Clinical trial results:
A Phase 2b, Open-Label, Multi-Center Study Assessing the Immunological Persistence of Antibodies at Approximately 2 years After the last Meningococcal Vaccination in Study V102_15 and the Response to a Booster dose of GSK MenABCWY or Meningococcal Serogroup B Vaccines, in Healthy Adolescents

Summary

EudraCT number	2016-002230-69
Trial protocol	FI PL
Global end of trial date	11 October 2018

Results information

Result version number	v2 (current)
This version publication date	01 September 2019
First version publication date	21 April 2019
Version creation reason	• Correction of full data set In response to NIH comments, further information has been added in the measure description for endpoints 1 and 2, to clarify that subjects in the group B_0_2 did not receive MenACWY vaccination in the parent study.

Trial information

Trial identification

Sponsor protocol code	205613

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02946385
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline
Sponsor organisation address	Rue del ' Institut 89, Rixensart, Belgium, B-1330
Public contact	Clinical Trials Call Center, GlaxoSmithKline Biologicals, 44 2089904466, GSKClinicalSupportHD@gsk.com
Scientific contact	Clinical Trials Call Center, GlaxoSmithKline Biologicals, 44 2089904466, GSKClinicalSupportHD@gsk.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
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	08 February 2019
Is this the analysis of the primary completion data?	Yes
Primary completion date	13 February 2018
Global end of trial reached?	Yes
Global end of trial date	11 October 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the persistence of bactericidal antibodies in subjects who previously received 2 or 3 doses of MenABCWY (administered according to 0, 2, 0, 6 & 0, 2, 6-month schedules) or 2 doses of rMenB+OMV (given at a 0, 2-mth schedule), 24 months after the last meningococcal vaccination in study V102_15 compared with baseline antibody levels in meningococcal naive subjects at enrolment, as measured by percent-ages of subjects with HT-hSBA titers ≥ lower limit of quantitation (LLOQ) and HT-hSBA geometric mean titers (GMTs) against N. meningitidis test strains for serogroup B, and serogroups A, C, W, and Y.

Protection of trial subjects:

All subjects will be observed for at least 30 minutes after vaccination/product administration with appropriate medical treatment readily available. Vaccines will be administered by qualified and trained personnel. Vaccines will be administered only to eligible subjects that have no contraindications to any components of the vaccines. Subjects will be followed-up for 180 days after the last vaccination administration (i.e. Day 181 for follow-on subjects and Day 241 for vaccine naïve subjects).

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	15 November 2016
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Finland: 283
Country: Number of subjects enrolled	Poland: 321
Worldwide total number of subjects	604
EEA total number of subjects	604

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)	0
Adolescents (12-17 years)	342
Adults (18-64 years)	262
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

All subjects enrolled in the study started the study.

Pre-assignment

Screening details:

Participant flow,baseline characteristics & immunogenicity analyses were performed on "randomized" population & Safety analysis on "treated" population.2 subjects from Naïve_ABCWY group received rMenB+OMV vaccine & not MenABCWY.Hence,number of subjects analyzed in Naïve_B & Naive_ABCWY groups in treated population differ from randomized population

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Blinding implementation details:

This was an open label study. No blinding methods were used.

Arms

Are arms mutually exclusive?	Yes
Arm title	B_0_2

Arm description:

Subjects who received 2 doses of rMenB+OMV vaccine at Month 0 and Month 2 in study V102_15 (NCT02212457), and will receive 1 dose of rMenB+OMV in this extension study

Arm type	Experimental
Investigational medicinal product name	rMenB +OMV Vaccine
Investigational medicinal product code	
Other name	Bexsero
Pharmaceutical forms	Suspension for injection in pre-filled syringe
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular injection of one booster dose of the rMenB+OMV vaccine to subjects in the B_0_2 group, primed with 2 doses of the vaccine and intramuscular injection of 2 doses at Days 1 and 61 in the deltoid area of the non-dominant arm to naïve subjects in the rMenB+OMV Naïve group

Arm title	ABCWY_0_2

Arm description:

Subjects who received 2 doses of MenABCWY vaccine at Month 0 and Month 2 in study V102_15 (NCT02212457), and will receive 1 dose of MenABCWY in this extension study

Arm type	Experimental
Investigational medicinal product name	MenABCWY Vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular injection of one booster dose at Day 1 to follow-on subjects in the ABCWY_ 0_2 Group, ABCWY_ 0_2_6 Group and ABCWY_ 0_6 Group, primed with 2 or 3 doses of the study vaccine and 2 doses at Days 1 and 61 to naïve subjects in the ABCWY naïve group

Arm title	Naive_B

Arm description:

Subjects who are meningococcal vaccine-naive and of similar age to subjects enrolled from the parent

study (NCT02212457), and will receive 2 doses of rMenB+OMV in this extension study

Arm type	Active comparator
Investigational medicinal product name	rMenB +OMV Vaccine
Investigational medicinal product code	
Other name	Bexsero
Pharmaceutical forms	Suspension for injection in pre-filled syringe
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular injection of one booster dose of the rMenB+OMV vaccine to subjects in the B_0_2 group, primed with 2 doses of the vaccine and intramuscular injection of 2 doses at Days 1 and 61 in the deltoid area of the non-dominant arm to naïve subjects in the rMenB+OMV Naïve group

Arm title	ABCWY_0_6

Arm description:

Subjects who received 2 doses of MenABCWY vaccine at Month 0 and Month 6 in study V102_15 (NCT02212457), and will receive 1 dose of MenABCWY in this extension study

Arm type	Experimental
Investigational medicinal product name	MenABCWY Vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular injection of one booster dose at Day 1 to follow-on subjects in the ABCWY_ 0_2 Group, ABCWY_ 0_2_6 Group and ABCWY_ 0_6 Group, primed with 2 or 3 doses of the study vaccine and 2 doses at Days 1 and 61 to naïve subjects in the ABCWY naïve group

Arm title	Naive_ABCWY

Arm description:

Subjects who are meningococcal vaccine-naive and of similar age to subjects enrolled from the parent study (NCT02212457), and will receive 2 doses of MenABCWY in this extension study

Arm type	Active comparator
Investigational medicinal product name	MenABCWY Vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular injection of one booster dose at Day 1 to follow-on subjects in the ABCWY_ 0_2 Group, ABCWY_ 0_2_6 Group and ABCWY_ 0_6 Group, primed with 2 or 3 doses of the study vaccine and 2 doses at Days 1 and 61 to naïve subjects in the ABCWY naïve group

Arm title	ABCWY_0_2_6

Arm description:

Subjects who received 3 doses of MenABCWY vaccine at Month 0, Month 2 and Month 6 in study V102_15 (NCT02212457), and will receive 1 dose of MenABCWY in this extension study

Arm type	Experimental
Investigational medicinal product name	MenABCWY Vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular injection of one booster dose at Day 1 to follow-on subjects in the ABCWY_ 0_2 Group, ABCWY_ 0_2_6 Group and ABCWY_ 0_6 Group, primed with 2 or 3 doses of the study vaccine and 2 doses at Days 1 and 61 to naïve subjects in the ABCWY naïve group

Number of subjects in period 1	B_0_2	ABCWY_0_2	Naive_B
Started	126	127	99
Completed	126	127	96
Not completed	0	0	3
Lost to follow-up	-	-	3

Number of subjects in period 1	ABCWY_0_6	Naive_ABCWY	ABCWY_0_2_6
Started	74	101	77
Completed	74	99	76
Not completed	0	2	1
Lost to follow-up	-	2	1

Baseline characteristics

Reporting groups	
Reporting group title	B_0_2
Reporting group description:	
Subjects who received 2 doses of rMenB+OMV vaccine at Month 0 and Month 2 in study V102_15 (NCT02212457), and will receive 1 dose of rMenB+OMV in this extension study	
Reporting group title	ABCWY_0_2
Reporting group description:	
Subjects who received 2 doses of MenABCWY vaccine at Month 0 and Month 2 in study V102_15 (NCT02212457), and will receive 1 dose of MenABCWY in this extension study	
Reporting group title	Naive_B
Reporting group description:	
Subjects who are meningococcal vaccine-naive and of similar age to subjects enrolled from the parent study (NCT02212457), and will receive 2 doses of rMenB+OMV in this extension study	
Reporting group title	ABCWY_0_6
Reporting group description:	
Subjects who received 2 doses of MenABCWY vaccine at Month 0 and Month 6 in study V102_15 (NCT02212457), and will receive 1 dose of MenABCWY in this extension study	
Reporting group title	Naive_ABCWY
Reporting group description:	
Subjects who are meningococcal vaccine-naive and of similar age to subjects enrolled from the parent study (NCT02212457), and will receive 2 doses of MenABCWY in this extension study	
Reporting group title	ABCWY_0_2_6
Reporting group description:	
Subjects who received 3 doses of MenABCWY vaccine at Month 0, Month 2 and Month 6 in study V102_15 (NCT02212457), and will receive 1 dose of MenABCWY in this extension study	

Reporting group values	B_0_2	ABCWY_0_2	Naive_B
Number of subjects	126	127	99
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)	0	0	0
Adolescents (12-17 years)	73	73	57
Adults (18-64 years)	53	54	42
From 65-84 years	0	0	0
85 years and over	0	0	0
Age continuous Units: years			
geometric mean	16.8	16.6	16.2
standard deviation	± 3.06	± 3.15	± 2.8
Sex: Female, Male Units: Subjects			
Female	82	69	58
Male	44	58	41

Race/Ethnicity, Customized Units: Subjects			
AMERICAN INDIAN OR ALASKA NATIVE	0	0	0
ASIAN	0	0	0
OTHER	0	0	2
WHITE	126	127	97

Reporting group values	ABCWY_0_6	Naive_ABCWY	ABCWY_0_2_6
Number of subjects	74	101	77
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)	0	0	0
Adolescents (12-17 years)	40	57	42
Adults (18-64 years)	34	44	35
From 65-84 years	0	0	0
85 years and over	0	0	0
Age continuous Units: years			
geometric mean	17.3	16.5	17.1
standard deviation	± 2.96	± 2.78	± 2.98
Sex: Female, Male Units: Subjects			
Female	44	60	50
Male	30	41	27
Race/Ethnicity, Customized Units: Subjects			
AMERICAN INDIAN OR ALASKA NATIVE	0	1	0
ASIAN	0	0	1
OTHER	1	0	1
WHITE	73	100	75

Reporting group values	Total		
Number of subjects	604		
Age categorical Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	0		
Newborns (0-27 days)	0		
Infants and toddlers (28 days-23 months)	0		
Children (2-11 years)	0		
Adolescents (12-17 years)	342		
Adults (18-64 years)	262		
From 65-84 years	0		

85 years and over	0		

Age continuous Units: years geometric mean standard deviation	- -		
Sex: Female, Male Units: Subjects			
Female	363		
Male	241		
Race/Ethnicity, Customized Units: Subjects			
AMERICAN INDIAN OR ALASKA NATIVE	1		
ASIAN	1		
OTHER	4		
WHITE	598		

End points

End points reporting groups

Reporting group title	B_0_2
Reporting group description:	
Subjects who received 2 doses of rMenB+OMV vaccine at Month 0 and Month 2 in study V102_15 (NCT02212457), and will receive 1 dose of rMenB+OMV in this extension study	
Reporting group title	ABCWY_0_2
Reporting group description:	
Subjects who received 2 doses of MenABCWY vaccine at Month 0 and Month 2 in study V102_15 (NCT02212457), and will receive 1 dose of MenABCWY in this extension study	
Reporting group title	Naive_B
Reporting group description:	
Subjects who are meningococcal vaccine-naive and of similar age to subjects enrolled from the parent study (NCT02212457), and will receive 2 doses of rMenB+OMV in this extension study	
Reporting group title	ABCWY_0_6
Reporting group description:	
Subjects who received 2 doses of MenABCWY vaccine at Month 0 and Month 6 in study V102_15 (NCT02212457), and will receive 1 dose of MenABCWY in this extension study	
Reporting group title	Naive_ABCWY
Reporting group description:	
Subjects who are meningococcal vaccine-naive and of similar age to subjects enrolled from the parent study (NCT02212457), and will receive 2 doses of MenABCWY in this extension study	
Reporting group title	ABCWY_0_2_6
Reporting group description:	
Subjects who received 3 doses of MenABCWY vaccine at Month 0, Month 2 and Month 6 in study V102_15 (NCT02212457), and will receive 1 dose of MenABCWY in this extension study	
Subject analysis set title	Naive_ALL
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Subjects who are meningococcal vaccine-naive and of similar age to subjects enrolled from the parent study (NCT02212457), and will receive 2 doses of MenABCWY or rMenB+OMV in this extension study	

Primary: Percentages of subjects with hSBA titers ≥LLOQ against 4 serogroup B test strains, and against N. meningitidis serogroups A, C, W and Y at 24 Months After Last Meningococcal Vaccination in Follow-on Subjects in V102_15 and at Day 1 in Naive Subjects

End point title	Percentages of subjects with hSBA titers ≥LLOQ against 4 serogroup B test strains, and against N. meningitidis serogroups A, C, W and Y at 24 Months After Last Meningococcal Vaccination in Follow-on Subjects in V102_15 and at Day 1 in Naive Subjects[1][2]
End point description:	
The immunogenicity of MenABCWY or rMenB+OMV vaccines, is measured as the percentage of subjects with High-Throughput Human Serum Bactericidal Assay (HT-hSBA) titers greater or equal than (≥) Lower limit of quantification (LLOQ) against N. meningitidis serogroup B test strains and serogroups A,C, W and Y. The test strains assessed were Meningitis B NZ98/254 Ab, Meningitis B M14459 Ab, Meningitis B M07-0241084 Ab and Meningitis B 96217 Ab. The analysis population included all subjects in the full analysis set (FAS) persistence (24 months after last vaccination in V102_15/Day 1) who were randomized(if naive), and provided evaluable serum sample with hSBA results for at least one serogroup B test strain or serogroups A, C,W or Y at Day 1 in the extension study.Subjects in the group B_0_2 did not receive MenACWY vaccine in the parent study V102_15.	
End point type	Primary
End point timeframe:	
At 24 months after the last meningococcal vaccination for all follow-on subjects and at Day 1 in the extension study for naive subjects	

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: The scope of this endpoint was descriptive analysis. Therefore, no statistical analyses were performed on this endpoint.

