21 May 2026
EMADOC-1700519818-2963646
Human Medicines Division

Assessment report for paediatric studies submitted in accordance with article 46 of regulation (EC) No 1901/2006

Rotarix

rotavirus vaccine, live

Procedure no: EMA/PAM/0000334559

Note

Assessment report as adopted by the CHMP with all information of a commercially confidential nature deleted.

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Status of this report and steps taken for the assessment			
Current step	**Description**	**Planned date**	**Actual Date**
☐	CHMP Rapporteur AR	28 April 2026	03 April 2026
☐	CHMP comments	11 May 2026	n/a
☐	Updated CHMP Rapporteur AR	13 May 2026	n/a
☒	CHMP outcome	21 May 2026	21 May 2026

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1. Introduction

On 26 February 2026, the MAH submitted a completed paediatric study for Rotarix, in accordance with Article 46 of Regulation (EC) No1901/2006, as amended.

A short critical expert overview has also been provided.

2. Scientific discussion

2.1. Information on the development program

The MAH stated that "A Phase 3b, Observer-Blind, Randomized, Placebo Controlled, Multi-Center Study to Assess the Safety and Immunogenicity of GSK Meningococcal Group B Vaccine and 13-valent Pneumococcal Vaccine when Administered Concomitantly with Routine Vaccines to Healthy Infants; (MENB REC 2ND GEN-023 (V72_57)" is a stand alone study.

2.2. Information on the pharmaceutical formulation used in the study

In study MENB REC 2ND GEN-023 (V72_57), Rotarix (lyophilized) was one of the routine infant vaccines (RIVs) co-administered with primary study vaccines Bexsero (GSK Meningococcal group B vaccine, also referred as rMenB+OMV NZ) and Prevnar13 (13-valent pneumococcal conjugate vaccine, PCV13) or Prevnar20 (20-valent pneumococcal conjugate vaccine, PCV20). The RIVs administered in this study included Pediarix (diphtheria, tetanus toxoids, and acellular pertussis adsorbed, hepatitis B recombinant, and inactivated poliovirus, DTPa-HBV-IPV), Hiberix (Hib), Rotarix (HRV), M-M-R II (measles, mumps, and rubella, MMR), and Varivax (varicella, VV).

Test product

Meningococcal group B vaccine (rMenB+OMV NZ; Bexsero) was supplied as a single 0.5 mL dose to be administered IM into the deltoid area according to the relevant European Union (EU) and US Product Information.

Pneumococcal polysaccharide conjugate vaccine (13-valent; adsorbed, Prevnar 13) was available as a 0.5 mL injection, four doses administered IM at 2, 4, 6, and 12 through 15 months of age.

Pneumococcal polysaccharide conjugate vaccine (20-valent; adsorbed, Prevnar 20) was available as a 0.5 mL injection, four doses administered IM at 2, 4, 6, and 12 through 15 months of age.

Other interventions

Diphtheria, tetanus toxoids and acellular pertussis adsorbed, hepatitis-B (recombinant) and inactivated poliovirus vaccine (*Pediarix*): available as a 0.5 mL injection, 3 doses administered IM at 2, 4, and 6 months of age.

GSK Biologicals'oral live attenuated human rotavirus (HRV) vaccine (*Rotarix*, GSK444563): each dose is 1 mL, administered orally. The first dose was administered to infants beginning at 6 weeks of age, and second dose after an interval of at least 4 weeks and up to 24 weeks of age.

GSK Biologicals' Haemophilus influenzae type b (Hib) conjugate vaccine (*Hiberix*, GSK208108): a 4-dose series, administered IM. Primary dose each at 2, 4, and 6 months of age. The booster dose at 12 through 15 months of age.

Merck's measles, mumps and rubella (MMR) virus live vaccine (*M-M-R II*): each dose is approximately 0.5 mL, for IM or subcutaneous (SC) injection. The first dose administered at 12 to 15 months of age. The second dose administered at 4 to 6 years of age.

Merck's Varicella virus live vaccine (*Varivax*): a single dose is approximately 0.5 mL, for IM or SC injection. The first dose administered at 12 to 15 months of age. The second dose administered at 4 to 6 years of age.

