Vaxneuvance®
Pneumococcal 15-valent Conjugate Vaccine [CRM_{197} Protein], adsorbed

PCV 15

Dear Healthcare Professionals,

You are cordially invited to the

VAXNEUVANCE® launch event

29th June 2024 • 1:30 pm–5:30 pm
Goodwood Park Hotel

Streptococcus pneumoniae was estimated to be responsible for **more than 300,000 deaths** in **children aged <5 years** worldwide every year.[1] With approximately 90 serotypes present [2], **SEROTYPE 3** is still one of the leading causes of invasive pneumococcal disease (IPD) among children. **SEROTYPE 22F** and **33F** are emerging causes of IPD.[3,4]

MSD Singapore is committed to help in the prevention of IPD with the introduction of Vaxneuvance®, a 15-valent pneumococcal conjugate vaccine. With that, MSD would like to invite you to embark on this journey with us at our **launch event**.

To RSVP, please contact:
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RSVP by 21st June 2024

AGENDA

1:30pm – 2:30pm	Lunch/Registration Opens	
2:30pm – 2:35pm	**Welcome** **Saving and Improving Lives:** **Bringing PNEU Advances to Singapore**	**Dr Abdullahi Sheriff** (MSD Managing Director)
2:35pm – 2:40pm	**Introduction** **Opening Scientific Exchange**	**A/Prof Daniel Goh** (National University Hospital)
2:40pm – 3:10pm	**Global Burden of Pneumococcal Disease and the Public Health Impact of Pneumococcal Vaccinations**	**Dr Paul Van Buynder** (Griffith University)
3:10pm – 3:40pm	**The Hong Kong Experience** **Disease Burden of Serotype 3**	**Dr Leung Ting Fan** (The Chinese University of Hong Kong)
3:40pm – 4:10pm	**Science of VAXNEUVANCE®: Pediatrics Clinical Data** **Delivering both strong immunogenicity and disease coverage**	**Prof Anne Goh** (KK Women's and Children's Hospital)
4:10pm – 4:20pm	Tea Break	
4:20pm – 4:50pm	**Science of VAXNEUVANCE®: Adults Clinical Data** **Sequential vaccination expands coverage without compromising immunogenicity**	**Dr Leong Hoe Nam** (Mount Elizabeth Novena Hospital Rophi Clinic)
4:50pm – 5:20pm	**Focusing on What Matters Most: Expert Panel Discussion (Q&A)**	All Speakers
5:20pm – 5:25pm	**Key Insights and Impact of VAXNEUVANCE**	**Dr Jin Oh Kim** (MSD Medical Affairs)
5:25pm – 5:30pm	**VAXNEUVANCE® Launches** **Building a healthier Singapore today and into the future**	All Speakers

CME Points pending accreditation *Agenda may be subjected to changes.

VAXNEUVANCE® is indicated for active immunization for the prevention of [5]

Invasive disease, pneumonia and acute otitis media	Infants, Children, Adolescent (from 6 weeks to less than 18 years of age)
Invasive disease and pneumonia	Adults (individuals 18 years of age and older)

caused by *Streptococcus pneumoniae* **serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F** and **33F**.

Vaccination Schedule: [5]

Infants and children aged 6 weeks to less than 2 years

- 3-Dose Regimen: Dose 1 - As early as 6 weeks of age, Dose 2 - Administered 8 weeks later, Dose 3 (booster) - Recommended between 11 through 15 months of age.
- 4-Dose Regimen: Dose 1 - As early as 6 to 12 weeks of age, Dose 2 & Dose 3 - with an interval of 4 to 8 weeks, Dose 4 (booster) - 11 through 15 months of age and at least 2 months after Dose 3.

Adults 18 years of age and older

- 1 dose

With a consistent **safety profile** studied in a **broad range of populations**, including infants and children at increased risk, Vaxneuvance® showed:[3a,b]

Superior immune responses for **serotypes 3, 22F and 33F**

Robust immune responses for **all shared serotypes**

Noninferior immune responses vs **PCV13** (13 shared serotypes)