[2] - 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: The results in this study were tabulated by age group and study period. Hence for each related endpoint, they are presented for only the respective groups in the baseline period, while the results for multiple endpoints account for all baseline groups.

End point values	B_0_2	ABCWY_0_2	ABCWY_0_6	ABCWY_0_2_6
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	125	127	74	75
Units: Percentage of subjects				
number (confidence interval 95%)				
M14459 (N-121,74,72,123,198)	17 (10.9 to 24.9)	18 (11.8 to 26.2)	25 (15.5 to 36.6)	16 (8.7 to 26.6)
96217(N-127,74,74,124,198)	81 (73.5 to 87.9)	71 (62.1 to 78.6)	73 (61.4 to 82.6)	81 (70.3 to 89.3)
NZ98/254(N-127,75,74,124,198)	15 (9.5 to 22.9)	16 (9.9 to 23.3)	18 (9.7 to 28.2)	15 (7.6 to 24.7)
M07-0241084(N-126,75,73,125,196)	28 (20.3 to 36.7)	29 (21.6 to 38.1)	36 (24.7 to 47.7)	31 (20.5 to 42.4)
Meningitis A(N-125,72,74,0,99)	0 (0 to 0)	15 (9.4 to 22.7)	27 (17.4 to 38.6)	25 (15.5 to 36.6)
Meningitis C(N-127,74,74,0,100)	0 (0 to 0)	83 (75.8 to 89.5)	85 (75.0 to 92.3)	86 (76.5 to 93.3)
Meningiti5 W(N-127,75,72,0,98)	0 (0 to 0)	52 (42.9 to 60.9)	64 (51.7 to 74.9)	73 (61.9 to 82.9)
Meningitis Y(N-126,73,73,0,99)	0 (0 to 0)	52 (43.3 to 61.3)	62 (49.5 to 72.8)	75 (63.9 to 84.7)

End point values	Naive_ALL			
Subject group type	Subject analysis set			
Number of subjects analysed	198			
Units: Percentage of subjects				
number (confidence interval 95%)				
M14459 (N-121,74,72,123,198)	5 (2.1 to 8.5)			
96217(N-127,74,74,124,198)	34 (27.3 to 40.9)			
NZ98/254(N-127,75,74,124,198)	3 (0.8 to 5.8)			
M07-0241084(N-126,75,73,125,196)	17 (12.3 to 23.4)			
Meningitis A(N-125,72,74,0,99)	3 (0.6 to 8.6)			
Meningitis C(N-127,74,74,0,100)	32 (23.0 to 42.1)			
Meningiti5 W(N-127,75,72,0,98)	27 (18.1 to 36.4)			
Meningitis Y(N-126,73,73,0,99)	7 (2.9 to 14.0)			

Statistical analyses

No statistical analyses for this end point

Primary: hSBA GMTs against each of four serogroup B test strains, and against N. meningitidis serogroups A, C, W and Y at 24 Months After Last Meningococcal Vaccination in Follow-on Subjects in V102_15 and at Day 1 in Naive Subjects

End point title	hSBA GMTs against each of four serogroup B test strains, and against N. meningitidis serogroups A, C, W and Y at 24 Months After Last Meningococcal Vaccination in Follow-on Subjects in V102_15 and at Day 1 in Naive Subjects[3][4]

End point description:

The immunogenicity of MenABCWY or rMenB+OMV vaccines, is measured as the HT-hSBA geometric mean titers (GMTs) against N. meningitidis serogroup B test strains and serogroups A,C, W and Y. The test strains assessed were Meningitis B NZ98/254 Ab, Meningitis B M14459 Ab, Meningitis B M07-0241084 Ab and Meningitis B 96217 Ab.
The analysis population included all subjects in the full analysis set (FAS) persistence (24 months after last vaccination in V102_15/Day 1) who were randomized(if naive), and provided evaluable serum sample with hSBA results for at least one serogroup B test strain or serogroups A, C,W or Y at Day 1 in the extension study.Subjects in the group B_0_2 did not receive MenACWY vaccine in the parent study V102_15.

End point type	Primary

End point timeframe:

At 24 months after the last meningococcal vaccination for all follow-on subjects and at Day 1 in the extension study for naive subjects

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: The scope of this endpoint was descriptive analysis. Therefore, no statistical analyses were performed on this endpoint.
[4] - 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: The results in this study were tabulated by age group and study period. Hence for each related endpoint, they are presented for only the respective groups in the baseline period, while the results for multiple endpoints account for all baseline groups.

End point values	B_0_2	ABCWY_0_2	ABCWY_0_6	ABCWY_0_2_6
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	125	127	74	75
Units: Titers				
geometric mean (confidence interval 95%)				
M14459(N-121,74,72,123,198)	2.02 (1.66 to 2.45)	2.05 (1.68 to 2.50)	2.55 (1.98 to 3.30)	2 (1.55 to 2.57)
96217(N-127,74,74,124,198)	20 (15 to 26)	13 (10 to 17)	15 (11 to 22)	19 (14 to 27)
NZ98/254(N-127,75,74,124,198)	1.72 (1.42 to 2.08)	1.78 (1.48 to 2.16)	2.1 (1.64 to 2.69)	1.72 (1.34 to 2.19)
M07-0241084(N-126,75,73,125,196)	4.21 (3.29 to 5.38)	3.95 (3.09 to 5.05)	5.2 (3.77 to 7.18)	4.22 (3.07 to 5.80)
Meningitis A(N-125,72,74,0,99)	0 (0 to 0)	2.25 (1.72 to 2.95)	4.89 (3.45 to 6.94)	4.52 (3.18 to 6.44)
Meningitis C(N-127,84,74,0,100)	0 (0 to 0)	18 (14 to 23)	20 (14 to 28)	29 (21 to 41)
Meningitis W(N-127,75,72,0,98)	0 (0 to 0)	39 (29 to 51)	44 (30 to 64)	53 (36 to 76)
Meningitis Y(N-126,73,73,0,99)	0 (0 to 0)	9.19 (6.85 to 12)	16 (11 to 24)	29 (20 to 43)

End point values	Naive_ALL			
Subject group type	Subject analysis set			
Number of subjects analysed	198			
Units: Titers				
geometric mean (confidence interval 95%)				
M14459(N-121,74,72,123,198)	1.21 (1.04 to 1.42)			
96217(N-127,74,74,124,198)	3.63 (2.94 to 4.48)			
NZ98/254(N-127,75,74,124,198)	1.1 (0.95 to 1.28)			
M07-0241084(N-126,75,73,125,196)	2.27 (1.87 to 2.77)			
Meningitis A(N-125,72,74,0,99)	1.21 (0.89 to 1.63)			
Meningitis C(N-127,84,74,0,100)	2.92 (2.19 to 3.89)			
Meningitis W(N-127,75,72,0,98)	6.32 (4.59 to 8.70)			
Meningitis Y(N-126,73,73,0,99)	1.52 (1.09 to 2.12)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentages of Subjects with HT-hSBA Titers ≥ LLOQ against 4 serogroup B test strains, and against N. meningitidis serogroups A, C, W and Y at Day 31 After MenABCWY Vaccination in V102_15E1

End point title	Percentages of Subjects with HT-hSBA Titers ≥ LLOQ against 4 serogroup B test strains, and against N. meningitidis serogroups A, C, W and Y at Day 31 After MenABCWY Vaccination in V102_15E1[5]

End point description:

The immunogenicity of MenABCWY vaccine, was measured as the percentages of subjects with HT-hSBA titers greater than or equal to (≥) Lower limit of quantification (LLOQ) against N. meningitidis serogroup B test strains and serogroups A,C, W and Y. The test strains assessed were Meningitis B NZ98/254 Ab, Meningitis B M14459 Ab, Meningitis B M07-0241084 Ab and Meningitis B 96217 Ab.
The analysis population included all subjects in the FAS immunogenicity (Day 31, after booster dose[follow-on]/first dose[naive]) who were randomized (if naive),received at least one study vaccination and provided evaluable serum sample with results for at least one serogroup B test strain or serogroups A, C, W or Y at Day 31 in the extension study.

End point type	Secondary

End point timeframe:

Day 31: One month after a booster dose of MenABCWY given at 24 months after last MenABCWY vaccination in groups: ABCWY_0_2, ABCWY_0_6 and ABCWY_0_2_6 and after first dose of MenABCWY in Naive_ABCWY Group

Notes:

[5] - 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: The results in this study were tabulated by age group and study period. Hence for each related endpoint, they are presented for only the respective groups in the baseline period, while the results for multiple endpoints account for all baseline groups.

End point values	ABCWY_0_2	ABCWY_0_6	Naive_ABCWY	ABCWY_0_2_6
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	127	73	100	77
Units: Percentage of subjects				
number (confidence interval 95%)				
M14459(N-126,75,73,100)	87 (79.3 to 91.9)	95 (86.6 to 98.5)	29 (20.4 to 38.9)	85 (75.3 to 92.4)
96217(N-127,77,73,100)	100 (97.1 to 100)	100 (95.1 to 100)	62 (51.7 to 71.5)	100 (95.3 to 100)
NZ98/254(N-127,76,72,100)	69 (60.5 to 77.2)	81 (69.5 to 88.9)	27 (18.6 to 36.8)	68 (56.7 to 78.6)
M07-0241084(N-126,77,73,100)	87 (79.3 to 91.9)	81 (69.9 to 89.1)	30 (21.2 to 40.0)	84 (74.4 to 91.7)
Meningitis A(N-125,77,73,98)	98 (94.3 to 99.81)	99 (92.6 to 99.97)	55 (44.7 to 65.2)	100 (95.3 to 100)
Meningitis C(N-127,75,73,100)	100 (97.1 to 100)	100 (95.1 to 100)	91 (83.6 to 95.8)	100 (95.2 to 100)
Meningitis W(N-124,74,73,100)	100 (97.1 to 100)	100 (95.1 to 100)	78 (68.6 to 85.7)	100 (95.1 to 100)
Meningitis Y(N-127,76,73,98)	100 (97.1 to 100)	99 (92.6 to 99.97)	71 (61.4 to 80.1)	100 (95.3 to 100)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentages of Subjects with 4-Fold Increase in HT-hSBA Titers against 4 serogroup B test strains, and against N. meningitidis serogroups A, C, W and Y at Day 31 After MenABCWY Vaccination in V102_15E1

End point title	Percentages of Subjects with 4-Fold Increase in HT-hSBA Titers against 4 serogroup B test strains, and against N. meningitidis serogroups A, C, W and Y at Day 31 After MenABCWY Vaccination in V102_15E1[6]

End point description:

The immunogenicity of MenABCWY vaccine, was measured as the percentages of subjects with 4-Fold Increase in HT-hSBA Titers against N. meningitidis serogroup B test strains and serogroups A,C, W and Y. The test strains assessed were Meningitis B NZ98/254 Ab, Meningitis B M14459 Ab, Meningitis B M07-0241084 Ab and Meningitis B 96217 Ab. The 4-fold titer rise is defined as: a) for subjects with pre-vaccination hSBA titers LLOQ, a post-vaccination hSBA ≥ 4 LLOQ; b) for subjects with a pre-vaccination hSBA titers ≥ LLOQ, an increase of at least 4 times of the pre-vaccination hSBA.
The analysis population included all subjects in the FAS immunogenicity (Day 31, after booster dose[follow-on]/first dose[naive]) who were randomized (if naive),received at least one study vaccination and provided evaluable serum sample with results for at least one serogroup B test strain or serogroups A, C, W or Y at Day 31 in the extension study.

End point type	Secondary

End point timeframe:

Day 31: One month after a booster dose of MenABCWY given at 24 months after last MenABCWY vaccination in groups: ABCWY_0_2, ABCWY_0_6 and ABCWY_0_2_6 and after first dose of MenABCWY in Naive_ABCWY Group

Notes:

[6] - 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: The results in this study were tabulated by age group and study period. Hence for each related endpoint, they are presented for only the respective groups in the baseline period, while the results for multiple endpoints account for all baseline groups.

End point values	ABCWY_0_2	ABCWY_0_6	Naive_ABCWY	ABCWY_0_2_6
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	127	73	99	75
Units: Percentage of subjects				
number (confidence interval 95%)				
M14459(N-120,73,72,99)	54 (44.8 to 63.3)	65 (53.1 to 76.1)	8 (3.6 to 15.3)	49 (37.4 to 61.3)
96217(N-127,74,73,99)	91 (84.1 to 95.0)	97 (90.5 to 99.67)	17 (10.3 to 26.1)	95 (86.7 to 98.5)
NZ98/254(N-127,75,72,99)	22 (15.2 to 30.3)	14 (6.9 to 24.1)	16 (9.5 to 24.9)	17 (9.6 to 27.8)
M07-0241084(N-125,75,72,99)	38 (29.1 to 46.7)	17 (8.9 to 27.3)	11 (5.7 to 19.0)	19 (10.6 to 29.3)
Meningitis A(N-123,72,73,97)	82 (74.2 to 88.4)	88 (77.9 to 94.2)	23 (14.8 to 32.3)	83 (72.7 to 91.1)
Meningitis C(N-127,74,73,99)	94 (88.0 to 97.2)	93 (84.7 to 97.7)	54 (43.2 to 63.6)	86 (76.5 to 93.3)
Meningitis W(N-124,72,71,97)	93 (86.7 to 96.6)	85 (74.0 to 92.0)	36 (26.6 to 46.5)	92 (82.7 to 96.9)
Meningitis Y(N-126,73,72,96)	94 (87.9 to 97.2)	90 (81.0 to 96.0)	46 (35.6 to 56.3)	89 (79.5 to 95.1)

Statistical analyses

No statistical analyses for this end point

Secondary: hSBA GMTs against each of four serogroup B test strains, and against N. meningitidis serogroups A, C, W and Y at Day 31 After MenABCWY Vaccination in V102_15E1

End point title	hSBA GMTs against each of four serogroup B test strains, and against N. meningitidis serogroups A, C, W and Y at Day 31 After MenABCWY Vaccination in V102_15E1[7]

End point description:

The immunogenicity of MenABCWY vaccine, was measured as the HT-hSBA Geometric Mean Titers (GMTs) against N. meningitidis serogroup B test strains and serogroups A,C, W and Y . The test strains assessed were Meningitis B NZ98/254 Ab, Meningitis B M14459 Ab, Meningitis B M07-0241084 Ab and Meningitis B 96217 Ab.
The analysis population included all subjects in the FAS immunogenicity (Day 31, after booster dose[follow-on]/first dose[naive]) who were randomized (if naive),received at least one study vaccination and provided evaluable serum sample with results for at least one serogroup B test strain or serogroups A, C, W or Y at Day 31 in the extension study.