Placebo: Each dose of the placebo contained 0.9% sodium chloride in water. The volume of the saline pre-filled syringe was between 0.6 mL and 0.8 mL and the full volume was to be injected.

2.3. Clinical aspects

2.3.1. Introduction

The MAH submitted a final report for:

MENB REC 2ND GEN-023 (V72_57) : A Phase 3b, Observer-Blind, Randomized, Placebo Controlled, Multi-Center Study to Assess the Safety and Immunogenicity of GSK Meningococcal Group B Vaccine and 13-valent Pneumococcal Vaccine when Administered Concomitantly with Routine Vaccines to Healthy Infants.

2.3.2. Clinical study

MENB REC 2ND GEN-023 (V72_57) : A Phase 3b, Observer-Blind, Randomized, Placebo Controlled, Multi-Center Study to Assess the Safety and Immunogenicity of GSK Meningococcal Group B Vaccine and 13-valent Pneumococcal Vaccine when Administered Concomitantly with Routine Vaccines to Healthy Infants.

Description

Context of the study:

As part of the US Food and Drug Administration's approval of a biologics license application for rMenB+OMV NZ, the study MENB REC 2ND GEN-023 (V72_57) is a required pediatric study under the Pediatric Research Equity Act to evaluate the safety and immunogenicity of rMenB+OMV NZ in North American infants from 6 weeks through 12 months of age.

Previous clinical studies conducted in Europe and other countries worldwide have shown that rMenB+OMV NZ demonstrated a robust immune response in all age groups against indicator test strains, H44/76 (fHbp), 5/99 (NadA), NZ98/254 (PorA P1.4), and M10713 (NHBA) and that the concomitant administration of rMenB+OMV NZ does not clinically interfere with response to the vaccine antigens present in routinely administered infant vaccines: diphtheria, tetanus, acellular pertussis, Haemophilus influenzae type b, inactivated poliomyelitis, hepatitis B, measles, mumps, rubella, varicella, and 7-valent pneumococcal conjugate vaccine. However, no data on the concomitant use of rMenB+OMV NZ with PCV13 and RIVs in North American infants was available prior to conducting this trial.

The purpose of this study therefore was to assess the safety and immunogenicity of rMenB+OMV NZ vaccine when administered concomitantly with the PCV13 and other US Advisory Committee on Immunization Practices recommended RIVs. The study also assessed the safety and the immunogenicity of the PCV13 vaccine when concomitantly administered with rMenB+OMV NZ vaccine

and RIVs, compared to PCV13 administered with a placebo and RIVs. In addition, the safety and immunogenicity of RIVs (DTPa-HBV-IPV, Hib, Rotarix [referred to as HRV throughout this document hereafter, in alignment with the nomenclature used in the clinical study report], MMR, VV) was assessed following their concomitant administration with rMenB+OMV NZ and/or PCV13.

No immunogenicity data were generated for HRV.

Design of the study:

Study MENB REC 2ND GEN-023 (V72_57) was a Phase 3b, observer-blind, randomized, placebo-controlled, multi-centric study with 2 parallel groups, conducted at 59 centers in the US.

Participants were randomized in a 2:1 ratio at Visit 1 (Day 1) to Group MenB+PCV and Group Placebo+PCV, respectively with the vaccination schedule as follows:

- Group MenB+PCV: rMenB+OMV NZ given concomitantly with PCV13 at 2, 4, 6, and 12 months of age along with other RIVs at applicable timepoints. Either PCV13 or PCV20 was allowed to be given at 12 months of age (Visit 5) for participants who had not reached Visit 5 at the time the protocol amendment 8 became effective.
- Group Placebo+PCV: Placebo and PCV13 given concomitantly at 2, 4, 6, and 12 months of age along with other RIVs at applicable timepoints. Either PCV13 or PCV20 was allowed to be given at 12 months of age (Visit 5) for participants who had not reached Visit 5 at the time the protocol amendment 8 became effective.

Three blood samples for immune response assessment of approximately 5 mL each were taken at Visit 4 (Day 151), i.e., 30 (-9 to +30) days after the third vaccination, Visit 5 (Day 301), i.e., 180 (-7 to 91) days after the third vaccination (pre-fourth vaccination), and Visit 6 (Day 331), i.e., 30 (-9 to +30) days after the fourth vaccination.

For each participant, the study duration was approximately 481 days (for participants who had not yet reached the 6-month follow-up after the last dose at the time protocol amendment 7 took effect) or 661 days (for all other participants).

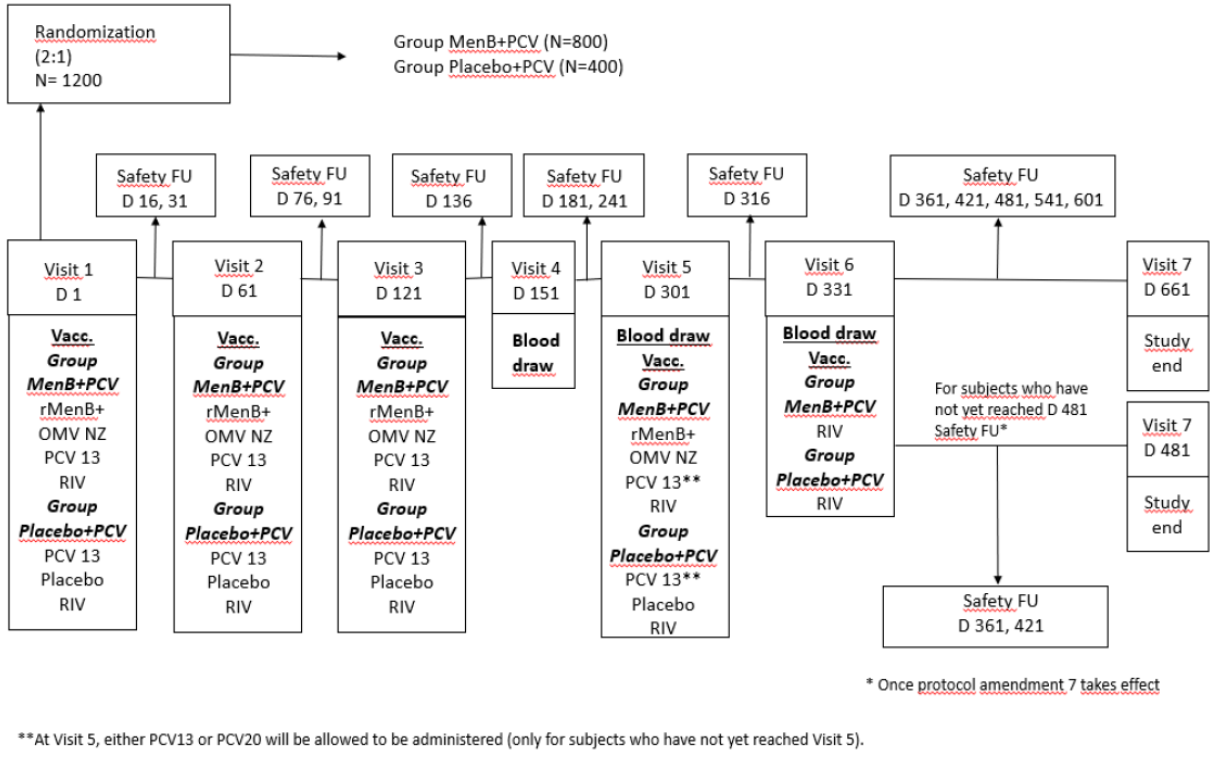

Figure 1. Overview of Study Design – V72_57 (source: protocol Figure 1). D: day; Vacc: vaccination, FU: follow-up call, RIV: routine infant vaccines (Visit 1 and Visit 2: DTPa-HBV-IPV, HRV, Hib; Visit 3: DTPa-HBV-IPV, Hib; Visit 5: MMR, VV)

Methods

Study participants

Most relevant inclusion criteria:

- A male or female between, and including, 42 and 84 days of age (i.e., 6 through 12 weeks) at the time of the first vaccination.
- Healthy subjects as established by medical history and clinical examination before entering into the study.
- Born full-term (i.e. after a gestation period of >= 38 weeks).

Most relevant exclusion criteria:

- Current or previous, confirmed or suspected disease caused by *N. meningitidis*
- Household contact with and/or intimate exposure from birth to an individual with laboratory confirmed *N. meningitidis* and/or *Streptococcus pneumoniae* infection or colonization.
- Previous administration of meningococcal B or pneumococcal vaccine at any time prior to informed consent.
- Received a dose of DTPa-HBV-IPV , HRV, MMR, VV and/or Hib at any time prior to informed consent. Receipt of one dose of HBV up to 4 weeks prior to informed consent is allowed.
- Uncorrected congenital malformation (such as Meckel’ s diverticulum) of the gastrointestinal tract that would predispose for Intussusception (IS).

Treatments

Table 1. Study Groups and Treatment Foreseen in the Study (Source: Protocol Table 2)

Treatment name	Vaccine name	Study Groups	
		MenB+PCV	Placebo+PCV
Bexsero	rMenB+OMV NZ	X	-
Prevnar13	PCV13*	X	X
Prevnar 20	***PCV20****	***X***	***X***
Placebo	NaCl	-	X
Pediarix	DTPa-HBV-IPV	X	X
Rotarix	HRV	X	X
Hiberix	Hib	X	X
M-M-R II	MMR	X	X
Varivax	VV	X	X

Note: Subjects in both groups will receive a fourth dose of Hib vaccine (*Hiberix*) and a single dose of DTPa vaccine (*Infanrix*) as non-study vaccines at Visit 6.

**** Either PCV13 or PCV20 is allowed to be given at 12 months of age (Visit 5) for subjects who have not reached Visit 5 at the time this protocol amendment becomes effective.***

Objective(s)

Note: All study objectives are listed below, with the specific objective related to HRV highlighted in italics.

Primary safety objective:

- *To assess the safety and tolerability of rMenB+OMV NZ, PCV13 and other RIV when administered concomitantly to healthy infants at 2, 4, 6, and 12 months of age, throughout the study duration.*

Co-primary immunogenicity objectives:

- To demonstrate the sufficiency of the immune response to rMenB+OMV NZ when administered concomitantly with PCV13 and other RIV to healthy infants at 2, 4, and 6 months of age, at 1 month after the third vaccination.
- To demonstrate the sufficiency of the immune response to rMenB+OMV NZ when administered concomitantly with PCV13 and other RIV to healthy infants at 2, 4, 6, and 12 months of age, at 1 month after the fourth vaccination.
- To demonstrate the immunological non-inferiority of PCV13 when administered concomitantly with rMenB+OMV NZ and other RIV to healthy infants at 2, 4, and 6 months of age, compared to PCV13 without rMenB+OMV NZ, at 1 month after the third vaccination.

Secondary immunogenicity objectives:

- To demonstrate the immunological non-inferiority of PCV13 when administered concomitantly with rMenB+OMV NZ and other RIV to healthy infants 2, 4, 6, and 12 months of age, compared to PCV13 and other RIV alone, at 1 month after the fourth vaccination.
- To demonstrate the immunological non-inferiority of PCV13 when administered concomitantly with rMenB+OMV NZ and other RIV to healthy infants at 2, 4, 6, and 12 months of age compared to PCV13 and other RIV alone, at both 1 month after the third and the fourth vaccinations.