Selected Safety Information for VAXNEUVANCE® INDICATIONS VAXNEUVANCE is a vaccine indicated in infants, children, and adolescents from 6 weeks through 17 years of age (prior to the 18th birthday) for active immunization for the prevention of invasive disease, pneumonia and acute otitis media caused by *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F and 33F. VAXNEUVANCE is indicated in adults 18 years of age and older for active immunization for the prevention of invasive disease and pneumonia caused by *Streptococcus pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F and 33F. VAXNEUVANCE may not prevent disease caused by *S. pneumoniae* serotypes that are not contained in the vaccine. **DOSAGE AND METHOD OF USE** The vaccination schedule for VAXNEUVANCE should be based on official recommendations. Administer a 0.5 mL dose of VAXNEUVANCE intramuscularly. For intramuscular use only. Do not inject intravascularly. The preferred site for injection is the anterolateral aspect of the thigh in infants or the deltoid muscle of the upper arm in children and adults. The vaccine should not be injected in the gluteal area or areas where there may be a major nerve trunk and/or blood vessel. **Routine Vaccination Schedule for Infants and Toddlers** *3-Dose Regimen (Two-Dose Primary Series Followed by a Toddler Dose)* The vaccination regimen consists of 3 doses of VAXNEUVANCE, with the first dose given as early as 6 weeks of age, and a second dose administered 8 weeks later. The third dose should be administered at approximately 11 through 15 months of age. *4-Dose Regimen (Three-Dose Primary Series Followed by a Toddler Dose)* The vaccination regimen consists of 4 doses of VAXNEUVANCE, with the first dose given as early as 6 to 12 weeks of age, with an interval of 4 to 8 weeks between doses in the primary series. The fourth dose should be administered at approximately 11 through 15 months of age and at least 2 months after the third dose. *Preterm Infants* Preterm infants (<37 weeks gestation at birth) should receive a 4-dose regimen (three-dose primary series followed by a toddler dose) of VAXNEUVANCE, with the first dose given as early as 6 to 12 weeks of age, with an interval of 4 to 8 weeks between doses in the primary series. The fourth dose should be administered at approximately 11 through 15 months of age and at least 2 months after the third dose. *Prior Vaccination with Another Pneumococcal Conjugate Vaccine* he vaccination regimen can be completed with VAXNEUVANCE if initiated with another pneumococcal conjugate vaccine. **Catch-Up Vaccination Schedule for Children 7 Months Through 17 Years of Age** For children 7 months through 17 years of age who are pneumococcal vaccine-naïve or not fully vaccinated or completed a dosing regimen with lower-valency pneumococcal conjugate vaccines, the following catch-up schedule should be considered: *Infants 7 Through 11 months of age* Three doses, with the first two doses given at least 4 weeks apart. The third dose is given after 12 months of age, separated from the second dose by at least 2 months. *Children 12 Through 23 months of age* Two doses, with an interval of 2 months between doses. *Children and adolescents 2 Through 17 years of age* One single dose. If a previous pneumococcal conjugate vaccine was administered, at least 2 months should elapse before receiving VAXNEUVANCE. **Adults** One single dose. **Special Populations** The dosing schedule in special populations should be guided by official recommendations and may include more than one dose of VAXNEUVANCE. VAXNEUVANCE should not be diluted or mixed with other vaccines. The full recommended dose of the vaccine should be used. When VAXNEUVANCE is administered at the same time as another injectable vaccine(s), the vaccines should always be given at different injection sites. Because this product is a suspension containing an adjuvant, hold horizontally and shake vigorously immediately prior to use to obtain an opalescent suspension in the vaccine container. Do not use the vaccine if it cannot be resuspended. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration. This product should not be used if particulate matter or discoloration is found. The prefilled syringe is for single use only and should not be used for more than one individual. Attach a needle by twisting in a clockwise direction until the needle fits securely on the syringe. Inject the entire contents of the syringe. Exercise caution to avoid harm from an accidental needle stick. **CONTRAINDICATIONS** VAXNEUVANCE is contraindicated in individuals with a history of a severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine or any diphtheria toxoid-containing vaccine. **WARNINGS AND PRECAUTIONS** Individuals with altered immunocompetence, including those receiving immunosuppressive therapy, may have a reduced immune response to VAXNEUVANCE. The potential risk of apnea should be considered when administering any intramuscular vaccine to infants born prematurely. As the benefit of vaccination is high in this group of infants, vaccination generally should not be withheld or delayed. As with any vaccine, VAXNEUVANCE may not protect all vaccine recipients. **ADVERSE EVENTS** Adverse Reactions in Infants and Toddlers *Solicited Adverse Reactions* The majority of solicited adverse reactions were mild to moderate (based on intensity or size) and of short duration (=3 days). Severe reactions (defined as being extremely distressed or unable to do usual activities or size >7.6 cm) occurred in =1.3% of infants and toddlers following each dose, with the exception of irritability, which occurred in =5.2% of the participants. Local adverse reactions including pain, erythema, swelling, and induration. Systemic reactions including decreased appetite, irritability, somnolence, urticaria, and elevated body temperature. *Unsolicited Adverse Reactions* Injection-site urticaria occurred in up to 0.3% of infants and toddlers following each dose of VAXNEUVANCE. Safety with Concomitant Administration The safety profile was similar when other routine pediatric vaccines were administered concomitantly with VAXNEUVANCE or Prevnar 13. *Safety of a Mixed Dose Regimen of Different Pneumococcal Conjugate Vaccine* The safety profiles of mixed 4-dose regimens of VAXNEUVANCE and Prevnar 13 were generally comparable to those of complete 4-dose regimens of either VAXNEUVANCE or Prevnar 13. Adults 18 Years of Age and Older *Solicited Adverse Reactions* The majority of solicited adverse reactions were mild (based on intensity or size) and of short duration (=3 days); severe reactions (defined as an event that prevents normal daily activity or size >10 cm) occurred in =1.5% of adults. Local reactions including pain, erythema and swelling. Systemic reactions including fatigue, headache, myalgia, arthralgia, and elevated body temperature. *Unsolicited Adverse Reactions* Injection-site pruritus occurred in 1.0% to 2.8% of pneumococcal vaccine-naïve adults vaccinated with VAXNEUVANCE. *Safety with Concomitant Influenza Vaccine Administration* The safety profile of VAXNEUVANCE when administered concomitantly with inactivated influenza vaccine was generally consistent with the safety profile of VAXNEUVANCE. **Before prescribing VAXNEUVANCE®, please consult full prescribing information.**