End point type	Secondary

End point timeframe:

Day 31: One month after a booster dose of MenABCWY given at 24 months after last MenABCWY vaccination in groups: ABCWY_0_2, ABCWY_0_6 and ABCWY_0_2_6 and after first dose of MenABCWY in Naive_ABCWY Group

Notes:

[7] - 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: The results in this study were tabulated by age group and study period. Hence for each related endpoint, they are presented for only the respective groups in the baseline period, while the results for multiple endpoints account for all baseline groups.

End point values	ABCWY_0_2	ABCWY_0_6	Naive_ABCWY	ABCWY_0_2_6
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	127	73	100	77
Units: Titers				
geometric mean (confidence interval 95%)				
M14459(N-126,75,73,100)	32 (25 to 41)	61 (44 to 85)	3.12 (2.34 to 4.14)	30 (22 to 42)
96217(N-127,77,73,100)	580 (467 to 722)	544 (408 to 725)	11 (8.25 to 13)	529 (400 to 700)
NZ98/254(N-127,76,72,100)	16 (12 to 21)	16 (12 to 23)	3.14 (2.32 to 4.24)	13 (9.04 to 18)
M07-0241084(N-126,77,73,100)	32 (26 to 41)	21 (16 to 29)	4.48 (3.47 to 5.78)	25 (18 to 33)
Meningitis A(N-125,77,73,98)	271 (211 to 348)	340 (245 to 472)	17 (13 to 22)	267 (194 to 367)
Meningitis C(N-125,75,73,100)	628 (498 to 791)	529 (391 to 718)	48 (37 to 62)	602 (446 to 812)
Meningitis W(N-124,74,73,100)	1309 (1062 to 1614)	979 (746 to 1286)	129 (102 to 162)	1078 (823 to 1413)
Meningitis Y(N-127,76,73,98)	616 (479 to 791)	578 (415 to 803)	33 (25 to 44)	606 (439 to 836)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentages of subjects with hSBA titers ≥LLOQ against 4 serogroup B test strains, and N. meningitidis serogroups A, C, W and Y at 24 Months At Days 1, 6, 31 in V102_15 Follow-on Subjects and at Day 1, 66, 91 in Naive Subjects, in MenABCWY Groups

End point title	Percentages of subjects with hSBA titers ≥LLOQ against 4 serogroup B test strains, and N. meningitidis serogroups A, C, W and Y at 24 Months At Days 1, 6, 31 in V102_15 Follow-on Subjects and at Day 1, 66, 91 in Naive Subjects, in MenABCWY Groups[8]

End point description:

The immunogenicity of MenABCWY vaccine, was measured as the percentages of subjects with HT-hSBA titers greater or equal than (≥) Lower limit of quantification (LLOQ) against N.meningitidis serogroup B test strains and serogroups A,C, W and Y. The test strains assessed were Meningitis B NZ98/254 Ab, Meningitis B M14459 Ab, Meningitis B M07-0241084 Ab and Meningitis B 96217 Ab.
All subjects in FAS immunogenicity(Days 6 and 31, after booster [follow-on]/D66 and 91 after dose 2[naive]) who were randomized(if naive), received at least 1 study vaccination and provided evaluable results for at least 1 serogroup B strain or serogroups A, C, W, Y at D1, and at least at D6 or D31(follow-on)/D 66 or D91(naive) in extension study.

End point type	Secondary

End point timeframe:

At Day 1, Day 6 and 31(after booster dose of MenABCWY given at 24 months after last MenABCWY vaccination) in ABCWY_0_2, ABCWY_0_6 and ABCWY_0_2_6 groups and at Day 1, Day 66 and 91(i.e. day 6 and 1 month after dose 2 of MenABCWY) in Naive_ABCWY Group

Notes:

[8] - 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: The results in this study were tabulated by age group and study period. Hence for each related endpoint, they are presented for only the respective groups in the baseline period, while the results for multiple endpoints account for all baseline groups.

End point values	ABCWY_0_2	ABCWY_0_6	Naive_ABCWY	ABCWY_0_2_6
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	127	72	96	75
Units: Percentage of subjects				
number (confidence interval 95%)				
M14459,Day1(N-119,72,70,94)	18 (12.0 to 26.6)	26 (16.0 to 37.6)	6 (2.4 to 13.4)	17 (8.9 to 27.3)
M14459, Day 6 Post Vacc(N-119,72,70,94)	64 (54.6 to 72.5)	89 (78.7 to 94.9)	64 (53.3 to 73.5)	82 (71.1 to 90.0)
M14459,1 MTH Post Vacc(N-119,72,70,94)	86 (78.1 to 91.5)	94 (86.0 to 98.4)	72 (62.2 to 81.1)	85 (74.3 to 92.1)
96217, Day 1(N-125,74,72,96)	71 (62.4 to 78.9)	74 (61.9 to 83.3)	32 (23.1 to 42.6)	81 (70.3 to 89.3)
96217,Day 6 Post Vacc(N-125,74,72,96)	98 (94.3 to 99.81)	97 (90.3 to 99.66)	91 (82.9 to 95.6)	100 (95.1 to 100.0)
96217,1 MTH Post Vacc(N-125,74,72,96)	100 (97.1 to 100.0)	100 (95.0 to 100.0)	98 (92.7 to 99.75)	100 (95.1 to 100.0)
NZ98/254, Day 1(N-127,74,71,94)	16 (9.9 to 23.3)	18 (10.1 to 29.3)	2 (0.26 to 7.5)	14 (6.7 to 23.5)
NZ98/254, Day 6 Post Vacc(N-127,74,71,94)	44 (35.3 to 53.2)	66 (54.0 to 77.0)	56 (45.8 to 66.6)	53 (40.7 to 64.4)
NZ98/254,1 MTH Post Vacc(N-127,74,71,94)	69 (60.5 to 77.2)	80 (69.1 to 88.8)	73 (63.3 to 82.0)	70 (58.5 to 80.3)
M07-0241084, Day 1(N-124,75,71,95)	30 (22.0 to 38.7)	37 (25.5 to 48.9)	18 (10.8 to 27.1)	31 (20.5 to 42.4)
M07-0241084, Day 6 Post Vacc(N-124,75,71,95)	65 (55.4 to 72.9)	76 (64.5 to 85.4)	55 (44.2 to 65.0)	72 (60.4 to 81.8)
M07-0241084,1 MTH Post Vacc(N-124,75,71,95)	86 (79.0 to 91.8)	80 (69.1 to 88.8)	62 (51.6 to 71.9)	85 (75.3 to 92.4)
Meningitis A, Day 1(N-122,71,72,93)	16 (9.6 to 23.2)	28 (17.9 to 39.6)	3 (0.7 to 9.1)	25 (15.8 to 37.1)
Meningitis A,Day 6 Post Vacc(N-122,71,72,93)	88 (80.5 to 93.0)	89 (79.3 to 95.1)	82 (72.4 to 89.0)	96 (88.1 to 99.1)
Meningitis A,1 MTH Post Vacc(N-122,71,72,93)	98 (94.2 to 99.80)	99 (92.5 to 99.96)	94 (86.5 to 97.6)	100 (94.9 to 100.0)
Meningitis C, Day 1(N-127,74,72,95)	83 (75.8 to 89.5)	86 (75.9 to 93.1)	32 (22.4 to 41.9)	86 (76.5 to 93.3)
Meningitis C,Day 6 Post Vacc(N-127,74,72,95)	99 (95.7 to 99.98)	99 (92.5 to 99.96)	99 (94.3 to 99.97)	100 (95.1 to 100.0)
Meningitis C,1 MTH Post Vacc(N-127,74,72,95)	100 (97.1 to 100.0)	100 (95.0 to 100.0)	100 (96.2 to 100.0)	100 (95.1 to 100.0)
Meningitis W, Day 1(N-121,71,69,93)	52 (42.8 to 61.2)	64 (51.3 to 75.0)	27 (18.2 to 37.1)	73 (61.4 to 83.1)
Meningitis W,Day 6 Post Vacc(N-121,71,69,93)	99 (95.5 to 99.98)	97 (89.9 to 99.65)	98 (92.4 to 99.74)	99 (92.4 to 99.96)
Meningitis W,1 MTH Post Vacc(N-121,71,69,93)	100 (97.0 to 100.0)	100 (94.8 to 100.0)	98 (92.4 to 99.74)	100 (94.9 to 100.0)
Meningitis Y, Day 1(N-125,72,71,94)	52 (42.9 to 61.0)	62 (49.7 to 73.2)	7 (3.0 to 14.7)	76 (64.9 to 85.6)
Meningitis Y, Day 6 Post Vacc(N-125,72,71,94)	97 (92.0 to 99.1)	97 (90.2 to 99.66)	95 (88.0 to 98.3)	100 (95.0 to 100.0)
Meningitis Y,1 MTH Post Vacc(N-125,72,71,94)	100 (97.1 to 100.0)	99 (92.4 to 99.96)	95 (88.0 to 98.3)	100 (95.0 to 100.0)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentages of Subjects with 4-Fold Increase in HT-hSBA Titers against 4 serogroup B test strains, and against N. meningitidis serogroups A, C, W and Y At Days 6, 31 in Follow-on Subjects in V102_15 and at Day 66, 91 in Naive Subjects, in MenABCWY Groups

End point title	Percentages of Subjects with 4-Fold Increase in HT-hSBA Titers against 4 serogroup B test strains, and against N. meningitidis serogroups A, C, W and Y At Days 6, 31 in Follow-on Subjects in V102_15 and at Day 66, 91 in Naive Subjects, in MenABCWY Groups[9]

End point description:

The immunogenicity of MenABCWY vaccine, was measured as the percentages of subjects with 4-Fold Increase in HT-hSBA Titers against N. meningitidis serogroup B test strains and serogroups A,C, W and Y. The test strains assessed were Meningitis B NZ98/254 Ab, Meningitis B M14459 Ab, Meningitis B M07-0241084 Ab and Meningitis B 96217 Ab. The 4-fold titer rise is defined as: a) for subjects with pre-vaccination hSBA titers LLOQ, a post-vaccination hSBA ≥ 4 LLOQ; b) for subjects with a pre-vaccination hSBA titers ≥ LLOQ, an increase of at least 4 times of the pre-vaccination hSBA.
The analysis was performed on all subjects in FAS immunogenicity(Days 6 and 31, after booster [follow-on]/D66 and 91 after dose 2[naive]) who were randomized(if naive), received at least 1 study vaccination and provided evaluable results for at least 1 serogroup B strain or serogroups A, C, W, Y at D1, and at least at D6 or D31(follow-on)/D 66 or D91(naive) in extension study.

End point type	Secondary

End point timeframe:

At Day 6 and 31(after booster dose of MenABCWY given at 24 months after last MenABCWY vaccination) in ABCWY_0_2, ABCWY_0_6 and ABCWY_0_2_6 groups and at Day 66 and 91(i.e. day 6 and 1 month after dose 2 of MenABCWY) in Naive_ABCWY Group

Notes:

[9] - 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: The results in this study were tabulated by age group and study period. Hence for each related endpoint, they are presented for only the respective groups in the baseline period, while the results for multiple endpoints account for all baseline groups.