- To demonstrate the immunological non-inferiority of DTaP-HBV-IPV and Hib vaccines when administered concomitantly with rMenB+OMV NZ and PCV13 to healthy infants at 2, 4, and 6 months compared to DTaP-HBV-IPV and Hib vaccines concomitantly administered with PCV13 without rMenB+OMV NZ, in terms of diphtheria toxoid, tetanus toxoid, pertussis toxin, pertactin, filamentous hemagglutinin, Hep B and Hib at 1 month after the third vaccination.
- To demonstrate the immunological non-inferiority of MMR and VV vaccines when administered concomitantly with rMenB+OMV NZ and PCV13 to healthy participants at 12 months compared to MMR and VV vaccines concomitantly administered with PCV13, without rMenB+OMV NZ, at 1 month after vaccination.
- To evaluate the immune response to rMenB+OMV NZ when administered concomitantly with PCV13 and other RIV to healthy infants at 2, 4, 6 and 12 months of age, at 1 month after the third vaccination, at 6 months after the third vaccination (immediately before the fourth vaccination), and at 1 month after the fourth vaccination against the M14459, 96217, NZ98/254 and M13520 test strains.
- To evaluate immune responses to routine infant vaccines DTaP-HBV-IPV, Hib, MMR and VV vaccines when administered concomitantly with rMenB+OMV NZ and PCV13 to healthy infants at 2, 4, 6, and 12 months of age, at 1 month after the third vaccination, at 1 month after the fourth vaccination.

Sample size

Target enrolment is 1200 subjects who will be randomly assigned to the 2 study groups in a 2:1 ratio.

Randomisation and blinding (masking)

Treatment allocation: Subjects to be randomized in a 2:1 ratio at Visit 1 (Day 1) to Groups MenB+PCV and Group Placebo+PCV, respectively.

Blinding: observer-blind study.

Statistical Methods

The primary objectives of this study include both safety and immunogenicity. The endpoints regarding safety objective were only descriptive.

Assessor's comment

MENB REC 2ND GEN-023 (V72_57) is a Phase 3b, observer-blind, randomized, placebo-controlled study conducted in the US to assess the safety and immunogenicity in health infants (6-12 week of age at first vaccination) of the Meningococcal Group B vaccine Bexsero and PCV13 when administered concomitantly with routine vaccines.

Subjects were randomized in a 2:1 ratio on Day 1 into groups receiving either Bexsero + PCV or Placebo + PCV, with a target enrolment of 1,200 subjects.

Bexsero or placebo was administered on D1, D61, D121 and D301.

PCV13 was administered on D1, D61 and D121. On D301, either PCV13 or PCV20 was administered (for participants who had not reached D301 when protocol amendment 8 became effective).

Routine vaccines were administered concomitantly at relevant timepoints, including Rotarix (D1 and D61), DTPa HBV IPV (D1 and D61), Hib (D1, D61 and D121), MMR (D301), and VV (D301).

The primary safety objective was to assess the safety and tolerability of Bexsero, PCV13 and other routine vaccines when administered concomitantly to healthy infants at 2, 4, 6, and 12 months of age, throughout the study duration. The associated safety endpoints were descriptive in nature.

Immunogenicity objectives were only related to Bexsero and PCV13, and no immunogenicity data were generated for Rotarix.

Results

Participant flow

A total of 1200 participants were planned to be enrolled in the study. Out of 1196 enrolled participants, 1195 (786 in MenB+PCV and 409 in Placebo+PCV) participants were randomized, 1184 received at least 1 dose of the study vaccination (Exposed Set) and 968 completed the study. A total of 1052 participants were included in the Full Analysis Set (FAS), and 983 participants were included in the Per Protocol Set (PPS).

Baseline data

- The mean (±SD) age (weeks) of the participants at enrollment was 8.7±1.0. Among them 608 (51.4%) were male and 576 (48.6%) were female.
- All the participants were from the United States (1184 [100%]).
- Overall, a total of 819 (69.2%) were White, 117 (9.9%) were Black or African American, 60 (5.1%) were Asian, 21 (1.8%) were American Indian or Alaska Native, and 167 (14.1%) were of another race.
- The mean (±SD) height at enrollment was 58.1 (±3.2) cm, and the mean weight was 5.3 (±0.7) kg.

Number analysed

During the study, all except 1 participant in the MenB+PCV group and all participants in the Placebo+PCV group were exposed to at least 1 dose of the rMenB+OMV NZ/placebo, and PCV13; while 3.2% participants in the MenB+PCV group and 3.5% participants in the Placebo+PCV group received at least 1 dose of PCV20 since the recommendation took effect.

Efficacy results

No efficacy or immunogenicity data were obtained for Rotarix in this study.

Safety results

Solicited AEs

- Within 30 minutes of any vaccination, the number of participants who had at least 1 solicited AE was 174 (22.3%) in the MenB+PCV group and 89 (22.1%) in the Placebo+PCV group.

During the 7 days follow-up following each vaccination and overall

- Within 7 days of any vaccination, there were 761 (98.1%) participants in the MenB+PCV group and 381 (95.0%) participants in the Placebo+PCV group who had at least 1 solicited AE.
- Overall, tenderness was the most frequently reported solicited administration-site AE (68.3%) after any rMenB+OMV NZ vaccination and irritability was the most frequently reported solicited systemic event (91.9%) after any vaccination in the MenB+PCV group. Overall, percentages of participants with solicited administration-site AEs and systemic AEs were numerically higher in the MenB+PCV group compared to the Placebo+PCV group.
- Overall, most of the solicited AEs were mild to moderate in intensity; severe solicited administration-site AEs were reported in 15.6% of participants in the MenB+PCV group after any rMenB+OMV NZ vaccination and severe solicited systemic AEs were reported in 16.9% of participants in the MenB+PCV group.

Unsolicited AEs

During the 30-day follow-up period after any vaccination:

- At least one unsolicited AE was reported by 515 (66.5%) participants in the MenB+PCV group and 260 (64.8%) participants in the Placebo+PCV group.
- At least one unsolicited AE related to the study intervention was reported by 61 (7.9%) participants in the MenB+PCV group and 34 (8.5%) participants in the Placebo+PCV group.
- The most frequently reported unsolicited AEs after any vaccination by SOC were infections and infestations, gastrointestinal disorders, and respiratory, thoracic and mediastinal disorders.

Throughout the study period:

- During the study period, unsolicited AEs were reported in 67.0% in the MenB+PCV group and 65.3% in the Placebo+PCV group.
- No deaths were reported in the study.
- SAEs were reported in 35 (4.5%) participants in the MenB+PCV group and 19 (4.7%) participants in the Placebo+PCV group. SAEs considered related to the study intervention were observed in 3 (0.5%) participants in the MenB+PCV group (pyrexia – 2 participants, febrile convulsion – 1 participant) and 1 (0.3%) participant in the Placebo+PCV group (tonsillar hypertrophy).
- Overall, there were 3 (0.4%) participants in the MenB+PCV group and 1 (0.2%) participant in the Placebo+PCV group who had at least 1 unsolicited AE leading to withdrawal. The events that led to withdrawal include movement disorder, neuroblastoma, and emotional distress, separately in 3 different participants in the MenB+PCV group and petit mal epilepsy in a participant in the Placebo+PCV group. The event of emotional distress was considered related to the study intervention.
- Six (0.8%) participants in the MenB+PCV group and 3 (0.7%) participants in the Placebo+PCV group reported unsolicited AESIs. The AESIs noted in the MenB+PCV group were febrile convulsion (3 participants), seizure (2 participants), type 1 diabetes mellitus (1 participant) and PFAPA syndrome (1 participant). One participant had severe febrile convulsion and was considered as related to study intervention.

- Overall, a total of 375 (48.4%) participants in the MenB+PCV group and 177 (44.1%) participants in the Placebo+PCV group had at least 1 medically attended unsolicited AE following any vaccination.

Assessor's comment

In total, 1196 participants were enrolled in the study, and 1184 received at least one dose of the study vaccine. These participants comprised the Exposed Set, used for the safety evaluation.

At time of enrolment, participants had a mean age of 8.7 ± 1.0 weeks. There was an even distribution by sex, with 51.4% being male and 48.6% female. Most participants were White (69.2%), followed by Black or African American (9.9%), Asian (5.1%), American Indian or Alaska Native (1.8%), and (14.1%) were of another race.

No immunogenicity data of relevance for Rotarix were generated in this study; therefore, immunogenicity results are not discussed.

Solicited AEs during 7 days following each vaccination were reported by 98.1% and 95.0% of participants in the Bexsero + PCV group and Placebo + PCV group, respectively.

