Clinical trial results:
A Phase 2b/3, Multi-Center, Extension Study of V72P10 to Assess Antibody Persistence at Eighteen Months After the Completion of the Vaccination Course in Study V72P10.

Due to a system error, the data reported in v1 is not correct and has been removed from public view.

Summary

EudraCT number	2014-004992-21
Trial protocol	Outside EU/EEA
Global end of trial date	17 January 2012

Results information

Result version number	v2 (current)
This version publication date	01 June 2016
First version publication date	19 March 2015
Version creation reason	• Correction of full data set re-QC study because of EudraCT system glitch and minor updates to results are required.

Trial information

Trial identification

Sponsor protocol code	V72P10E1

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01148524
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Novartis Vaccines and Diagnostics
Sponsor organisation address	Via Fiorentina 1, Siena, Italy, 53100
Public contact	Posting director, Novartis Vaccines, RegistryContactVaccinesUS@novartis.com
Scientific contact	Posting director, Novartis Vaccines, RegistryContactVaccinesUS@novartis.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?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	18 October 2012
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	17 January 2012
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To explore antibody persistence at eighteen months after the completion of the vaccination course in subjects enrolled in the V72P10 study.

Protection of trial subjects:

This trial was performed with the ethical principles that have their origin in the latest version of the Declaration of Helsinki accepted by the local authorities and that are consistent with Good Clinical Practices (GCPs) and the applicable regulatory requirement(s) for the country in which the trial is conducted, GCPs according to International Conference on Harmonization (ICH) guidelines, the applicable regulatory requirements(s) for the country in which the study is conducted, and applicable standard operating procedures (SOPs).

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	05 August 2010
Long term follow-up planned	Yes
Long term follow-up rationale	Efficacy
Long term follow-up duration	24 Months
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Chile: 817
Worldwide total number of subjects	817
EEA total number of subjects	0

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	611
Adults (18-64 years)	206

From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Subjects were enrolled at 6 study centers in Chile.

Pre-assignment

Screening details:

All enrolled subjects were included in the trial.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	rMenB0

Arm description:

Subjects received 1 dose of Recombinant Meningococcal B Vaccine with Outer Membrane Vesicle from the New Zealand Strain (rMenB+OMV-NZ) at 0 month and 3 doses of placebo at 1, 2 and 6 months in V72P10.

Arm type	Experimental
Investigational medicinal product name	rMenB+OMV NZ
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Single of dose of 0.5mL vaccine or 0.5 mL placebo is administered at each schedule by IM injection into deltoid muscle of non-dominant arm.

Arm title	rMenB06

Arm description:

Subjects received 2 doses each of rMenB+OMV-NZ at 0 and 6 months and placebo at 1 and 2 months in V72P10.

Arm type	Experimental
Investigational medicinal product name	rMenB+OMV NZ
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Single of dose of 0.5mL vaccine or 0.5 mL placebo is administered at each schedule by IM injection into deltoid muscle of non-dominant arm.

Arm title	rMenB01

Arm description:

Subjects received 2 doses each of rMenB+OMV-NZ at 0 and 1 months and placebo at 2 and 6 months in V71P10.

Arm type	Experimental

Investigational medicinal product name	rMenB+OMV NZ
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Single of dose of 0.5mL vaccine or 0.5 mL placebo is administered at each schedule by IM injection into deltoid muscle of non-dominant arm.

Arm title	rMenB016

Arm description:

Subjects received 3 doses of rMenB+OMV-NZ at 0, 1 and 6 months and 1 dose of placebo at 2 months in V72P10.

Arm type	Experimental
Investigational medicinal product name	rMenB+OMV NZ
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Single of dose of 0.5mL vaccine or 0.5 mL placebo is administered at each schedule by IM injection into deltoid muscle of non-dominant arm.

Arm title	rMenB02

Arm description:

Subjects received 2 doses each of rMenB+OMV-NZ at 0 and 2 months and placebo at 1 and 6 months in V72P10.

Arm type	Experimental
Investigational medicinal product name	rMenB+OMV NZ
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Single of dose of 0.5mL vaccine or 0.5 mL placebo is administered at each schedule by IM injection into deltoid muscle of non-dominant arm.

Arm title	rMenB026

Arm description:

Subjects received 3 doses of rMenB+OMV-NZ at 0, 2 and 6 months and 1 dose of placebo at 1 month in V72P10.

Arm type	Experimental
Investigational medicinal product name	rMenB+OMV NZ
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Single of dose of 0.5mL vaccine or 0.5 mL placebo is administered at each schedule by IM injection into deltoid muscle of non-dominant arm.

Arm title	rMenB012

Arm description:

Subjects received 3 doses of rMenB+OMV-NZ at 0, 1 and 2 months and placebo at 6 months in V72P10.

Arm type	Experimental

Investigational medicinal product name	rMenB+OMV NZ
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Single of dose of 0.5mL vaccine or 0.5 mL placebo is administered at each schedule by IM injection into deltoid muscle of non-dominant arm.

Arm title	rMenB6

Arm description:

Subjects received 1 dose of rMenB+OMV-NZ at 6 months and 3 doses of placebo at 0, 1 and 2 months in V72P10.

Arm type	Experimental
Investigational medicinal product name	rMenB+OMV NZ
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Single of dose of 0.5mL vaccine or 0.5 mL placebo is administered at each schedule by IM injection into deltoid muscle of non-dominant arm.

Arm title	Naive

Arm description:

Subjects did not receive any vaccination and were of similar age to the follow-on subjects from V72P10.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Number of subjects in period 1	rMenB0	rMenB06	rMenB01
Started	95	49	102
Completed	95	49	102

Number of subjects in period 1	rMenB016	rMenB02	rMenB026
Started	53	106	57
Completed	53	106	57

Number of subjects in period 1	rMenB012	rMenB6	Naive
Started	153	51	151
Completed	153	51	151

Baseline characteristics

Reporting groups	
Reporting group title	rMenB0
Reporting group description:	
Subjects received 1 dose of Recombinant Meningococcal B Vaccine with Outer Membrane Vesicle from the New Zealand Strain (rMenB+OMV-NZ) at 0 month and 3 doses of placebo at 1, 2 and 6 months in V72P10.	
Reporting group title	rMenB06
Reporting group description:	
Subjects received 2 doses each of rMenB+OMV-NZ at 0 and 6 months and placebo at 1 and 2 months in V72P10.	
Reporting group title	rMenB01
Reporting group description:	
Subjects received 2 doses each of rMenB+OMV-NZ at 0 and 1 months and placebo at 2 and 6 months in V71P10.	
Reporting group title	rMenB016
Reporting group description:	
Subjects received 3 doses of rMenB+OMV-NZ at 0, 1 and 6 months and 1 dose of placebo at 2 months in V72P10.	
Reporting group title	rMenB02
Reporting group description:	
Subjects received 2 doses each of rMenB+OMV-NZ at 0 and 2 months and placebo at 1 and 6 months in V72P10.	
Reporting group title	rMenB026
Reporting group description:	
Subjects received 3 doses of rMenB+OMV-NZ at 0, 2 and 6 months and 1 dose of placebo at 1 month in V72P10.	
Reporting group title	rMenB012
Reporting group description:	
Subjects received 3 doses of rMenB+OMV-NZ at 0, 1 and 2 months and placebo at 6 months in V72P10.	
Reporting group title	rMenB6
Reporting group description:	
Subjects received 1 dose of rMenB+OMV-NZ at 6 months and 3 doses of placebo at 0, 1 and 2 months in V72P10.	
Reporting group title	Naive
Reporting group description:	
Subjects did not receive any vaccination and were of similar age to the follow-on subjects from V72P10.	