End point values	ABCWY_0_2	ABCWY_0_6	Naive_ABCWY	ABCWY_0_2_6
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	127	72	96	75
Units: Percentage of subjects				
number (confidence interval 95%)				
M14459, Day 6 Post Vacc(N-119,72,70,94)	26 (18.4 to 34.9)	50 (37.8 to 62.2)	30 (20.8 to 40.1)	36 (25.1 to 48.3)
M14459, 1 MTH Post Vacc(N-119,72,70,94)	55 (45.2 to 63.8)	64 (51.9 to 75.4)	24 (16.2 to 34.4)	49 (36.7 to 60.7)
96217, Day 6 Post Vacc(N-125,73,72,96)	86 (79.1 to 91.9)	85 (74.3 to 92.1)	65 (54.2 to 74.1)	92 (83.2 to 97.0)
96217,1 MTH Post Vacc(N-125,73,72,96)	90 (83.8 to 94.9)	97 (90.3 to 99.66)	73 (62.9 to 81.5)	95 (86.7 to 98.5)
NZ98/254, Day 6 Post Vacc(N-127,74,71,94)	4 (1.3 to 8.9)	14 (7.0 to 24.4)	24 (16.2 to 34.4)	8 (3.0 to 16.8)
NZ98/254,1 MTH Post Vacc(N-127,74,71,94)	22 (15.2 to 30.3)	14 (7.0 to 24.4)	21 (13.5 to 30.9)	18 (9.7 to 28.2)
M07-0241084, Day 6 Post Vacc(N-124,75,71,95)	14 (8.2 to 21.0)	8 (3.2 to 17.5)	8 (3.7 to 15.9)	11 (4.7 to 19.9)
M07-0241084,1 MTH Post Vacc(N-124,75,71,95)	37 (28.6 to 46.2)	15 (8.0 to 26.0)	16 (9.1 to 24.7)	19 (10.6 to 29.3)
Meningitis A, Day 6 Post Vacc(N-122,71,72,93)	66 (56.4 to 73.9)	75 (63.4 to 85.4)	53 (42.1 to 63.1)	76 (64.5 to 85.4)
Meningitis A,1 MTH Post Vacc(N-122,71,72,93)	82 (74.0 to 88.3)	88 (77.6 to 94.1)	46 (35.8 to 56.9)	85 (74.0 to 92.0)

Meningitis C, Day 6 Post Vacc(N-127,74,72,95)	88 (81.3 to 93.2)	78 (66.4 to 86.7)	83 (74.1 to 90.1)	86 (76.5 to 93.3)
Meningitis C,1 MTH Post Vacc(N-127,74,72,95)	94 (88.0 to 97.2)	93 (84.5 to 97.7)	91 (82.8 to 95.6)	86 (76.5 to 93.3)
Meningitis W, Day 6 Post Vacc(N-121,71,69,93)	80 (71.9 to 86.9)	75 (63.5 to 84.9)	62 (51.7 to 72.2)	85 (74.0 to 92.0)
Meningitis W,1 MTH Post Vacc(N-121,71,69,93)	93 (86.3 to 96.5)	84 (73.3 to 91.8)	71 (60.6 to 79.9)	92 (82.5 to 96.8)
Meningitis Y, Day 6 Post Vacc(N-125,72,71,94)	81 (72.8 to 87.3)	79 (67.6 to 87.7)	78 (67.9 to 85.6)	85 (74.3 to 92.1)
Meningitis Y,1 MTH Post Vacc(N-125,72,71,94)	94 (87.8 to 97.2)	90 (80.7 to 95.9)	83 (73.8 to 89.9)	89 (79.3 to 95.1)

Statistical analyses

No statistical analyses for this end point

Secondary: hSBA GMTs against each of four serogroup B test strains, and against N. meningitidis serogroups A, C, W and Y At Days 1, 6, 31 in Follow-on Subjects in V102_15 and at Day 1, 66, 91 in Naive Subjects, in MenABCWY Groups

End point title	hSBA GMTs against each of four serogroup B test strains, and against N. meningitidis serogroups A, C, W and Y At Days 1, 6, 31 in Follow-on Subjects in V102_15 and at Day 1, 66, 91 in Naive Subjects, in MenABCWY Groups[10]

End point description:

The immunogenicity of MenABCWY vaccine, was measured as the HT-hSBA geometric mean titers (GMTs) against N. meningitidis serogroup B test strains and serogroups A,C, W and Y . The test strains assessed were Meningitis B NZ98/254 Ab, Meningitis B M14459 Ab, Meningitis B M07-0241084 Ab and Meningitis B 96217 Ab.
The analysis was performed on all subjects in FAS immunogenicity(Days 6 and 31, after booster [follow-on]/D66 and 91 after dose 2[naive]) who were randomized(if naive), received at least 1 study vaccination and provided evaluable results for at least 1 serogroup B strain or serogroups A, C, W, Y at D1, and at least at D6 or D31(follow-on)/D 66 or D91(naive) in extension study.

End point type	Secondary

End point timeframe:

At Day 1, Day 6 and 31(after booster dose of MenABCWY given at 24 months after last MenABCWY vaccination) in ABCWY_0_2, ABCWY_0_6 and ABCWY_0_2_6 groups and at Day 1, Day 66 and 91(i.e. day 6 and 1 month after dose 2 of MenABCWY) in Naive_ABCWY Group

Notes:

[10] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The results in this study were tabulated by age group and study period. Hence for each related endpoint, they are presented for only the respective groups in the baseline period, while the results for multiple endpoints account for all baseline groups.

End point values	ABCWY_0_2	ABCWY_0_6	Naive_ABCWY	ABCWY_0_2_6
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	127	72	96	75
Units: Titers				
geometric mean (confidence interval 95%)				
M14459, Day 1(N-119,72,70,94)	2.08 (1.70 to 2.54)	2.62 (2.02 to 3.41)	1.28 (1.02 to 1.61)	2.04 (1.58 to 2.64)
M14459, Day 6 post Vacc(N-119,72,70,94)	13 (9.77 to 18)	40 (27 to 58)	10 (7.48 to 14)	21 (14 to 31)

M14459,1 MTH Post Vacc(N-119,72,70,94)	30 (24 to 39)	61 (44 to 84)	14 (10 to 18)	30 (22 to 42)
96217, Day 1(N-125,74,72,96)	13 (10 to 17)	16 (11 to 23)	3.12 (2.31 to 4.22)	19 (14 to 27)
96217, Day 6 post Vacc(N-125,74,72,96)	376 (287 to 493)	401 (281 to 571)	70 (51 to 95)	486 (343 to 690)
96217 Ab,1 MTH post Vacc(N-125,74,72,96)	587 (496 to 695)	550 (440 to 687)	94 (77 to 114)	524 (421 to 652)
NZ98/254, Day 1(N-127,74,71,94)	1.78 (1.47 to 2.16)	2.17 (1.68 to 2.80)	1.07 (0.85 to 1.33)	1.66 (1.30 to 2.14)
NZ98/254, Day 6 post Vacc(N-127,74,71,94)	6.02 (4.58 to 7.92)	12 (8.56 to 18)	8.95 (6.52 to 12)	7.63 (5.33 to 11)
NZ98/254,1 MTH post Vacc(N-127,74,71,94)	17 (13 to 21)	17 (12 to 23)	14 (10 to 18)	14 (10 to 19)
M07-0241084, Day 1(N-124,75,71,95)	3.97 (3.10 to 5.09)	5.3 (3.81 to 7.35)	2.18 (1.64 to 2.89)	4.22 (3.07 to 5.80)
M07-0241084, Day 6 post Vacc(N-124,75,71,95)	14 (11 to 18)	16 (12 to 23)	8.68 (6.52 to 12)	17 (12 to 24)
M07-0241084,1 MTH Post Vacc(N-124,75,71,95)	32 (26 to 40)	22 (16 to 28)	11 (8.60 to 14)	26 (20 to 34)
Meningitis A, Day 1(N-122,71,72,93)	2.31 (1.75 to 3.04)	5.13 (3.59 to 7.34)	1.22 (0.89 to 1.68)	4.53 (3.16 to 6.48)
Meningitis A, Day 6 post Vacc(N-122,71,72,93)	137 (98 to 191)	229 (149 to 352)	59 (41 to 87)	221 (143 to 341)
Meningitis A,1 MTH post Vacc(N-122,71,72,93)	270 (222 to 327)	340 (264 to 437)	85 (68 to 106)	275 (213 to 354)
Meningitis C, Day 1(N-127,74,72,95)	18 (14 to 23)	21 (15 to 29)	2.91 (2.17 to 3.92)	29 (21 to 41)
Meningitis C,Day 6 post Vacc(N-127,74,72,95)	524 (414 to 662)	520 (381 to 710)	153 (117 to 200)	694 (511 to 942)
Meningitis C,1 MTH post Vacc(N-127,74,72,95)	628 (523 to 753)	539 (423 to 686)	177 (143 to 218)	612 (482 to 776)
Meningitis W, Day 1(N-121,71,69,93)	38 (28 to 51)	44 (30 to 65)	6.25 (4.48 to 8.72)	51 (35 to 75)
Meningitis W,Day 6 post Vacc(N-121,71,69,93)	820 (665 to 1011)	916 (694 to 1208)	279 (220 to 353)	993 (756 to 1304)
Meningitis W,1 MTH post Vacc(N-121,71,69,93)	1345 (1142 to 1584)	999 (805 to 1240)	298 (247 to 359)	1050 (849 to 1299)
Meningitis Y, Day 1(N-125,72,71,94)	9.11 (6.77 to 12)	17 (12 to 25)	1.54 (1.10 to 2.16)	31 (21 to 45)
Meningitis Y,Day 6 Post Vacc(N-125,72,71,94)	351 (274 to 449)	425 (307 to 589)	145 (109 to 192)	606 (439 to 837)
Meningitis Y,1 MTH Post Vacc(N-125,72,71,94)	623 (517 to 750)	586 (458 to 750)	129 (104 to 159)	646 (506 to 824)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentages of Subjects with HT-hSBA Titers ≥ LLOQ against 4 serogroup B test strains at Day 31 After rMenB+OMV Vaccination in V102_15E1

End point title	Percentages of Subjects with HT-hSBA Titers ≥ LLOQ against 4 serogroup B test strains at Day 31 After rMenB+OMV Vaccination in V102_15E1[11]

End point description:

The immunogenicity of rMenB+OMV vaccine, was measured as the percentages of subjects with HT-hSBA titers greater or equal than (≥) Lower limit of quantification (LLOQ) against N. meningitidis serogroup B test strains. The test strains assessed were Meningitis B NZ98/254 Ab, Meningitis B M14459

Ab, Meningitis B M07-0241084 Ab and Meningitis B 96217 Ab.
The analysis was performed on all subjects in the FAS immunogenicity (Day 31, after booster dose[follow-on]/first dose[naive]) who were randomized (if naive),received at least one study vaccination and provided evaluable serum sample with results for at least one serogroup B test strain at Day 31 in the extension study.

End point type	Secondary

End point timeframe:

Day 31: One month after a booster dose of rMenB+OMV given at 24 months after last rMenB+OMVl vaccination in B_0_2 Group and after first dose of rMenB+OMV in Naive_B Group

Notes:

[11] - 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: The results in this study were tabulated by age group and study period. Hence for each related endpoint, they are presented for only the respective groups in the baseline period, while the results for multiple endpoints account for all baseline groups.

End point values	B_0_2	Naive_B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	124	98		
Units: Percentage of subjects				
number (confidence interval 95%)				
Meningitis B M14459 Ab(N-123,96)	94 (88.6 to 97.7)	28 (19.4 to 38.2)		
Meningitis B 96217 Ab	100 (97.1 to 100.0)	74 (64.7 to 82.8)		
Meningitis B NZ98/254 Ab	87 (79.9 to 92.4)	27 (18.1 to 36.4)		
Meningitis B M07-0241084 Ab	95 (89.8 to 98.2)	33 (23.5 to 42.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentages of Subjects with 4-Fold Increase in HT-hSBA Titers against 4 serogroup B test strains at Day 31 After rMenB+OMV Vaccination in V102_15E1

End point title	Percentages of Subjects with 4-Fold Increase in HT-hSBA Titers against 4 serogroup B test strains at Day 31 After rMenB+OMV Vaccination in V102_15E1[12]

End point description:

The immunogenicity of rMenB+OMV vaccine, was measured as the percentages of subjects with 4-Fold Increase in HT-hSBA Titers against N. meningitidis serogroup B test strains. The test strains assessed were Meningitis B NZ98/254 Ab, Meningitis B M14459 Ab, Meningitis B M07-0241084 Ab and Meningitis B 96217 Ab. The 4-fold titer rise is defined as: a) for subjects with pre-vaccination hSBA titers LLOQ, a post-vaccination hSBA ≥ 4 LLOQ; b) for subjects with a pre-vaccination hSBA titers ≥ LLOQ, an increase of at least 4 times of the pre-vaccination hSBA.
The analysis was performed on all subjects in the FAS immunogenicity (Day 31, after booster dose[follow-on]/first dose[naive]) who were randomized (if naive),received at least one study vaccination and provided evaluable serum sample with results for at least one serogroup B test strain at Day 31 in the extension study.

End point type	Secondary

End point timeframe:

Day 31: One month after a booster dose of rMenB+OMV given at 24 months after last rMenB+OMV vaccination in B_0_2 Group and after first dose of rMenB+OMV in Naive_B Group

Notes:

[12] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The results in this study were tabulated by age group and study period. Hence for each related endpoint, they are presented for only the respective groups in the baseline period, while the results for multiple endpoints account for all baseline groups.

End point values	B_0_2	Naive_B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	123	97		
Units: Percentage of subjects				
number (confidence interval 95%)				
Meningitis B M14459 Ab(N-120,95)	67 (57.5 to 75.0)	15 (8.3 to 23.5)		
Meningitis B 96217 Ab(N-122,97)	97 (91.8 to 99.1)	19 (11.4 to 27.7)		
Meningitis B NZ98/254 Ab(N-122,97)	40 (31.4 to 49.4)	16 (9.7 to 25.4)		
Meningitis B M07-0241084 Ab(N-123,95)	53 (43.6 to 61.9)	8 (3.7 to 15.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: hSBA GMTs against each of four serogroup B test strains, at Day 31 After rMenB+OMV Vaccination in V102_15E1

End point title	hSBA GMTs against each of four serogroup B test strains, at Day 31 After rMenB+OMV Vaccination in V102_15E1[13]

End point description:

The immunogenicity of rMenB+OMV vaccine, was measured as the HT-hSBA geometric mean titers (GMTs) against N. meningitidis serogroup B test strains. The test strains assessed were Meningitis B NZ98/254 Ab, Meningitis B M14459 Ab, Meningitis B M07-0241084 Ab and Meningitis B 96217 Ab.
The analysis was performed on all subjects in the FAS immunogenicity (Day 31, after booster dose[follow-on]/first dose[naive]) who were randomized (if naive),received at least one study vaccination and provided evaluable serum sample with results for at least one serogroup B test strain at Day 31 in the extension study.

End point type	Secondary

End point timeframe:

Day 31: One month after a booster dose of rMenB+OMV given at 24 months after last rMenB+OMV vaccination in B_0_2 Group and after first dose of rMenB+OMV in Naive_B Group

Notes:

[13] - 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: The results in this study were tabulated by age group and study period. Hence for each related endpoint, they are presented for only the respective groups in the baseline period, while the results for multiple endpoints account for all baseline groups.