Systemic solicited AE, were reported following D1 by 94.1% and 85.3% of participants, in the Bexsero + PCV group and Placebo + PCV group respectively; and following D61 by 89.7% and 76.4%, respectively in both groups. Severe systemic AEs following D1 and D61 were reported by less than 7% of participants.

Local solicited AEs are not relevant for Rotarix, as the vaccine is administered orally and therefore are not discussed.

Unsolicited AEs were reported in 67.0% in the Bexsero + PCV group and 65.3% in the Placebo + PCV group throughout the study. SAEs were reported in 35 (4.5%) participants in the Bexsero + PCV group and 19 (4.7%) participants in the Placebo + PCV group. Intussusception was not reported.

Six (0.8%) participants in the Bexsero + PCV group and 3 (0.7%) participants in the Placebo + PCV group reported unsolicited AESIs, including febrile convulsion (3 participants), seizure (2 participants), type 1 diabetes mellitus (1 participant) and PFAPA syndrome (1 participant). One participant had severe febrile convulsion and was considered as related to study intervention.

No death was reported in the study.

2.3.3. Discussion on clinical aspects

MENB REC 2ND GEN-023 (V72_57) is a Phase 3b, observer-blind, randomized, placebo controlled study conducted in the US to assess the safety and immunogenicity in healthy infants (6-12 week of age at first vaccination) of the Meningococcal Group B vaccine Bexsero and PCV13 when administered concomitantly with routine vaccines, including Rotarix, DTPa-HBV-IPV, Hib, MMR and VV.

Rotarix is a live attenuated human rotavirus (2-dose regimen) vaccine for oral administration. The current indication is active immunization of infants aged 6 to 24 weeks for prevention of gastroenteritis due to rotavirus infection. Information on co-administration of Rotarix and meningococcal group B vaccine is not included in the Rotarix Product information. According to the Rotarix Product

Information, Rotarix can be administered at the same time as diphtheria, tetanus, pertussis, hepatitis B, oral or inactivated polio, Haemophilus influenzae type b (Hib) as well as pneumococcal, and meningococcal serogroup C conjugate vaccines.

In this study, subjects were randomized in a 2:1 ratio on Day 1 into groups receiving either Bexsero + PCV or Placebo + PCV. All participants received Rotarix on Day 1 and Day 61.

The primary safety objective was to assess the safety and tolerability of Bexsero, PCV13 and other routine vaccines when administered concomitantly to healthy infants at 2, 4, 6, and 12 months of age, throughout the study duration. The associated safety endpoints were descriptive in nature.

Immunogenicity objectives were only related to Bexsero and PCV13. No immunogenicity data were generated for Rotarix.

In total, 1196 participants were enrolled in the study, and 1184 received at least one dose of the study vaccine. Participants were on average 8.7 ± 1.0 weeks old at enrolment, with a balanced sex distribution, and were predominantly White, with smaller proportions of Black or African American, Asian, American Indian or Alaska Native, Native Hawaiian or Other Pacific Islander, and other races.

Systemic solicited AE, were reported following D1 by 94.1% and 85.3% of participants, in the Bexsero + PCV group and Placebo + PCV group respectively; and following D61 by 89.7% and 76.4%, respectively in both groups. Severe systemic AEs following D1 and D61 were reported by less than 7% of participants.

Unsolicited AEs were reported in 67.0% in the Bexsero + PCV group and 65.3% in the Placebo + PCV group throughout the study. SAEs were reported in 35 (4.5%) participants in the Bexsero + PCV group and 19 (4.7%) participants in the Placebo + PCV group. Intussusception was not reported.

No death were reported in the study.

To conclude, the study findings are of limited relevance for Rotarix and relate only to safety outcomes, as no Rotarix-specific immunogenicity assessments were performed. Given that all participants received Rotarix concomitantly with multiple other vaccines, the safety data provide only limited information specific to Rotarix. As no safety concerns were identified, no update to the Rotarix SmPC is deemed necessary.

3. CHMP overall conclusion and recommendation

☒ **Fulfilled:**

No regulatory action required.