	
occurrences (all)	0	0	
Ligament sprain			
subjects affected / exposed	1 / 101 (0.99%)	0 / 73 (0.00%)	
occurrences (all)	1	0	
Eye injury			
subjects affected / exposed	0 / 101 (0.00%)	1 / 73 (1.37%)	
occurrences (all)	0	1	
Contusion			
subjects affected / exposed	0 / 101 (0.00%)	0 / 73 (0.00%)	
occurrences (all)	0	0	
Congenital, familial and genetic disorders			
Pectus excavatum			
subjects affected / exposed	0 / 101 (0.00%)	0 / 73 (0.00%)	
occurrences (all)	0	0	
Cardiac disorders			
Tachycardia			
subjects affected / exposed	0 / 101 (0.00%)	0 / 73 (0.00%)	
occurrences (all)	0	0	
Nervous system disorders			
Syncope			
subjects affected / exposed	0 / 101 (0.00%)	0 / 73 (0.00%)	
occurrences (all)	0	0	
Headache			
subjects affected / exposed	1 / 101 (0.99%)	1 / 73 (1.37%)	
occurrences (all)	1	1	
Dizziness			
subjects affected / exposed	0 / 101 (0.00%)	0 / 73 (0.00%)	
occurrences (all)	0	0	

Migraine			
subjects affected / exposed	1 / 101 (0.99%)	0 / 73 (0.00%)	
occurrences (all)	1	0	
Headache (HEADACHE)			
alternative assessment type: Systematic			
subjects affected / exposed	35 / 101 (34.65%)	31 / 73 (42.47%)	
occurrences (all)	35	31	
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 101 (0.00%)	0 / 73 (0.00%)	
occurrences (all)	0	0	
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 101 (0.00%)	0 / 73 (0.00%)	
occurrences (all)	0	0	
Nausea			
subjects affected / exposed	2 / 101 (1.98%)	0 / 73 (0.00%)	
occurrences (all)	2	0	
Abdominal pain			
subjects affected / exposed	0 / 101 (0.00%)	1 / 73 (1.37%)	
occurrences (all)	0	1	
Constipation			
subjects affected / exposed	0 / 101 (0.00%)	0 / 73 (0.00%)	
occurrences (all)	0	0	
Vomiting			
subjects affected / exposed	0 / 101 (0.00%)	0 / 73 (0.00%)	
occurrences (all)	0	0	
Diarrhoea (DIARRHEA)			
alternative assessment type: Systematic			
subjects affected / exposed	7 / 101 (6.93%)	7 / 73 (9.59%)	
occurrences (all)	7	7	
Vomiting (VOMITING)			
alternative assessment type: Systematic			
subjects affected / exposed	2 / 101 (1.98%)	1 / 73 (1.37%)	
occurrences (all)	2	1	
Skin and subcutaneous tissue disorders			

Dermatitis contact			
subjects affected / exposed	0 / 101 (0.00%)	0 / 73 (0.00%)	
occurrences (all)	0	0	
Eczema			
subjects affected / exposed	0 / 101 (0.00%)	0 / 73 (0.00%)	
occurrences (all)	0	0	
Urticaria			
subjects affected / exposed	0 / 101 (0.00%)	0 / 73 (0.00%)	
occurrences (all)	0	0	
Erythema (REDNESS)			
alternative assessment type: Systematic			
subjects affected / exposed	16 / 101 (15.84%)	14 / 73 (19.18%)	
occurrences (all)	19	18	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 101 (0.99%)	0 / 73 (0.00%)	
occurrences (all)	1	0	
Back pain			
subjects affected / exposed	0 / 101 (0.00%)	0 / 73 (0.00%)	
occurrences (all)	0	0	
Scoliosis			
subjects affected / exposed	0 / 101 (0.00%)	1 / 73 (1.37%)	
occurrences (all)	0	1	
Pain in extremity			
subjects affected / exposed	0 / 101 (0.00%)	0 / 73 (0.00%)	
occurrences (all)	0	0	
Arthralgia (JOINT PAIN)			
alternative assessment type: Systematic			
subjects affected / exposed	16 / 101 (15.84%)	9 / 73 (12.33%)	
occurrences (all)	16	9	
Myalgia (MUSCLE PAIN)			
alternative assessment type: Systematic			
subjects affected / exposed	24 / 101 (23.76%)	13 / 73 (17.81%)	
occurrences (all)	24	13	
Infections and infestations			