End point values	B_0_2	Naive_B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	124	98		
Units: Titers				
geometric mean (confidence interval 95%)				
Meningitis B M14459 Ab(N-123,96)	50 (39 to 65)	3.48 (2.60 to 4.65)		
Meningitis B 96217 Ab	820 (658 to 1023)	18 (14 to 23)		
Meningitis B NZ98/254 Ab	27 (21 to 35)	3.14 (2.32 to 4.26)		
Meningitis B M07-0241084 Ab	59 (47 to 74)	4.82 (3.72 to 6.24)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentages of subjects with hSBA titers ≥LLOQ against 4 serogroup B test strains at 24 Months At Days 1, 6, 31 in Follow-on Subjects in V102_15 and at Day 1, 66, 91 in Naive Subjects, in rMenB+OMV groups

End point title	Percentages of subjects with hSBA titers ≥LLOQ against 4 serogroup B test strains at 24 Months At Days 1, 6, 31 in Follow-on Subjects in V102_15 and at Day 1, 66, 91 in Naive Subjects, in rMenB+OMV groups[14]

End point description:

The immunogenicity of rMenB+OMV vaccine, was measured as the percentages of subjects with HT-hSBA titers greater or equal than (≥) Lower limit of quantification (LLOQ) against N. meningitidis serogroup B test strains. The test strains assessed were Meningitis B NZ98/254 Ab, Meningitis B M14459 Ab, Meningitis B M07-0241084 Ab and Meningitis B 96217 Ab.
The analysis was performed on all subjects in FAS immunogenicity(Days 6 and 31, after booster[follow-on]/D66 and 91 after dose 2[naive]) who were randomized(if naive), received at least 1 study vaccination and provided evaluable results for at least 1 serogroup B strain or serogroups A, C, W, Y at D1, and at least at D6 or D31(follow-on)/D 66 or D91(naive) in extension study.

End point type	Secondary

End point timeframe:

At Day 1, at Day 6 and 31(after a booster dose of rMenB+OMV given at 24 months after last rMenB+OMV vaccination) in B_0_2 Group, and at Day 1, at Day 66 and 91(i.e. day 6 and 1 month after second dose of rMenB+OMV) in Naive_B Group

Notes:

[14] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The results in this study were tabulated by age group and study period. Hence for each related endpoint, they are presented for only the respective groups in the baseline period, while the results for multiple endpoints account for all baseline groups.

End point values	B_0_2	Naive_B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	122	94		
Units: Percentage of subjects				
number (confidence interval 95%)				
Meningitis B 96217 Ab, Day 1(N-121,94)	82 (73.8 to 88.2)	36 (26.5 to 46.7)		

Meningitis B 96217 Ab, Day 6 Post Vacc(N-121,94)	98 (92.9 to 99.5)	88 (80.0 to 94.0)		
Meningitis B 96217 Ab, 1 month Post Vacc(N-121,94)	100 (97.0 to 100.0)	98 (92.5 to 99.74)		
Meningitis B M07-0241084, Day 1(N-122,92)	28 (20.1 to 36.7)	16 (9.4 to 25.5)		
Meningitis B M07-0241084,Day 6 Post Vacc(N-122,92)	70 (60.7 to 77.7)	57 (45.8 to 66.8)		
Meningitis B M07-0241084,1 MTH Post Vacc(N-122,92)	95 (89.6 to 98.2)	72 (61.4 to 80.6)		
Meningitis B M14459 Ab, Day 1(N-119,94)	18 (11.3 to 25.7)	3 (0.7 to 9.0)		
Meningitis B M14459 Ab, Day 6 Post Vacc(N-119,94)	70 (60.7 to 77.8)	68 (57.7 to 77.3)		
Meningitis B M14459 Ab,1 month Post Vacc(N-119,94)	94 (88.3 to 97.6)	78 (67.9 to 85.6)		
Meningitis B NZ98/254, Day 1(N-121,94)	16 (9.7 to 23.4)	3 (0.7 to 9.0)		
Meningitis B NZ98/254 Ab,Day 6 Post Vacc(N-121,94)	49 (39.6 to 58.0)	62 (51.1 to 71.5)		
Meningitis B NZ98/254 Ab,1 MTH Post Vacc(N-121,94)	87 (79.4 to 92.2)	82 (72.6 to 89.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentages of Subjects with 4-Fold Increase in HT-hSBA Titers against 4 serogroup B test strains At Days 6, 31 in Follow-on Subjects in V102_15 and at Day 66, 91 in Naive Subjects, in rMenB+OMV groups

End point title	Percentages of Subjects with 4-Fold Increase in HT-hSBA Titers against 4 serogroup B test strains At Days 6, 31 in Follow-on Subjects in V102_15 and at Day 66, 91 in Naive Subjects, in rMenB+OMV groups[15]

End point description:

The immunogenicity of rMenB+OMV vaccine, was measured as the percentages of subjects with 4-Fold Increase in HT-hSBA Titers against N. meningitidis serogroup B test strains. The test strains assessed were Meningitis B NZ98/254 Ab, Meningitis B M14459 Ab, Meningitis B M07-0241084 Ab and Meningitis B 96217 Ab. The 4-fold titer rise is defined as: a) for subjects with pre-vaccination hSBA titers LLOQ, a post-vaccination hSBA ≥ 4 LLOQ; b) for subjects with a pre-vaccination hSBA titers ≥ LLOQ, an increase of at least 4 times of the pre-vaccination hSBA.
The analysis was performed on all subjects in FAS immunogenicity(Days 6 and 31, after booster[follow-on]/D66 and 91 after dose 2[naive]) who were randomized(if naive), received at least 1 study vaccination and provided evaluable results for at least 1 serogroup B strain or serogroups A, C, W, Y at D1, and at least at D6 or D31(follow-on)/D 66 or D91(naive) in extension study.

End point type	Secondary

End point timeframe:

At Day 6 and 31(after a booster dose of rMenB+OMV given at 24 months after last rMenB+OMV vaccination) in B_0_2 Group, and at Day 66 and 91(i.e. day 6 and 1 month after second dose of rMenB+OMV) in Naive_B Group

Notes:

[15] - 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: The results in this study were tabulated by age group and study period. Hence for each related endpoint, they are presented for only the respective groups in the baseline period, while the results for multiple endpoints account for all baseline groups.

End point values	B_0_2	Naive_B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	116	78		
Units: Percentage of subjects				
number (confidence interval 95%)				
Meningitis B M14459,Day 6 Post Vacc(N-113,77)	34 (25.0 to 43.1)	22 (13.4 to 33.0)		
Meningitis B M14459,1 MTH Post Vacc(N-113,77)	66 (56.9 to 75.0)	31 (21.1 to 42.7)		
Meningitis B 96217, Day 6 Post Vacc(N-116,77)	78 (69.9 to 85.5)	69 (57.3 to 78.9)		
Meningitis B 96217, 1 MTH Post Vacc(N-116,77)	97 (92.6 to 99.5)	81 (69.9 to 88.7)		
Meningitis B NZ98/254,Day 6 Post Vacc(N-115,78)	13 (7.5 to 20.6)	21 (12.2 to 31.2)		
Meningitis B NZ98/254,1 MTH Post Vacc(N-115,78)	41 (31.8 to 50.4)	41 (30.0 to 52.7)		
Meningitis B M07-0241084,Day 6 Post vacc(N-116,76)	21 (13.7 to 29.2)	14 (7.5 to 24.4)		
Meningitis B M07-0241084,1 MTH Post Vacc(N-116,76)	53 (43.1 to 61.9)	24 (14.7 to 34.8)		

Statistical analyses

No statistical analyses for this end point

Secondary: hSBA GMTs against each of four serogroup B test strains At Days 1, 6, 31 in Follow-on Subjects in V102_15 and at Day 1, 66, 91 in Naive Subjects, in rMenB+OMV groups

End point title	hSBA GMTs against each of four serogroup B test strains At Days 1, 6, 31 in Follow-on Subjects in V102_15 and at Day 1, 66, 91 in Naive Subjects, in rMenB+OMV groups[16]

End point description:

The immunogenicity of rMenB+OMV vaccine, was measured as the HT-hSBA geometric mean titers (GMTs) against N. meningitidis serogroup B test strains. The test strains assessed were Meningitis B NZ98/254 Ab, Meningitis B M14459 Ab, Meningitis B M07-0241084 Ab and Meningitis B 96217 Ab.
The analysis was performed on all subjects in FAS immunogenicity(Days 6 and 31, after booster[follow-on]/D66 and 91 after dose 2[naive]) who were randomized(if naive), received at least 1 study vaccination and provided evaluable results for at least 1 serogroup B strain or serogroups A, C, W, Y at D1, and at least at D6 or D31(follow-on)/D 66 or D91(naive) in extension study.

End point type	Secondary

End point timeframe:

At Day 1, at Day 6 and 31(after a booster dose of rMenB+OMV given at 24 months after last rMenB+OMV vaccination) in B_0_2 Group, and at Day 1, at Day 66 and 91(i.e. day 6 and 1 month after second dose of rMenB+OMV) in Naive_B Group

Notes:

[16] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The results in this study were tabulated by age group and study period. Hence for each related endpoint, they are presented for only the respective groups in the baseline period, while the results for multiple endpoints account for all baseline groups.

End point values	B_0_2	Naive_B		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	122	94		
Units: Titers				
geometric mean (confidence interval 95%)				
Meningitis B M14459 Ab, Day 1(N-119,94)	2.04 (1.67 to 2.49)	1.18 (0.94 to 1.47)		
Meningitis B M14459 Ab,Day 6 post Vacc(N-119,94)	14 (11 to 19)	12 (8.41 to 16)		
Meningitis B M14459 Ab,1 MTH Post Vacc(N-119,94)	49 (38 to 63)	16 (12 to 21)		
Meningitis B 96217 Ab, Day 1(N-121,94)	20 (15 to 26)	4.38 (3.23 to 5.93)		
Meningitis B 96217 Ab,Day 6 post Vacc(N-121,94)	341 (259 to 448)	85 (63 to 116)		
Meningitis B 96217 Ab,1 MTH post Vacc(N-121,94)	822 (692 to 975)	122 (100 to 148)		
Meningitis B NZ98/254 Ab,Day 1(N-121,94)	1.72 (1.41 to 2.09)	1.15 (0.92 to 1.44)		
Meningitis B NZ98/254 Ab,Day 6 post Vacc(N-121,94)	6.39 (4.83 to 8.45)	9.38 (6.83 to 13)		
Meningitis B NZ98/254 Ab,1 MTH post Vacc(N-121,94)	27 (21 to 34)	22 (17 to 29)		
Meningitis B M07-0241084 Ab,Day 1(N-122,92)	4.24 (3.30 to 5.45)	2.36 (1.77 to 3.15)		
Meningitis B M07-0241084,Day 6 post Vacc(N-122,92)	17 (13 to 21)	11 (8.54 to 15)		
Meningitis B M07-0241084,1 MTH post Vacc(N-122,92)	59 (47 to 72)	17 (13 to 22)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any solicited local or systemic AEs and other indicators of reactogenicity within 30 minutes after vaccination

End point title	Number of subjects with any solicited local or systemic AEs and other indicators of reactogenicity within 30 minutes after vaccination

End point description:

Assessed solicited symptoms were Pain, erythema and induration. Assessed solicited systemic symptoms were Fatigue, headache, myalgia, arthralgia, loss of appetite, nausea, chills, and fever (body temperature ≥38.0°C).
Analysis was done on subjects in Solicited Safety Set: all screened subjects who provided informed consent, demographic and/or other baseline screening measurements, regardless of the subject's randomization and vaccination status in the trial, received subject ID and study vaccination, and provided post-vaccination solicited adverse events data.

End point type	Secondary

End point timeframe:

within 30 minutes after vaccination at Day 1 (for all subjects) and also Day 61 (for naive subjects only)

End point values	B_0_2	ABCWY_0_2	Naive_B	ABCWY_0_6
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	126	127	99[17]	74
Units: Participants				
number (not applicable)				
Local: Erythema(N-125,77,74,125,99,101)	0	1	0	1
Local: Induration(N-126,77,74,125,99,101)	0	0	0	0
Local: Pain	11	6	13	3
Systemic: Arthralgia	0	0	0	0
Systemic: Chills	0	0	0	0
Systemic: Fatigue	2	0	2	0
Systemic: Fever	0	0	0	0
Systemic: Headache	0	1	1	1
Systemic: Loss Of Appetite	0	0	0	0
Systemic: Myalgia	0	1	0	0
Systemic: Nausea(N-127,77,74,125,99,101)	1	1	2	0
Indicator: Prevention Of Pain / Fever	0	0	0	0
Indicator: Treatment Of Pain / Fever	0	0	0	0

Notes:

[17] - 2 subjects from Naïve_ABCWY group received Bexsero and not ABCWY(99+2=101 analyzed in this group)

End point values	Naive_ABCWY	ABCWY_0_2_6		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	101[18]	77		
Units: Participants				
number (not applicable)				
Local: Erythema(N-125,77,74,125,99,101)	0	1		
Local: Induration(N-126,77,74,125,99,101)	0	1		
Local: Pain	10	4		
Systemic: Arthralgia	1	0		
Systemic: Chills	0	0		
Systemic: Fatigue	3	1		
Systemic: Fever	0	0		
Systemic: Headache	2	0		
Systemic: Loss Of Appetite	1	0		
Systemic: Myalgia	2	0		
Systemic: Nausea(N-127,77,74,125,99,101)	0	0		
Indicator: Prevention Of Pain / Fever	0	0		
Indicator: Treatment Of Pain / Fever	0	0		

Notes:

[18] - 2 subjects from Naïve_ABCWY group received Bexsero and not ABCWY (101-2=99 analyzed in this group)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any unsolicited AEs within 30 minutes after vaccination

End point title	Number of subjects with any unsolicited AEs within 30 minutes after vaccination

End point description:

An unsolicited adverse event is an adverse event that was not solicited and that was spontaneously communicated by a subject and/or parent/legal guardian who has signed the informed consent. Number of subjects reporting any unsolicited AE within 30 minutes after each vaccination. Note: unsolicited AEs within 30 minutes were not collected
Analysis was to be done on subjects in Unsolicited Safety Set but was not performed as AEs within 30 minutes after vaccination were not collected.