References: 1. Center for Disease Control and Prevention (CDC). Global Pneumococcal Disease and Vaccination. Available at: https://www.cdc.gov/pneumococcal/global.html .Last Accessed: 8thFebruary 2024. **2.** World Health Organization (WHO). Pneumococcal Disease. Available at: https://www.who.int/teams/health-product-policy -and-standards/standards-and-specifications/vaccine-standardization/pneumococcal-disease. Last Accessed: 8th February 2024. **3.** European Centre for Disease Prevention and Control. Surveillance Atlas of Infectious Diseases. **4.** Balsells E, Guillot L, Nair H, Kyaw MH. Serotype distribution of Streptococcus pneumoniae causing invasive disease in children in the post-PCV era: a systematic review and meta-analysis. PLoS One. 2017;12(5):e0177113 **5.** Vaxneuvance® Product Insert Singapore. Available at: SG- Register of Therapeutic Products, Health Science Authority. https://www.hsa.gov.sg/e-services/infosearch

[a]**Study Design:** A pivotal, double-blind, active comparator controlled study where 1720 participants were randomized to receive VAXNEUVANCE® (N=558) or PCV13 (N=856) in a 4-dose regimen concomitantly with other pediatric vaccines. The primary series was administered at 2, 4, and 6 months of age and the toddler dose was administered at 12 through 15 months of age. A conclusion of noninferiority was based on ≥10-point difference in percentages of the lower bound of the 2-sided 95% CI for IgG response rates ≥0.35µ/mL 30 days post primary series for VAXNEUVANCE® vs PCV13 for 13 shared serotypes. A conclusion of superiority was based on >10-point difference in percentages of the lower bound of the 2-sided 95% CI for IgG response rates for VAXNEUVANCE® vs PCV13 for the 2 unique serotypes (22F and 33F), and >0- point difference for serotype 3. [b]**Coprimary endpoint:** Serotype-specific IgG GMCs were noninferior to PCV13 for 12 of the 13 shared serotypes, based on the lower bound of the 2-sided 95% CI for the GMC ratio (VAXNEUVANCE®/PCV13) being >0.5 for VAXNEUVANCE® vs PCV13 following a 3-dose primary series. The IgG GMC for serotype 6A narrowly missed the prespeci ed noninferiority criteria by a small margin (the lower bound of the 2- sided 95% CI for the GMC ratio [VAXNEUVANCE® vs PCV13] being 0.48 vs >0.5).VAXNEUVANCE® was superior to PCV13 as assessed by IgG GMCs, based on the lower bound of the 2- sided 95% CI for the GMC ratio being >2.0 for serotypes 22F and 33F and >1.2 for serotype 3.

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