COVID-19			
subjects affected / exposed	4 / 101 (3.96%)	2 / 73 (2.74%)	
occurrences (all)	4	2	
Ear infection			
subjects affected / exposed	0 / 101 (0.00%)	0 / 73 (0.00%)	
occurrences (all)	0	0	
Gastroenteritis			
subjects affected / exposed	0 / 101 (0.00%)	0 / 73 (0.00%)	
occurrences (all)	0	0	
Bronchitis			
subjects affected / exposed	0 / 101 (0.00%)	0 / 73 (0.00%)	
occurrences (all)	0	0	
Bacterial vaginosis			
subjects affected / exposed	0 / 101 (0.00%)	0 / 73 (0.00%)	
occurrences (all)	0	0	
Acute sinusitis			
subjects affected / exposed	0 / 101 (0.00%)	0 / 73 (0.00%)	
occurrences (all)	0	0	
Gastroenteritis viral			
subjects affected / exposed	0 / 101 (0.00%)	0 / 73 (0.00%)	
occurrences (all)	0	0	
Pharyngitis			
subjects affected / exposed	0 / 101 (0.00%)	0 / 73 (0.00%)	
occurrences (all)	0	0	
Otitis media acute			
subjects affected / exposed	0 / 101 (0.00%)	0 / 73 (0.00%)	
occurrences (all)	0	0	
Otitis media			
subjects affected / exposed	0 / 101 (0.00%)	0 / 73 (0.00%)	
occurrences (all)	0	0	
Otitis externa			
subjects affected / exposed	0 / 101 (0.00%)	0 / 73 (0.00%)	
occurrences (all)	0	0	
Nasopharyngitis			
subjects affected / exposed	1 / 101 (0.99%)	0 / 73 (0.00%)	
occurrences (all)	1	0	

Influenza			
subjects affected / exposed	0 / 101 (0.00%)	0 / 73 (0.00%)	
occurrences (all)	0	0	
Impetigo			
subjects affected / exposed	0 / 101 (0.00%)	0 / 73 (0.00%)	
occurrences (all)	0	0	
Pharyngitis streptococcal			
subjects affected / exposed	0 / 101 (0.00%)	0 / 73 (0.00%)	
occurrences (all)	0	0	
Upper respiratory tract infection			
subjects affected / exposed	0 / 101 (0.00%)	1 / 73 (1.37%)	
occurrences (all)	0	1	
Tonsillitis			
subjects affected / exposed	0 / 101 (0.00%)	0 / 73 (0.00%)	
occurrences (all)	0	0	
Sinusitis			
subjects affected / exposed	0 / 101 (0.00%)	0 / 73 (0.00%)	
occurrences (all)	0	0	
Urinary tract infection			
subjects affected / exposed	0 / 101 (0.00%)	1 / 73 (1.37%)	
occurrences (all)	0	1	
Viral pharyngitis			
subjects affected / exposed	0 / 101 (0.00%)	0 / 73 (0.00%)	
occurrences (all)	0	0	
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 101 (0.00%)	0 / 73 (0.00%)	
occurrences (all)	0	0	
Metabolism and nutrition disorders			
Hypercholesterolaemia			
subjects affected / exposed	0 / 101 (0.00%)	0 / 73 (0.00%)	
occurrences (all)	0	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
09 July 2019	1. Opened enrollment in Stage 2 to ACWY-experienced subjects in addition to ACWY-naïve subjects. This was based on the recommendation from the Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) to obtain data on the persistence of the immune response after 2 doses of MenABCWY as well as on the safety and immunogenicity of the booster response in individuals who had previously received an ACWY-containing vaccine.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported