Clinical trial results:

Title of the trial: A Phase 3, Open-Label, Multi-Center, Extension Study of V72P13E1 to Assess Antibody Persistence at One Year After a Fourth Dose Boost or Two Catch-Up Doses of Novartis Meningococcal B Recombinant Vaccine Administered Starting at 12 Months of Age and to Evaluate the Response to a Third Dose Boost or Two Catch-Up Doses Starting at 24 Months of Age.

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Summary

Results information

Trial information

Trial identification					
Additional study identifiers					

Sponsors

Paediatric regulatory details

Results analysis stage			

General information about the trial

Population of trial subjects Subjects enrolled per country				
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Subjects enrolled per age group	
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Recruitment

Pre-assignment

Period 1

Arms					
Arm title					

Arm title	

Arm title	

Arm title	

Arm title	

Arm title	

Number of subjects in period 1		
Number of cubiects in period 1		

Number of Subjects in period 1		

Reporting group values		

End points	
End points reporting groups	
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Primary: Geometric Mean Titers (GMTs) to assess antibody persistence at one year after a booster dose of rMenB+OMV NZ Vaccination

End point values		

Primary: Percentage of subjects with hSBA \geq 1:5 and hSBA \geq 1:8 to assess antibody persistence at one year after a booster dose of rMenB+OMV NZ Vaccination			

End point values		

Primary: Geometric Mean concentrations (GMCs) to assess antibody persistence at one year after a booster dose of rMenB+OMV NZ Vaccination			

End point values		

Secondary: GMTs to assess antibe	ody persistence at 12 months after two catch-up
doses and 6 months after booste	r dose of rMenB+OMV NZ Vaccination



End point values		

Secondary: Percentage of subjects with hSBA \geq 1:5 and hSBA \geq 1:8 to assess antibody persistence at 12 months after two catch up doses and 6 months after a booster doses of rMenB+OMV NZ Vaccination.



End point values		

Secondary: Percentage of subjects with at least four fold increase in hSBA titers to evaluate antibody response 1 month post booster dose of rMenB+OMV NZ Vaccination

End point values		

Secondary: GMCs to assess antibody persistence at one year after two catch-up
doses and 6 months after booster of rMenB+OMV NZ Vaccination against 287-953
strain.

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End point values		

Statistical analyses

Secondary: GMTs to characterize antibody response at 1 month and 6 months post two catch-up doses of rMenB+OMV NZ administered to naive children at 24 and 26 months of age.

End point values		

Secondary: Percentage of subjects with hSBA ≥1:5 and hSBA ≥1:8 to assess antibody response at 1 month and 6 month post two catch-up doses of rMenB+OMV NZ administered to naive children at 24 and 26 months of age

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End point values		

Secondary: Percentage of subject	ts with fourfold increases in hSBA to assess
antibody response at 1 month po	st two catch-up doses of rMenB+OMV NZ
administered to naive children at	: 24 and 26 months of age

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End point values		
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Secondary: Number of subjects reporting solicited local and systemic AEs after receiving a booster (3rd) dose of rMenB+OMV NZ administered at 1year after 2 catch-up doses of rMenB+OMV NZ, previously administered at either 12 & 14 or 13 & 15 months of age in V72P13E1



End point values		

Secondary: Number of Subjects Reporting Unsolicited AEs after receiving a booster (3rd) dose of rMenB+OMV NZ administered at 1 year after 2 catch-up doses of rMenB+OMV NZ,previously administered to children at either 12 & 14 or 13 &15 months of age in V72P13E2

End point values		

Statistical analyses

Secondary: Number of subjects reporting solicited local and systemic AEs after two catch-up doses of rMenB+OMV NZ administered to naive children at 24 and 26 months of age.

End point values		

Secondary: Number of Subjects Reporting Unsolicited Adverse Events after receiving two catch-up doses of rMenB+OMV NZ administered to naive children at 24 and 26 months of age.

End point values		

Adverse events information

Dictionary used	
Reporting groups	

Serious adverse events			
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Non-serious adverse events		



More information

Substantial protocol amendments (globally)

Date	Amendment

Interruptions (globally)

Limitations and caveats