End point type	Secondary

End point timeframe:

Within 30 minutes after vaccination at Day 1 (for all subjects) and also Day 61 (for naive subjects only)

End point values	B_0_2	ABCWY_0_2	Naive_B	ABCWY_0_6
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[19]	0[20]	0[21]	0[22]
Units: Participants				
number (not applicable)				

Notes:

[19] - unsolicited AEs within 30 minutes were not collected

[20] - unsolicited AEs within 30 minutes were not collected

[21] - unsolicited AEs within 30 minutes were not collected

[22] - unsolicited AEs within 30 minutes were not collected

End point values	Naive_ABCWY	ABCWY_0_2_6		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0[23]	0[24]		
Units: Participants				
number (not applicable)				

Notes:

[23] - unsolicited AEs within 30 minutes were not collected

[24] - unsolicited AEs within 30 minutes were not collected

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any solicited local or systemic adverse events (AEs) and other indicators of reactogenicity from Day 1 to Day 7.

End point title	Number of subjects with any solicited local or systemic adverse events (AEs) and other indicators of reactogenicity from Day 1 to Day 7.

End point description:

Assessed solicited symptoms were pain, erythema and induration. Assessed solicited systemic symptoms were Fatigue, headache, myalgia, arthralgia, loss of appetite, nausea, chills, and fever (body temperature ≥38.0°C).
Analysis was done on subjects in Solicited Safety Set: all screened subjects who provided informed consent, demographic and/or other baseline screening measurements, regardless of the subject's randomization and vaccination status in the trial, received subject ID and study vaccination, and provided post-vaccination solicited adverse events data.

End point type	Secondary

End point timeframe:

At Day 1 (6 hours) to Day 7 after vaccination at Day 1 (for all subjects) and Day 61 to Day 67 (for naive subjects only)

End point values	B_0_2	ABCWY_0_2	Naive_B	ABCWY_0_6
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	126	127	99[25]	74
Units: Participants				
number (not applicable)				
Local: Erythema	22	22	20	14
Local: Induration	20	18	15	6
Local: Pain	115	108	93	64
Systemic: Arthralgia	15	12	17	9
Systemic: Chills	27	23	26	12
Systemic: Fatigue	64	58	55	31
Systemic: Fever	6	8	6	1
Systemic: Headache	61	55	45	28
Systemic: Loss Of Appetite	20	15	16	7
Systemic: Myalgia	22	26	21	14
Systemic: Nausea	24	13	19	8
Indicator: Prevention Of Pain / Fever	29	21	26	8
Indicator: Treatment Of Pain / Fever	56	37	39	19

Notes:

[25] - 2 subjects from Naïve_ABCWY group received Bexsero and not ABCWY(99+2=101 analyzed in this group)

End point values	Naive_ABCWY	ABCWY_0_2_6		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	101[26]	77		
Units: Participants				
number (not applicable)				
Local: Erythema	23	10		
Local: Induration	22	14		
Local: Pain	95	67		
Systemic: Arthralgia	19	5		
Systemic: Chills	25	8		
Systemic: Fatigue	59	33		
Systemic: Fever	3	3		
Systemic: Headache	61	19		
Systemic: Loss Of Appetite	20	9		
Systemic: Myalgia	26	13		
Systemic: Nausea	20	8		
Indicator: Prevention Of Pain / Fever	24	8		
Indicator: Treatment Of Pain / Fever	47	18		

Notes:

[26] - 2 subjects from Naïve_ABCWY group received Bexsero and not ABCWY (101-2=99 analyzed in this group)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with unsolicited AEs, 30 days after any vaccination

End point title	Number of subjects with unsolicited AEs, 30 days after any vaccination

End point description:

An unsolicited adverse event is an adverse event that was not solicited and that was spontaneously communicated by a subject and/or parent/legal guardian who has signed the informed consent. Number of subjects reporting any unsolicited AE within 30 minutes after each vaccination.
Analysis was done on subjects in Unsolicited Safety Set: all screened subjects who provided informed consent, demographic and/or other baseline screening measurements, regardless of subject's randomization and vaccination status in the trial, received subject ID and study vaccination, and provided post-vaccination unsolicited adverse events data.

End point type	Secondary

End point timeframe:

From Day 1 to Day 31 for all subjects and Day 61 to Day 91 for naive subjects

End point values	B_0_2	ABCWY_0_2	Naive_B	ABCWY_0_6
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	126	127	99[27]	74
Units: Participants				
number (not applicable)	26	27	36	10

Notes:

[27] - 2 subjects from Naïve_ABCWY group received Bexsero and not ABCWY(99+2=101 analyzed in this group)

End point values	Naive_ABCWY	ABCWY_0_2_6		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	101[28]	77		
Units: Participants				
number (not applicable)	40	12		

Notes:

[28] - 2 subjects from Naïve_ABCWY group received Bexsero and not ABCWY (101-2=99 analyzed in this group)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any serious AE (SAE), medically attended AEs (MAAEs), AEs leading to premature withdrawal

End point title	Number of subjects with any serious AE (SAE), medically attended AEs (MAAEs), AEs leading to premature withdrawal

End point description:

Serious adverse events (SAEs), medically attended adverse events & AEs leading to withdrawal are reported. An SAE is defined as any untoward medical occurrence that at any dose results in one or more of the following: Death,Is life-threatening,Required or prolonged hospitalization,Persistent or significant disability/incapacity,congenital anomaly/or birth defect,An important and significant medical event that may not be immediately life threatening or resulting in death or hospitalization but, based upon appropriate medical judgment, may jeopardize the subject or may require intervention to prevent one of the other outcomes listed above.Analysis was done on subjects in Unsolicited Safety Set: all screened subjects who provided informed consent, demographic &/or other baseline screening measurements,

regardless of subject's randomization & vaccination status in the trial, received subject ID & study vaccination & provided post-vaccination unsolicited adverse events data

End point type	Secondary

End point timeframe:

During the entire study period (up to Day 181 for follow-on subjects and up to Day 241 for naive subjects)

End point values	B_0_2	ABCWY_0_2	Naive_B	ABCWY_0_6
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	126	127	99[29]	74
Units: Participants				
number (not applicable)				
Any medically attended AE	20	18	21	8
Any serious AE	2	0	1	0
AEs leading to premature withdrawal	0	0	0	0

Notes:

[29] - 2 subjects from Naïve_ABCWY group received Bexsero and not ABCWY(99+2=101 analyzed in this group)

End point values	Naive_ABCWY	ABCWY_0_2_6		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	101[30]	77		
Units: Participants				
number (not applicable)				
Any medically attended AE	24	7		
Any serious AE	0	0		
AEs leading to premature withdrawal	0	0		

Notes:

[30] - 2 subjects from Naïve_ABCWY group received Bexsero and not ABCWY (101-2=99 analyzed in this group)

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Solicited AEs were collected from Day 1 to Day 7, and Unsolicited AEs from Day 1 to Day 30, after any vaccination. SAEs were collected throughout the entire study period (up to Day 181 for follow-on subjects and up to Day 241 for naive subjects).

Adverse event reporting additional description:

Safety analysis was performed on the treated population.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	21.0

Reporting groups

Reporting group title	B_0_2

Reporting group description:

Subjects who received 2 doses of rMenB+OMV vaccine at Month 0 and Month 2 in study V102_15 (NCT02212457), and will receive 1 dose of rMenB+OMV in this extension study

Reporting group title	ABCWY_0_2

Reporting group description:

Subjects who received 2 doses of MenABCWY vaccine at Month 0 and Month 2 in study V102_15 (NCT02212457), and will receive 1 dose of MenABCWY in this extension study

Reporting group title	Naive_B

Reporting group description:

Subjects who are meningococcal vaccine-naive and of similar age to subjects enrolled from the parent study (NCT02212457), and will receive 2 doses of rMenB+OMV in this extension study

Reporting group title	ABCWY_0_6

Reporting group description:

Subjects who received 2 doses of MenABCWY vaccine at Month 0 and Month 6 in study V102_15 (NCT02212457), and will receive 1 dose of MenABCWY in this extension study

Reporting group title	Naive_ABCWY

Reporting group description:

Subjects who are meningococcal vaccine-naive and of similar age to subjects enrolled from the parent study (NCT02212457), and will receive 2 doses of MenABCWY in this extension study

Reporting group title	ABCWY_0_2_6

Reporting group description:

Subjects who received 3 doses of MenABCWY vaccine at Month 0, Month 2 and Month 6 in study V102_15 (NCT02212457), and will receive 1 dose of MenABCWY in this extension study

Serious adverse events	B_0_2	ABCWY_0_2	Naive_B
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 126 (1.59%)	0 / 127 (0.00%)	1 / 101 (0.99%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Nervous system disorders			
Headache			

subjects affected / exposed	0 / 126 (0.00%)	0 / 127 (0.00%)	1 / 101 (0.99%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Depression			
subjects affected / exposed	1 / 126 (0.79%)	0 / 127 (0.00%)	0 / 101 (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
Infections and infestations			
Gastroenteritis			
subjects affected / exposed	1 / 126 (0.79%)	0 / 127 (0.00%)	0 / 101 (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

Serious adverse events	ABCWY_0_6	Naive_ABCWY	ABCWY_0_2_6
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 74 (0.00%)	0 / 99 (0.00%)	0 / 77 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 74 (0.00%)	0 / 99 (0.00%)	0 / 77 (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			
Depression			
subjects affected / exposed	0 / 74 (0.00%)	0 / 99 (0.00%)	0 / 77 (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			
Gastroenteritis			
subjects affected / exposed	0 / 74 (0.00%)	0 / 99 (0.00%)	0 / 77 (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

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	B_0_2	ABCWY_0_2	Naive_B
Total subjects affected by non-serious adverse events			
subjects affected / exposed	120 / 126 (95.24%)	116 / 127 (91.34%)	99 / 101 (98.02%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Skin papilloma			
subjects affected / exposed	0 / 126 (0.00%)	0 / 127 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	0 / 126 (0.00%)	0 / 127 (0.00%)	1 / 101 (0.99%)
occurrences (all)	0	0	1
Chills			
subjects affected / exposed	27 / 126 (21.43%)	23 / 127 (18.11%)	26 / 101 (25.74%)
occurrences (all)	50	39	62
Fatigue			
subjects affected / exposed	64 / 126 (50.79%)	58 / 127 (45.67%)	55 / 101 (54.46%)
occurrences (all)	164	114	206
Hangover			
subjects affected / exposed	0 / 126 (0.00%)	0 / 127 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 126 (0.00%)	0 / 127 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Injection site erythema			
subjects affected / exposed	59 / 126 (46.83%)	50 / 127 (39.37%)	49 / 101 (48.51%)
occurrences (all)	129	100	137
Injection site haemorrhage			
subjects affected / exposed	0 / 126 (0.00%)	0 / 127 (0.00%)	2 / 101 (1.98%)
occurrences (all)	0	0	2
Injection site induration			
subjects affected / exposed	40 / 126 (31.75%)	43 / 127 (33.86%)	43 / 101 (42.57%)
occurrences (all)	117	107	172
Injection site pain			

subjects affected / exposed	116 / 126 (92.06%)	108 / 127 (85.04%)	93 / 101 (92.08%)
occurrences (all)	421	321	683
Injection site pruritus			
subjects affected / exposed	0 / 126 (0.00%)	0 / 127 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Injection site rash			
subjects affected / exposed	0 / 126 (0.00%)	0 / 127 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Injection site reaction			
subjects affected / exposed	0 / 126 (0.00%)	1 / 127 (0.79%)	0 / 101 (0.00%)
occurrences (all)	0	1	0
Injection site swelling			
subjects affected / exposed	0 / 126 (0.00%)	0 / 127 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Injection site warmth			
subjects affected / exposed	0 / 126 (0.00%)	0 / 127 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 126 (0.00%)	0 / 127 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 126 (0.00%)	1 / 127 (0.79%)	0 / 101 (0.00%)
occurrences (all)	0	1	0
Pyrexia			
subjects affected / exposed	7 / 126 (5.56%)	10 / 127 (7.87%)	6 / 101 (5.94%)
occurrences (all)	7	11	6
Vaccination site pain			
subjects affected / exposed	0 / 126 (0.00%)	0 / 127 (0.00%)	1 / 101 (0.99%)
occurrences (all)	0	0	1
Immune system disorders			
Allergy to animal			
subjects affected / exposed	1 / 126 (0.79%)	0 / 127 (0.00%)	0 / 101 (0.00%)
occurrences (all)	1	0	0
Hypersensitivity			
subjects affected / exposed	1 / 126 (0.79%)	0 / 127 (0.00%)	0 / 101 (0.00%)
occurrences (all)	1	0	0