Reporting group values	rMenB0	rMenB06	rMenB01
Number of subjects	95	49	102
Age categorical Units: Subjects			
Age continuous Units: years arithmetic mean standard deviation	 16 ± 2	 16.2 ± 1.9	 16.1 ± 1.9
Gender categorical Units: Subjects			
Female	53	30	57

Male	42	19	45

Reporting group values	rMenB016	rMenB02	rMenB026
Number of subjects	53	106	57
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	16.2	15.9	15.6
standard deviation	± 2.1	± 1.8	± 1.9
Gender categorical Units: Subjects			
Female	33	61	38
Male	20	45	19

Reporting group values	rMenB012	rMenB6	Naive
Number of subjects	153	51	151
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	15.9	16	15.6
standard deviation	± 1.9	± 1.9	± 1.7
Gender categorical Units: Subjects			
Female	96	33	61
Male	57	18	90

Reporting group values	Total		
Number of subjects	817		
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean			
standard deviation	-		
Gender categorical Units: Subjects			
Female	462		
Male	355		

Subject analysis sets

Subject analysis set title	All Enrolled Set
Subject analysis set type	Full analysis

Subject analysis set description:
All subjects who enrolled in this study.

Reporting group values	All Enrolled Set		
Number of subjects	817		
Age categorical Units: Subjects			

Age continuous Units: years			
arithmetic mean	15.9		
standard deviation	± 1.9		
Gender categorical Units: Subjects			
Female	462		
Male	355		

End points

End points reporting groups

Reporting group title	rMenB0
Reporting group description:	
Subjects received 1 dose of Recombinant Meningococcal B Vaccine with Outer Membrane Vesicle from the New Zealand Strain (rMenB+OMV-NZ) at 0 month and 3 doses of placebo at 1, 2 and 6 months in V72P10.	
Reporting group title	rMenB06
Reporting group description:	
Subjects received 2 doses each of rMenB+OMV-NZ at 0 and 6 months and placebo at 1 and 2 months in V72P10.	
Reporting group title	rMenB01
Reporting group description:	
Subjects received 2 doses each of rMenB+OMV-NZ at 0 and 1 months and placebo at 2 and 6 months in V71P10.	
Reporting group title	rMenB016
Reporting group description:	
Subjects received 3 doses of rMenB+OMV-NZ at 0, 1 and 6 months and 1 dose of placebo at 2 months in V72P10.	
Reporting group title	rMenB02
Reporting group description:	
Subjects received 2 doses each of rMenB+OMV-NZ at 0 and 2 months and placebo at 1 and 6 months in V72P10.	
Reporting group title	rMenB026
Reporting group description:	
Subjects received 3 doses of rMenB+OMV-NZ at 0, 2 and 6 months and 1 dose of placebo at 1 month in V72P10.	
Reporting group title	rMenB012
Reporting group description:	
Subjects received 3 doses of rMenB+OMV-NZ at 0, 1 and 2 months and placebo at 6 months in V72P10.	
Reporting group title	rMenB6
Reporting group description:	
Subjects received 1 dose of rMenB+OMV-NZ at 6 months and 3 doses of placebo at 0, 1 and 2 months in V72P10.	
Reporting group title	Naive
Reporting group description:	
Subjects did not receive any vaccination and were of similar age to the follow-on subjects from V72P10.	
Subject analysis set title	All Enrolled Set
Subject analysis set type	Full analysis
Subject analysis set description:	
All subjects who enrolled in this study.	

Primary: 1. Percentage of subjects with hSBA titer ≥1:4 at 18 months after the completion of the vaccination course in subjects enrolled in the V72P10 study and in Naive Subjects.

End point title	1. Percentage of subjects with hSBA titer ≥1:4 at 18 months after the completion of the vaccination course in subjects enrolled in the V72P10 study and in Naive Subjects.[1]
End point description:	
Immunogenicity was evaluated by measuring the percentage of subjects with serum bactericidal activity using human complement(hSBA) titter >1:4 against 44/76_SL, 5/99, NZ98/254 strains after 18 months. The analysis was performed as per the Modified Intention To Treat (MITT) dataset.	
End point type	Primary

End point timeframe:

Month 0 (bl=baseline), month 1 and Month 18 after last vaccination in V72P10 study.

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: There was no statistical null hypothesis associated with this immunogenicity objective.