Seasonal allergy			
subjects affected / exposed	0 / 126 (0.00%)	1 / 127 (0.79%)	0 / 101 (0.00%)
occurrences (all)	0	1	0
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	1 / 126 (0.79%)	1 / 127 (0.79%)	3 / 101 (2.97%)
occurrences (all)	1	1	5
Scrotal varicose veins			
subjects affected / exposed	0 / 126 (0.00%)	0 / 127 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	1 / 126 (0.79%)	0 / 127 (0.00%)	0 / 101 (0.00%)
occurrences (all)	1	0	0
Cough			
subjects affected / exposed	1 / 126 (0.79%)	0 / 127 (0.00%)	0 / 101 (0.00%)
occurrences (all)	1	0	0
Epistaxis			
subjects affected / exposed	1 / 126 (0.79%)	0 / 127 (0.00%)	0 / 101 (0.00%)
occurrences (all)	1	0	0
Nasal congestion			
subjects affected / exposed	0 / 126 (0.00%)	0 / 127 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	1 / 126 (0.79%)	0 / 127 (0.00%)	2 / 101 (1.98%)
occurrences (all)	1	0	2
Rhinitis allergic			
subjects affected / exposed	1 / 126 (0.79%)	0 / 127 (0.00%)	0 / 101 (0.00%)
occurrences (all)	1	0	0
Rhinorrhoea			
subjects affected / exposed	1 / 126 (0.79%)	0 / 127 (0.00%)	1 / 101 (0.99%)
occurrences (all)	1	0	1
Sinus polyp			
subjects affected / exposed	0 / 126 (0.00%)	0 / 127 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract irritation			

subjects affected / exposed	0 / 126 (0.00%)	0 / 127 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 126 (0.79%)	0 / 127 (0.00%)	0 / 101 (0.00%)
occurrences (all)	1	0	0
Dyssomnia			
subjects affected / exposed	0 / 126 (0.00%)	0 / 127 (0.00%)	1 / 101 (0.99%)
occurrences (all)	0	0	1
Investigations			
Body temperature increased			
subjects affected / exposed	0 / 126 (0.00%)	0 / 127 (0.00%)	1 / 101 (0.99%)
occurrences (all)	0	0	1
Injury, poisoning and procedural complications			
Clavicle fracture			
subjects affected / exposed	0 / 126 (0.00%)	1 / 127 (0.79%)	0 / 101 (0.00%)
occurrences (all)	0	1	0
Hand fracture			
subjects affected / exposed	0 / 126 (0.00%)	0 / 127 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Ligament rupture			
subjects affected / exposed	0 / 126 (0.00%)	0 / 127 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			
subjects affected / exposed	1 / 126 (0.79%)	0 / 127 (0.00%)	0 / 101 (0.00%)
occurrences (all)	1	0	0
Nail injury			
subjects affected / exposed	0 / 126 (0.00%)	0 / 127 (0.00%)	1 / 101 (0.99%)
occurrences (all)	0	0	1
Post procedural complication			
subjects affected / exposed	0 / 126 (0.00%)	0 / 127 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Wrist fracture			
subjects affected / exposed	0 / 126 (0.00%)	0 / 127 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			

Dizziness			
subjects affected / exposed	0 / 126 (0.00%)	0 / 127 (0.00%)	1 / 101 (0.99%)
occurrences (all)	0	0	1
Headache			
subjects affected / exposed	62 / 126 (49.21%)	55 / 127 (43.31%)	46 / 101 (45.54%)
occurrences (all)	132	96	160
Hypoaesthesia			
subjects affected / exposed	0 / 126 (0.00%)	0 / 127 (0.00%)	1 / 101 (0.99%)
occurrences (all)	0	0	1
Migraine			
subjects affected / exposed	1 / 126 (0.79%)	0 / 127 (0.00%)	0 / 101 (0.00%)
occurrences (all)	1	0	0
Migraine-triggered seizure			
subjects affected / exposed	0 / 126 (0.00%)	0 / 127 (0.00%)	1 / 101 (0.99%)
occurrences (all)	0	0	1
Syncope			
subjects affected / exposed	0 / 126 (0.00%)	0 / 127 (0.00%)	1 / 101 (0.99%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
Iron deficiency anaemia			
subjects affected / exposed	0 / 126 (0.00%)	0 / 127 (0.00%)	1 / 101 (0.99%)
occurrences (all)	0	0	1
Lymphadenopathy			
subjects affected / exposed	0 / 126 (0.00%)	0 / 127 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Microcytic anaemia			
subjects affected / exposed	1 / 126 (0.79%)	0 / 127 (0.00%)	0 / 101 (0.00%)
occurrences (all)	1	0	0
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 126 (0.00%)	0 / 127 (0.00%)	1 / 101 (0.99%)
occurrences (all)	0	0	2
Eye disorders			
Swelling of eyelid			
subjects affected / exposed	0 / 126 (0.00%)	0 / 127 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Vision blurred			

subjects affected / exposed	1 / 126 (0.79%)	0 / 127 (0.00%)	0 / 101 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 126 (0.79%)	1 / 127 (0.79%)	0 / 101 (0.00%)
occurrences (all)	1	1	0
Abdominal pain upper			
subjects affected / exposed	0 / 126 (0.00%)	1 / 127 (0.79%)	1 / 101 (0.99%)
occurrences (all)	0	1	1
Diarrhoea			
subjects affected / exposed	1 / 126 (0.79%)	1 / 127 (0.79%)	0 / 101 (0.00%)
occurrences (all)	1	1	0
Dyspepsia			
subjects affected / exposed	1 / 126 (0.79%)	1 / 127 (0.79%)	0 / 101 (0.00%)
occurrences (all)	2	1	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 126 (0.00%)	1 / 127 (0.79%)	0 / 101 (0.00%)
occurrences (all)	0	1	0
Nausea			
subjects affected / exposed	26 / 126 (20.63%)	13 / 127 (10.24%)	21 / 101 (20.79%)
occurrences (all)	39	20	39
Noninfective sialoadenitis			
subjects affected / exposed	0 / 126 (0.00%)	0 / 127 (0.00%)	1 / 101 (0.99%)
occurrences (all)	0	0	1
Retching			
subjects affected / exposed	1 / 126 (0.79%)	0 / 127 (0.00%)	0 / 101 (0.00%)
occurrences (all)	1	0	0
Tooth impacted			
subjects affected / exposed	0 / 126 (0.00%)	0 / 127 (0.00%)	1 / 101 (0.99%)
occurrences (all)	0	0	1
Tooth loss			
subjects affected / exposed	0 / 126 (0.00%)	0 / 127 (0.00%)	1 / 101 (0.99%)
occurrences (all)	0	0	1
Toothache			
subjects affected / exposed	1 / 126 (0.79%)	1 / 127 (0.79%)	0 / 101 (0.00%)
occurrences (all)	1	1	0

Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 126 (0.00%)	2 / 127 (1.57%)	2 / 101 (1.98%)
occurrences (all)	0	2	2
Alopecia			
subjects affected / exposed	0 / 126 (0.00%)	0 / 127 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	0 / 126 (0.00%)	0 / 127 (0.00%)	1 / 101 (0.99%)
occurrences (all)	0	0	1
Dermatitis contact			
subjects affected / exposed	0 / 126 (0.00%)	0 / 127 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 126 (0.00%)	0 / 127 (0.00%)	1 / 101 (0.99%)
occurrences (all)	0	0	1
Pruritus			
subjects affected / exposed	0 / 126 (0.00%)	0 / 127 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Psoriasis			
subjects affected / exposed	0 / 126 (0.00%)	1 / 127 (0.79%)	0 / 101 (0.00%)
occurrences (all)	0	1	0
Rash			
subjects affected / exposed	0 / 126 (0.00%)	0 / 127 (0.00%)	1 / 101 (0.99%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	15 / 126 (11.90%)	13 / 127 (10.24%)	17 / 101 (16.83%)
occurrences (all)	33	21	33
Bursitis			
subjects affected / exposed	0 / 126 (0.00%)	0 / 127 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 126 (0.00%)	0 / 127 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			

subjects affected / exposed	0 / 126 (0.00%)	0 / 127 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	22 / 126 (17.46%)	26 / 127 (20.47%)	21 / 101 (20.79%)
occurrences (all)	42	36	40
Neck pain			
subjects affected / exposed	0 / 126 (0.00%)	0 / 127 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 126 (0.00%)	1 / 127 (0.79%)	0 / 101 (0.00%)
occurrences (all)	0	1	0
Spinal flattening			
subjects affected / exposed	0 / 126 (0.00%)	0 / 127 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	1 / 126 (0.79%)	0 / 127 (0.00%)	2 / 101 (1.98%)
occurrences (all)	1	0	2
Cellulitis			
subjects affected / exposed	0 / 126 (0.00%)	0 / 127 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Chlamydial infection			
subjects affected / exposed	0 / 126 (0.00%)	1 / 127 (0.79%)	0 / 101 (0.00%)
occurrences (all)	0	1	0
Conjunctivitis			
subjects affected / exposed	1 / 126 (0.79%)	0 / 127 (0.00%)	1 / 101 (0.99%)
occurrences (all)	1	0	1
Cystitis			
subjects affected / exposed	0 / 126 (0.00%)	0 / 127 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	2 / 126 (1.59%)	1 / 127 (0.79%)	0 / 101 (0.00%)
occurrences (all)	2	1	0
Gastroenteritis			
subjects affected / exposed	0 / 126 (0.00%)	2 / 127 (1.57%)	1 / 101 (0.99%)
occurrences (all)	0	2	1

Infectious mononucleosis			
subjects affected / exposed	0 / 126 (0.00%)	0 / 127 (0.00%)	1 / 101 (0.99%)
occurrences (all)	0	0	1
Influenza			
subjects affected / exposed	4 / 126 (3.17%)	1 / 127 (0.79%)	0 / 101 (0.00%)
occurrences (all)	4	1	0
Nasopharyngitis			
subjects affected / exposed	4 / 126 (3.17%)	1 / 127 (0.79%)	3 / 101 (2.97%)
occurrences (all)	5	1	4
Otitis media			
subjects affected / exposed	1 / 126 (0.79%)	0 / 127 (0.00%)	0 / 101 (0.00%)
occurrences (all)	1	0	0
Peritonsillar abscess			
subjects affected / exposed	0 / 126 (0.00%)	0 / 127 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	1 / 126 (0.79%)	8 / 127 (6.30%)	2 / 101 (1.98%)
occurrences (all)	1	8	2
Pharyngitis bacterial			
subjects affected / exposed	0 / 126 (0.00%)	0 / 127 (0.00%)	2 / 101 (1.98%)
occurrences (all)	0	0	2
Pneumonia			
subjects affected / exposed	1 / 126 (0.79%)	0 / 127 (0.00%)	1 / 101 (0.99%)
occurrences (all)	1	0	1
Pyelonephritis			
subjects affected / exposed	0 / 126 (0.00%)	0 / 127 (0.00%)	1 / 101 (0.99%)
occurrences (all)	0	0	1
Respiratory tract infection			
subjects affected / exposed	1 / 126 (0.79%)	0 / 127 (0.00%)	0 / 101 (0.00%)
occurrences (all)	1	0	0
Respiratory tract infection viral			
subjects affected / exposed	0 / 126 (0.00%)	1 / 127 (0.79%)	0 / 101 (0.00%)
occurrences (all)	0	1	0
Rhinitis			
subjects affected / exposed	1 / 126 (0.79%)	0 / 127 (0.00%)	1 / 101 (0.99%)
occurrences (all)	1	0	1

Sinusitis			
subjects affected / exposed	1 / 126 (0.79%)	0 / 127 (0.00%)	2 / 101 (1.98%)
occurrences (all)	2	0	2
Tonsillitis			
subjects affected / exposed	1 / 126 (0.79%)	3 / 127 (2.36%)	0 / 101 (0.00%)
occurrences (all)	1	4	0
Tonsillitis bacterial			
subjects affected / exposed	1 / 126 (0.79%)	0 / 127 (0.00%)	0 / 101 (0.00%)
occurrences (all)	1	0	0
Tonsillitis streptococcal			
subjects affected / exposed	0 / 126 (0.00%)	0 / 127 (0.00%)	1 / 101 (0.99%)
occurrences (all)	0	0	1
Tooth infection			
subjects affected / exposed	1 / 126 (0.79%)	0 / 127 (0.00%)	2 / 101 (1.98%)
occurrences (all)	1	0	2
Tracheitis			
subjects affected / exposed	0 / 126 (0.00%)	0 / 127 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	5 / 126 (3.97%)	8 / 127 (6.30%)	11 / 101 (10.89%)
occurrences (all)	5	8	13
Urinary tract infection			
subjects affected / exposed	1 / 126 (0.79%)	1 / 127 (0.79%)	0 / 101 (0.00%)
occurrences (all)	1	1	0
Viral pharyngitis			
subjects affected / exposed	0 / 126 (0.00%)	0 / 127 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 126 (0.00%)	0 / 127 (0.00%)	1 / 101 (0.99%)
occurrences (all)	0	0	1
Wound infection			
subjects affected / exposed	0 / 126 (0.00%)	0 / 127 (0.00%)	1 / 101 (0.99%)
occurrences (all)	0	0	1
Metabolism and nutrition disorders			
Decreased appetite			

subjects affected / exposed	20 / 126 (15.87%)	15 / 127 (11.81%)	16 / 101 (15.84%)
occurrences (all)	39	15	38