End point values	rMenB0	rMenB06	rMenB01	rMenB016
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	95	49	102	53
Units: Percentage of Subjects				
number (confidence interval 95%)				
Str.44/76_SL-bl (N=95,49,102,53,106,57,153,51,0)	40 (30 to 51)	31 (18 to 45)	32 (23 to 42)	40 (26 to 54)
Str.44/76_SL-1m (N=95,49,102,53,106,57,153,51,0)	93 (85 to 97)	100 (93 to 100)	100 (96 to 100)	100 (93 to 100)
Str.44/76_SL-m18	73 (63 to 81)	84 (70 to 93)	82 (74 to 89)	92 (82 to 98)
Str.5/99-bl (N=95,49,102,53,106,57,153,51,0)	33 (23 to 43)	22 (12 to 37)	26 (18 to 36)	28 (17 to 42)
Str.5/99-1m (N=95,49,102,53,106,57,153,51,0)	96 (90 to 99)	98 (89 to 100)	100 (96 to 100)	100 (93 to 100)
Str.5/99-m18	65 (55 to 75)	94 (83 to 99)	93 (86 to 97)	98 (90 to 100)
Str.NZ98/254-bl (N=95,49,102,53,106,57,153,51,0)	31 (21 to 41)	29 (17 to 43)	24 (16 to 33)	32 (20 to 46)
Str.NZ98/254-1m (N=95,49,102,53,106,57,153,51,0)	94 (87 to 98)	100 (93 to 100)	100 (96 to 100)	100 (93 to 100)
Str.NZ98/254-m18	62 (52 to 72)	86 (73 to 94)	75 (65 to 83)	98 (90 to 100)

End point values	rMenB02	rMenB026	rMenB012	rMenB6
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	106	57	153	51
Units: Percentage of Subjects				
number (confidence interval 95%)				
Str.44/76_SL-bl (N=95,49,102,53,106,57,153,51,0)	41 (31 to 51)	32 (20 to 45)	44 (36 to 52)	47 (33 to 62)
Str.44/76_SL-1m (N=95,49,102,53,106,57,153,51,0)	100 (97 to 100)	100 (94 to 100)	100 (98 to 100)	94 (84 to 99)
Str.44/76_SL-m18	81 (72 to 88)	86 (74 to 94)	83 (76 to 89)	73 (58 to 84)
Str.5/99-bl (N=95,49,102,53,106,57,153,51,0)	30 (22 to 40)	21 (11 to 34)	34 (27 to 42)	33 (21 to 48)
Str.5/99-1m (N=95,49,102,53,106,57,153,51,0)	100 (97 to 100)	100 (94 to 100)	100 (98 to 100)	88 (76 to 96)
Str.5/99-m18	95 (89 to 98)	100 (94 to 100)	96 (92 to 99)	73 (58 to 84)
Str.NZ98/254-bl (N=95,49,102,53,106,57,153,51,0)	30 (22 to 40)	21 (11 to 34)	30 (22 to 38)	29 (17 to 44)
Str.NZ98/254-1m (N=95,49,102,53,106,57,153,51,0)	100 (97 to 100)	98 (91 to 100)	99 (96 to 100)	92 (81 to 98)
Str.NZ98/254-m18	75 (66 to 83)	96 (88 to 100)	86 (79 to 91)	61 (46 to 74)

End point values	Naive			
Subject group type	Reporting group			
Number of subjects analysed	151			
Units: Percentage of Subjects				
number (confidence interval 95%)				
Str.44/76_SL-bl (N=95,49,102,53,106,57,153,51,0)	0 (0 to 0)			
Str.44/76_SL-1m (N=95,49,102,53,106,57,153,51,0)	0 (0 to 0)			
Str.44/76_SL-m18	50 (42 to 59)			
Str.5/99-bl (N=95,49,102,53,106,57,153,51,0)	0 (0 to 0)			
Str.5/99-1m (N=95,49,102,53,106,57,153,51,0)	0 (0 to 0)			
Str.5/99-m18	25 (18 to 33)			
Str.NZ98/254-bl (N=95,49,102,53,106,57,153,51,0)	0 (0 to 0)			
Str.NZ98/254-1m (N=95,49,102,53,106,57,153,51,0)	0 (0 to 0)			
Str.NZ98/254-m18	40 (32 to 48)			

Statistical analyses

No statistical analyses for this end point

Primary: 2. Geometric Mean Titers (GMTs) at eighteen months after the completion of the vaccination course in subjects enrolled in the V72P10 study and in Naive Subjects.

End point title	2. Geometric Mean Titers (GMTs) at eighteen months after the completion of the vaccination course in subjects enrolled in the V72P10 study and in Naive Subjects.[2]

End point description:

Immunogenicity was evaluated by measuring the GMTs after primary and booster vaccination against 44/76_SL, 5/99, NZ98/254. The analysis was performed as per the MITT set.

End point type	Primary

End point timeframe:

Month 0 (bl=baseline), month 1 and Month 18 after last vaccination in V72P10 study.

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: There was no statistical null hypothesis associated with this immunogenicity objective.

End point values	rMenB0	rMenB06	rMenB01	rMenB016
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	95	49	102	53
Units: Titers				
geometric mean (confidence interval 95%)				
S.44/76 GMT-bl (N=95,49,102,53,106,57,153,51,0)	3.75 (2.75 to 5.12)	2.83 (1.85 to 4.31)	2.74 (2.04 to 3.68)	3.56 (2.37 to 5.34)
S.44/76 GMT-1m (N=95,49,102,53,106,57,153,51,0)	47 (36 to 60)	227 (161 to 320)	189 (149 to 241)	316 (227 to 439)
S.44/76 GMT-m18	16 (11 to 23)	27 (16 to 45)	29 (20 to 42)	50 (30 to 83)

S.5/99 GMT-bl (N=95,49,102,53,106,57,153,51,0)	2.65 (2.04 to 3.44)	2.31 (1.62 to 3.3)	2.22 (1.73 to 2.85)	2.55 (1.81 to 3.6)
S.5/99 GMT-1m (N=95,49,102,53,106,57,153,51,0)	63 (49 to 81)	802 (574 to 1121)	445 (352 to 562)	1181 (856 to 1630)
S.5/99 GMT-m18	7.1 (5.24 to 9.6)	65 (43 to 98)	40 (30 to 54)	121 (82 to 180)
S.NZ98/254 GMT-bl (N=95,49,102,53,106,57,153,51,0)	2.65 (1.99 to 3.53)	2.66 (1.8 to 3.92)	2.15 (1.63 to 2.82)	3.68 (2.53 to 5.35)
S.NZ98/254 GMT-1m (N=95,49,102,53,106,57,153,51,0)	33 (25 to 43)	154 (107 to 221)	78 (60 to 100)	174 (123 to 248)
S.NZ98/254 GMT-m18	8.71 (6.12 to 12)	27 (17 to 43)	17 (12 to 24)	42 (26 to 66)

End point values	rMenB02	rMenB026	rMenB012	rMenB6
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	106	57	153	51
Units: Titers				
geometric mean (confidence interval 95%)				
S.44/76 GMT-bl (N=95,49,102,53,106,57,153,51,0)	3.24 (2.43 to 4.34)	2.76 (1.86 to 4.1)	3.86 (3.02 to 4.93)	4.33 (2.86 to 6.56)
S.44/76 GMT-1m (N=95,49,102,53,106,57,153,51,0)	227 (179 to 287)	265 (192 to 365)	253 (208 to 309)	62 (44 to 86)
S.44/76 GMT-m18	34 (24 to 49)	44 (27 to 73)	42 (31 to 56)	19 (12 to 32)
S.5/99 GMT-bl (N=95,49,102,53,106,57,153,51,0)	2.36 (1.84 to 3.01)	1.72 (1.23 to 2.39)	2.63 (2.14 to 3.23)	2.67 (1.88 to 3.79)
S.5/99 GMT-1m (N=95,49,102,53,106,57,153,51,0)	727 (577 to 916)	1105 (808 to 1510)	605 (499 to 735)	68 (49 to 94)
S.5/99 GMT-m18	43 (33 to 58)	100 (68 to 146)	73 (57 to 92)	9.85 (6.57 to 15)
S.NZ98/254 GMT-bl (N=95,49,102,53,106,57,153,51,0)	2.63 (2.01 to 3.44)	2.15 (1.5 to 3.1)	2.75 (2.19 to 3.44)	2.68 (1.82 to 3.93)
S.NZ98/254 GMT-1m (N=95,49,102,53,106,57,153,51,0)	115 (89 to 148)	170 (121 to 238)	129 (105 to 160)	43 (30 to 62)
S.NZ98/254 GMT-m18	19 (14 to 27)	41 (26 to 64)	23 (18 to 31)	9.16 (5.71 to 15)

End point values	Naive			
Subject group type	Reporting group			
Number of subjects analysed	151			
Units: Titers				
geometric mean (confidence interval 95%)				
S.44/76 GMT-bl (N=95,49,102,53,106,57,153,51,0)	0 (0 to 0)			
S.44/76 GMT-1m (N=95,49,102,53,106,57,153,51,0)	0 (0 to 0)			
S.44/76 GMT-m18	4.52 (3.52 to 5.82)			
S.5/99 GMT-bl (N=95,49,102,53,106,57,153,51,0)	0 (0 to 0)			
S.5/99 GMT-1m (N=95,49,102,53,106,57,153,51,0)	0 (0 to 0)			

S.5/99 GMT-m18	2.13 (1.73 to 2.63)			
S.NZ98/254 GMT-bl (N=95,49,102,53,106,57,153,51,0)	0 (0 to 0)			
S.NZ98/254 GMT-1m (N=95,49,102,53,106,57,153,51,0)	0 (0 to 0)			
S.NZ98/254 GMT-m18	3.23 (2.52 to 4.14)			

Statistical analyses

No statistical analyses for this end point

Primary: 4. Geometric Mean Concentrations (GMCs) of antibodies to vaccine antigen 287-953.

End point title	4. Geometric Mean Concentrations (GMCs) of antibodies to vaccine antigen 287-953.[3]

End point description:

Immunogenicity was evaluated by measuring the GMCs against Antigen 287-953, at 18 months after the completion of the vaccination course in subjects enrolled in V72P10 Study and in Naive Subjects. The analysis was performed as per the MITT dataset.

End point type	Primary

End point timeframe:

18 months after completion of vaccination course in the V72P10 study.

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: There was no statistical null hypothesis associated with this immunogenicity objective.

End point values	rMenB0	rMenB06	rMenB01	rMenB016
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	34	35	35	35
Units: IU/mL				
geometric mean (confidence interval 95%)				
18 m post-last vac. in V72P10	55 (37 to 82)	272 (186 to 397)	217 (148 to 319)	555 (376 to 818)

End point values	rMenB02	rMenB026	rMenB012	rMenB6
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	35	35	35	34
Units: IU/mL				
geometric mean (confidence interval 95%)				
18 m post-last vac. in V72P10	150 (101 to 221)	490 (333 to 721)	175 (119 to 256)	59 (40 to 88)

End point values	Naive			
Subject group type	Reporting group			
Number of subjects analysed	35			
Units: IU/mL				
geometric mean (confidence interval 95%)				
18 m post-last vac. in V72P10	24 (20 to 27)			

Statistical analyses

No statistical analyses for this end point

Primary: 3. Geometric Mean Ratio (GMRs) over baselines at month 0 and at one month after the last rMenB+OMV NZ vaccination in the V72P10 study.

End point title	3. Geometric Mean Ratio (GMRs) over baselines at month 0 and at one month after the last rMenB+OMV NZ vaccination in the V72P10 study.[4]

End point description:

Immunogenicity was evaluated by measuring the GMRs against meningococcal strains 44/76_SL, 5/99, NZ98/254. The analysis was performed as per the MITT dataset.

End point type	Primary

End point timeframe:

Month 0 (bl=baseline), month 1 and Month 18 after last vaccination in V72P10 study.

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: There was no statistical null hypothesis associated with this immunogenicity objective.

End point values	rMenB0	rMenB06	rMenB01	rMenB016
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	95	49	102	53
Units: Ratio				
geometric mean (confidence interval 95%)				
S.44/76_SL-1m/bl (N=95,49,102,53,106,57,153,51,0)	12 (9.18 to 17)	80 (53 to 122)	69 (52 to 92)	89 (60 to 133)
S.44/76_SL-18m/bl (N=95,49,102,53,106,57,153,51,0)	4.26 (3.01 to 6.03)	9.51 (5.93 to 15)	11 (7.6 to 15)	14 (8.95 to 22)
S.44/76_SL-18m/1m (N=95,49,102,53,106,57,153,51,0)	0.34 (0.25 to 0.47)	0.12 (0.077 to 0.18)	0.15 (0.11 to 0.21)	0.16 (0.1 to 0.24)
S.5/99-1m/bl (N=95,49,102,53,106,57,153,51,0)	24 (17 to 33)	347 (223 to 541)	200 (147 to 273)	462 (301 to 709)
S.5/99-18m/bl (N=95,49,102,53,106,57,153,51,0)	2.68 (1.94 to 3.7)	28 (18 to 44)	18 (13 to 25)	47 (31 to 73)
S.5/99-18m/1m (N=95,49,102,53,106,57,153,51,0)	0.11 (0.085 to 0.15)	0.081 (0.055 to 0.12)	0.091 (0.07 to 0.12)	0.1 (0.071 to 0.15)
S.NZ98/254-1m/bl (N=95,49,102,53,106,57,151,51,0)	12 (9.22 to 17)	58 (39 to 87)	36 (27 to 48)	47 (32 to 70)
S.NZ98/254-18m/bl (N=95,49,102,53,106,57,152,51,0)	3.29 (2.41 to 4.5)	10 (6.62 to 15)	7.93 (5.89 to 11)	11 (7.57 to 17)
S.NZ98/254-18m/1m (N=95,49,102,53,106,57,153,51,0)	0.27 (0.2 to 0.35)	0.17 (0.12 to 0.26)	0.22 (0.17 to 0.29)	0.24 (0.16 to 0.35)

End point values	rMenB02	rMenB026	rMenB012	rMenB6
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	106	57	153	51
Units: Ratio				
geometric mean (confidence interval 95%)				
S.44/76_SL-1m/bl (N=95,49,102,53,106,57,153,51,0)	70 (52 to 93)	96 (65 to 141)	66 (52 to 83)	14 (9.47 to 21)
S.44/76_SL-18m/bl (N=95,49,102,53,106,57,153,51,0)	11 (7.67 to 15)	16 (10 to 25)	11 (8.2 to 14)	4.46 (2.8 to 7.11)
S.44/76_SL-18m/1m (N=95,49,102,53,106,57,153,51,0)	0.15 (0.11 to 0.21)	0.17 (0.11 to 0.25)	0.16 (0.13 to 0.21)	0.31 (0.2 to 0.48)
S.5/99-1m/bl (N=95,49,102,53,106,57,153,51,0)	309 (227 to 419)	644 (425 to 976)	230 (178 to 298)	25 (16 to 39)
S.5/99-18m/bl (N=95,49,102,53,106,57,153,51,0)	18 (14 to 25)	58 (38 to 87)	28 (21 to 36)	3.69 (2.39 to 5.7)
S.5/99-18m/1m (N=95,49,102,53,106,57,153,51,0)	0.06 (0.046 to 0.078)	0.09 (0.063 to 0.13)	0.12 (0.096 to 0.15)	0.15 (0.1 to 0.21)
S.NZ98/254-1m/bl (N=95,49,102,53,106,57,151,51,0)	44 (33 to 58)	79 (54 to 115)	47 (37 to 60)	16 (11 to 24)
S.NZ98/254-18m/bl (N=95,49,102,53,106,57,152,51,0)	7.37 (5.5 to 9.88)	19 (13 to 28)	8.42 (6.59 to 11)	3.43 (2.25 to 5.2)
S.NZ98/254-18m/1m (N=95,49,102,53,106,57,153,51,0)	0.17 (0.13 to 0.22)	0.24 (0.17 to 0.35)	0.18 (0.14 to 0.23)	0.21 (0.14 to 0.31)

End point values	Naive			
Subject group type	Reporting group			
Number of subjects analysed	151			
Units: Ratio				
geometric mean (confidence interval 95%)				
S.44/76_SL-1m/bl (N=95,49,102,53,106,57,153,51,0)	0 (0 to 0)			
S.44/76_SL-18m/bl (N=95,49,102,53,106,57,153,51,0)	0 (0 to 0)			
S.44/76_SL-18m/1m (N=95,49,102,53,106,57,153,51,0)	0 (0 to 0)			
S.5/99-1m/bl (N=95,49,102,53,106,57,153,51,0)	0 (0 to 0)			
S.5/99-18m/bl (N=95,49,102,53,106,57,153,51,0)	0 (0 to 0)			
S.5/99-18m/1m (N=95,49,102,53,106,57,153,51,0)	0 (0 to 0)			
S.NZ98/254-1m/bl (N=95,49,102,53,106,57,151,51,0)	0 (0 to 0)			
S.NZ98/254-18m/bl (N=95,49,102,53,106,57,152,51,0)	0 (0 to 0)			
S.NZ98/254-18m/1m (N=95,49,102,53,106,57,153,51,0)	0 (0 to 0)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

18 months after vaccination.

Adverse event reporting additional description:

There was no vaccine administered in the study. Only Safety data related to the blood draw procedure were collected.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	17.1

Reporting groups

Reporting group title	rMenB06

Reporting group description:

Subjects received 2 doses each of rMenB+OMV-NZ at 0 and 6 months and placebo at 1 and 2 months in V72P10.

Reporting group title	rMenB0

Reporting group description:

Subjects received 1 dose of rMenB+OMV-NZ at 0 month and 3 doses of placebo at 1, 2 and 6 months in V72P10.

Reporting group title	rMenB02

Reporting group description:

Subjects received 2 doses each of rMenB+OMV-NZ at 0 and 2 months and placebo at 1 and 6 months in V72P10.

Reporting group title	Naive

Reporting group description:

Subjects did not receive any vaccination and of similar age to the follow-on subjects from V72P10.

Reporting group title	rMenB012

Reporting group description:

Subjects received 3 doses of rMenB+OMV-NZ at 0, 1 and 2 months and placebo at 6 months in V72P10.

Reporting group title	rMenB01

Reporting group description:

Subjects received 2 doses each of rMenB+OMV-NZ at 0 and 1 months and placebo at 2 and 6 months in V71P10.

Reporting group title	rMenB6

Reporting group description:

Subjects received 1 dose of rMenB+OMV-NZ at 6 months and 3 doses of placebo at 0, 1 and 2 months in V72P10.

Reporting group title	rMenB016

Reporting group description:

Subjects received 3 doses of rMenB+OMV-NZ at 0, 1 and 6 months and 1 dose of placebo at 2 months in V72P10.

Reporting group title	rMenB026

Reporting group description:

Subjects received 3 doses of rMenB+OMV-NZ at 0, 2 and 6 months and 1 dose of placebo at 1 month in V71P10.

Serious adverse events	rMenB06	rMenB0	rMenB02
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 49 (0.00%)	0 / 95 (0.00%)	0 / 106 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from	0	0	0

adverse events

Serious adverse events	Naive	rMenB012	rMenB01
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 151 (0.00%)	0 / 153 (0.00%)	0 / 102 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0

Serious adverse events	rMenB6	rMenB016	rMenB026
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 51 (0.00%)	0 / 53 (0.00%)	0 / 57 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0

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

Non-serious adverse events	rMenB06	rMenB0	rMenB02
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 49 (0.00%)	0 / 95 (0.00%)	0 / 106 (0.00%)

Non-serious adverse events	Naive	rMenB012	rMenB01
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 151 (0.00%)	0 / 153 (0.00%)	0 / 102 (0.00%)

Non-serious adverse events	rMenB6	rMenB016	rMenB026
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 51 (0.00%)	0 / 53 (0.00%)	0 / 57 (0.00%)

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.

Justification: All safety analyses were run in the safety population. No Serious Adverse Event occurred.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported

Online references

http://www.ncbi.nlm.nih.gov/pubmed/23811804