Non-serious adverse events	ABCWY_0_6	Naive_ABCWY	ABCWY_0_2_6
Total subjects affected by non-serious adverse events			
subjects affected / exposed	67 / 74 (90.54%)	96 / 99 (96.97%)	70 / 77 (90.91%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Skin papilloma			
subjects affected / exposed	0 / 74 (0.00%)	1 / 99 (1.01%)	0 / 77 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	0 / 74 (0.00%)	0 / 99 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	12 / 74 (16.22%)	25 / 99 (25.25%)	8 / 77 (10.39%)
occurrences (all)	20	51	12
Fatigue			
subjects affected / exposed	31 / 74 (41.89%)	59 / 99 (59.60%)	33 / 77 (42.86%)
occurrences (all)	77	201	67
Hangover			
subjects affected / exposed	0 / 74 (0.00%)	0 / 99 (0.00%)	1 / 77 (1.30%)
occurrences (all)	0	0	1
Influenza like illness			
subjects affected / exposed	0 / 74 (0.00%)	1 / 99 (1.01%)	0 / 77 (0.00%)
occurrences (all)	0	1	0
Injection site erythema			
subjects affected / exposed	27 / 74 (36.49%)	45 / 99 (45.45%)	23 / 77 (29.87%)
occurrences (all)	67	148	53
Injection site haemorrhage			
subjects affected / exposed	0 / 74 (0.00%)	0 / 99 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Injection site induration			
subjects affected / exposed	18 / 74 (24.32%)	46 / 99 (46.46%)	23 / 77 (29.87%)
occurrences (all)	51	200	58
Injection site pain			

subjects affected / exposed	64 / 74 (86.49%)	95 / 99 (95.96%)	67 / 77 (87.01%)
occurrences (all)	226	593	227
Injection site pruritus			
subjects affected / exposed	0 / 74 (0.00%)	0 / 99 (0.00%)	1 / 77 (1.30%)
occurrences (all)	0	0	1
Injection site rash			
subjects affected / exposed	0 / 74 (0.00%)	1 / 99 (1.01%)	0 / 77 (0.00%)
occurrences (all)	0	1	0
Injection site reaction			
subjects affected / exposed	0 / 74 (0.00%)	0 / 99 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Injection site swelling			
subjects affected / exposed	1 / 74 (1.35%)	0 / 99 (0.00%)	0 / 77 (0.00%)
occurrences (all)	1	0	0
Injection site warmth			
subjects affected / exposed	1 / 74 (1.35%)	2 / 99 (2.02%)	0 / 77 (0.00%)
occurrences (all)	1	2	0
Malaise			
subjects affected / exposed	0 / 74 (0.00%)	1 / 99 (1.01%)	0 / 77 (0.00%)
occurrences (all)	0	1	0
Pain			
subjects affected / exposed	0 / 74 (0.00%)	0 / 99 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	1 / 74 (1.35%)	5 / 99 (5.05%)	4 / 77 (5.19%)
occurrences (all)	1	6	5
Vaccination site pain			
subjects affected / exposed	0 / 74 (0.00%)	0 / 99 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Allergy to animal			
subjects affected / exposed	0 / 74 (0.00%)	0 / 99 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Hypersensitivity			
subjects affected / exposed	0 / 74 (0.00%)	1 / 99 (1.01%)	0 / 77 (0.00%)
occurrences (all)	0	1	0

Seasonal allergy			
subjects affected / exposed	0 / 74 (0.00%)	0 / 99 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	3 / 74 (4.05%)	2 / 99 (2.02%)	0 / 77 (0.00%)
occurrences (all)	3	2	0
Scrotal varicose veins			
subjects affected / exposed	0 / 74 (0.00%)	1 / 99 (1.01%)	0 / 77 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 74 (0.00%)	0 / 99 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 74 (0.00%)	0 / 99 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 74 (0.00%)	0 / 99 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 74 (0.00%)	1 / 99 (1.01%)	0 / 77 (0.00%)
occurrences (all)	0	1	0
Oropharyngeal pain			
subjects affected / exposed	0 / 74 (0.00%)	2 / 99 (2.02%)	0 / 77 (0.00%)
occurrences (all)	0	2	0
Rhinitis allergic			
subjects affected / exposed	1 / 74 (1.35%)	2 / 99 (2.02%)	0 / 77 (0.00%)
occurrences (all)	1	2	0
Rhinorrhoea			
subjects affected / exposed	0 / 74 (0.00%)	0 / 99 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Sinus polyp			
subjects affected / exposed	0 / 74 (0.00%)	0 / 99 (0.00%)	1 / 77 (1.30%)
occurrences (all)	0	0	1
Upper respiratory tract irritation			

subjects affected / exposed	0 / 74 (0.00%)	1 / 99 (1.01%)	0 / 77 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 74 (0.00%)	0 / 99 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Dyssomnia			
subjects affected / exposed	0 / 74 (0.00%)	0 / 99 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Investigations			
Body temperature increased			
subjects affected / exposed	0 / 74 (0.00%)	0 / 99 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Clavicle fracture			
subjects affected / exposed	0 / 74 (0.00%)	0 / 99 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Hand fracture			
subjects affected / exposed	0 / 74 (0.00%)	1 / 99 (1.01%)	0 / 77 (0.00%)
occurrences (all)	0	1	0
Ligament rupture			
subjects affected / exposed	0 / 74 (0.00%)	1 / 99 (1.01%)	0 / 77 (0.00%)
occurrences (all)	0	1	0
Ligament sprain			
subjects affected / exposed	1 / 74 (1.35%)	1 / 99 (1.01%)	0 / 77 (0.00%)
occurrences (all)	1	1	0
Nail injury			
subjects affected / exposed	0 / 74 (0.00%)	0 / 99 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Post procedural complication			
subjects affected / exposed	0 / 74 (0.00%)	0 / 99 (0.00%)	1 / 77 (1.30%)
occurrences (all)	0	0	1
Wrist fracture			
subjects affected / exposed	0 / 74 (0.00%)	0 / 99 (0.00%)	1 / 77 (1.30%)
occurrences (all)	0	0	1
Nervous system disorders			

Dizziness			
subjects affected / exposed	0 / 74 (0.00%)	2 / 99 (2.02%)	0 / 77 (0.00%)
occurrences (all)	0	3	0
Headache			
subjects affected / exposed	28 / 74 (37.84%)	62 / 99 (62.63%)	20 / 77 (25.97%)
occurrences (all)	64	183	41
Hypoaesthesia			
subjects affected / exposed	0 / 74 (0.00%)	0 / 99 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 74 (0.00%)	0 / 99 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Migraine-triggered seizure			
subjects affected / exposed	0 / 74 (0.00%)	0 / 99 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 74 (0.00%)	0 / 99 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Iron deficiency anaemia			
subjects affected / exposed	0 / 74 (0.00%)	0 / 99 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 74 (0.00%)	1 / 99 (1.01%)	0 / 77 (0.00%)
occurrences (all)	0	1	0
Microcytic anaemia			
subjects affected / exposed	0 / 74 (0.00%)	0 / 99 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 74 (0.00%)	1 / 99 (1.01%)	0 / 77 (0.00%)
occurrences (all)	0	1	0
Eye disorders			
Swelling of eyelid			
subjects affected / exposed	0 / 74 (0.00%)	0 / 99 (0.00%)	1 / 77 (1.30%)
occurrences (all)	0	0	1
Vision blurred			

subjects affected / exposed	0 / 74 (0.00%)	0 / 99 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 74 (0.00%)	0 / 99 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 74 (0.00%)	1 / 99 (1.01%)	1 / 77 (1.30%)
occurrences (all)	0	2	1
Diarrhoea			
subjects affected / exposed	0 / 74 (0.00%)	1 / 99 (1.01%)	0 / 77 (0.00%)
occurrences (all)	0	1	0
Dyspepsia			
subjects affected / exposed	0 / 74 (0.00%)	0 / 99 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 74 (0.00%)	0 / 99 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	8 / 74 (10.81%)	20 / 99 (20.20%)	8 / 77 (10.39%)
occurrences (all)	10	39	10
Noninfective sialoadenitis			
subjects affected / exposed	0 / 74 (0.00%)	0 / 99 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Retching			
subjects affected / exposed	0 / 74 (0.00%)	0 / 99 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Tooth impacted			
subjects affected / exposed	0 / 74 (0.00%)	0 / 99 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Tooth loss			
subjects affected / exposed	0 / 74 (0.00%)	0 / 99 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 74 (0.00%)	1 / 99 (1.01%)	0 / 77 (0.00%)
occurrences (all)	0	1	0

Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	2 / 74 (2.70%)	0 / 99 (0.00%)	0 / 77 (0.00%)
occurrences (all)	2	0	0
Alopecia			
subjects affected / exposed	0 / 74 (0.00%)	0 / 99 (0.00%)	1 / 77 (1.30%)
occurrences (all)	0	0	1
Dermatitis			
subjects affected / exposed	0 / 74 (0.00%)	0 / 99 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Dermatitis contact			
subjects affected / exposed	0 / 74 (0.00%)	1 / 99 (1.01%)	0 / 77 (0.00%)
occurrences (all)	0	1	0
Hyperhidrosis			
subjects affected / exposed	0 / 74 (0.00%)	0 / 99 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	1 / 74 (1.35%)	1 / 99 (1.01%)	0 / 77 (0.00%)
occurrences (all)	1	1	0
Psoriasis			
subjects affected / exposed	0 / 74 (0.00%)	0 / 99 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 74 (0.00%)	2 / 99 (2.02%)	0 / 77 (0.00%)
occurrences (all)	0	2	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	9 / 74 (12.16%)	20 / 99 (20.20%)	6 / 77 (7.79%)
occurrences (all)	18	38	9
Bursitis			
subjects affected / exposed	1 / 74 (1.35%)	0 / 99 (0.00%)	0 / 77 (0.00%)
occurrences (all)	1	0	0
Muscle spasms			
subjects affected / exposed	0 / 74 (0.00%)	1 / 99 (1.01%)	0 / 77 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal pain			

subjects affected / exposed	0 / 74 (0.00%)	0 / 99 (0.00%)	1 / 77 (1.30%)
occurrences (all)	0	0	1
Myalgia			
subjects affected / exposed	14 / 74 (18.92%)	26 / 99 (26.26%)	13 / 77 (16.88%)
occurrences (all)	34	57	17
Neck pain			
subjects affected / exposed	0 / 74 (0.00%)	0 / 99 (0.00%)	1 / 77 (1.30%)
occurrences (all)	0	0	1
Pain in extremity			
subjects affected / exposed	1 / 74 (1.35%)	0 / 99 (0.00%)	0 / 77 (0.00%)
occurrences (all)	1	0	0
Spinal flattening			
subjects affected / exposed	0 / 74 (0.00%)	0 / 99 (0.00%)	1 / 77 (1.30%)
occurrences (all)	0	0	1
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 74 (0.00%)	2 / 99 (2.02%)	0 / 77 (0.00%)
occurrences (all)	0	2	0
Cellulitis			
subjects affected / exposed	0 / 74 (0.00%)	1 / 99 (1.01%)	0 / 77 (0.00%)
occurrences (all)	0	1	0
Chlamydial infection			
subjects affected / exposed	0 / 74 (0.00%)	0 / 99 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 74 (0.00%)	0 / 99 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	1 / 74 (1.35%)	0 / 99 (0.00%)	0 / 77 (0.00%)
occurrences (all)	1	0	0
Ear infection			
subjects affected / exposed	0 / 74 (0.00%)	0 / 99 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	0 / 74 (0.00%)	2 / 99 (2.02%)	0 / 77 (0.00%)
occurrences (all)	0	2	0

Infectious mononucleosis			
subjects affected / exposed	0 / 74 (0.00%)	0 / 99 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 74 (0.00%)	1 / 99 (1.01%)	0 / 77 (0.00%)
occurrences (all)	0	1	0
Nasopharyngitis			
subjects affected / exposed	1 / 74 (1.35%)	6 / 99 (6.06%)	1 / 77 (1.30%)
occurrences (all)	1	7	1
Otitis media			
subjects affected / exposed	0 / 74 (0.00%)	1 / 99 (1.01%)	0 / 77 (0.00%)
occurrences (all)	0	1	0
Peritonsillar abscess			
subjects affected / exposed	1 / 74 (1.35%)	0 / 99 (0.00%)	0 / 77 (0.00%)
occurrences (all)	1	0	0
Pharyngitis			
subjects affected / exposed	0 / 74 (0.00%)	4 / 99 (4.04%)	0 / 77 (0.00%)
occurrences (all)	0	4	0
Pharyngitis bacterial			
subjects affected / exposed	0 / 74 (0.00%)	0 / 99 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 74 (0.00%)	0 / 99 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Pyelonephritis			
subjects affected / exposed	0 / 74 (0.00%)	0 / 99 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	1 / 74 (1.35%)	0 / 99 (0.00%)	2 / 77 (2.60%)
occurrences (all)	1	0	2
Respiratory tract infection viral			
subjects affected / exposed	0 / 74 (0.00%)	0 / 99 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 74 (0.00%)	0 / 99 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0

Sinusitis			
subjects affected / exposed	0 / 74 (0.00%)	2 / 99 (2.02%)	0 / 77 (0.00%)
occurrences (all)	0	2	0
Tonsillitis			
subjects affected / exposed	2 / 74 (2.70%)	2 / 99 (2.02%)	1 / 77 (1.30%)
occurrences (all)	2	2	1
Tonsillitis bacterial			
subjects affected / exposed	0 / 74 (0.00%)	0 / 99 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Tonsillitis streptococcal			
subjects affected / exposed	0 / 74 (0.00%)	0 / 99 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 74 (0.00%)	0 / 99 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Tracheitis			
subjects affected / exposed	0 / 74 (0.00%)	1 / 99 (1.01%)	0 / 77 (0.00%)
occurrences (all)	0	1	0
Upper respiratory tract infection			
subjects affected / exposed	4 / 74 (5.41%)	6 / 99 (6.06%)	1 / 77 (1.30%)
occurrences (all)	4	8	1
Urinary tract infection			
subjects affected / exposed	0 / 74 (0.00%)	1 / 99 (1.01%)	0 / 77 (0.00%)
occurrences (all)	0	1	0
Viral pharyngitis			
subjects affected / exposed	0 / 74 (0.00%)	1 / 99 (1.01%)	0 / 77 (0.00%)
occurrences (all)	0	1	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 74 (0.00%)	2 / 99 (2.02%)	0 / 77 (0.00%)
occurrences (all)	0	2	0
Wound infection			
subjects affected / exposed	0 / 74 (0.00%)	0 / 99 (0.00%)	0 / 77 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			

subjects affected / exposed occurrences (all)	7 / 74 (9.46%) 13	20 / 99 (20.20%) 49	9 / 77 (11.69%) 11

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
04 April 2018	Following up on the response to CBER comments, to change the defined criterion for concluding relative vaccine effectiveness, the Company agreed to remove it from the V102_15E1 study protocol and all analyses for the vaccine effectiveness objectives to be descriptive in nature. Further to this decision, in this amendment the effectiveness of the MenABCWY vaccine using enc-hSBA will no longer be assessed in any of the V102_15E1 study objectives (primary, secondary or exploratory). All the study objectives will aim to evaluate the immunogenicity of the MenABCWY vaccine against N. meningitidis serogroup B test strains (M14459 (fHbp), 96217 (NadA), NZ98/254 (PorA) and M07-0241084 (NHBA)) using HT-hSBA, accordingly.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported