NATIONAL PHARMACEUTICAL REGULATORY AGENCY
MINISTRY OF HEALTH MALAYSIA

TECHNICAL EVALUATION SUMMARY

PRODUCT NAME:
VAXNEUVANCE (Pneumococcal 15-Valent Conjugate Vaccine) Suspension For Injection Prefilled Syringe (MAL23126010AZ)

ACTIVE INGREDIENT:
Each 0.5 mL dose contains 32 mcg of total pneumococcal polysaccharide (2.0 mcg each of polysaccharide serotypes 1, 3, 4, 5, 6A, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F, and 33F, and 4.0 mcg of polysaccharide serotype 6B) conjugated to 30 mcg of CRM197 carrier protein.

PRODUCT REGISTRATION HOLDER:
Merck Sharp & Dohme (Malaysia) Sdn. Bhd.

PRODUCT MANUFACTURER:
Merck Sharp & Dohme B.V., Haarlem, Netherlands

APPROVAL DATE:
7 December 2023 (DCA 391)

1.0 BACKGROUND INFORMATION

- VAXNEUVANCE is a pneumococcal conjugate vaccine (PCV) that contains 15 distinct pneumococcal capsular polysaccharides individually conjugated to the CRM197 carrier protein originating from Corynebacterium diphtheriae C7.
- VAXNEUVANCE contains the 13 serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, and 23F) included in the registered vaccine Prevenar 13 (pneumococcal 13-valent conjugate vaccine [diphtheria CRM197 protein]), plus 2 additional serotypes (22F and 33F) that are not included in any currently registered conjugated PCV.

1.1 Proposed Indication:

VAXNEUVANCE is indicated for active immunisation 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 in infants, children and adolescents from 6 weeks to less than 18 years of age.

VAXNEUVANCE is indicated for active immunisation 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 in individuals 18 years of age and older.

VAXNEUVANCE may not prevent disease caused by S. pneumoniae serotypes that are not contained in the vaccine.

The use of this vaccine should be in accordance with official recommendations.

1.2 Proposed Posology:

Dosage
Administer a 0.5 mL dose of VAXNEUVANCE intramuscularly.

Routine vaccination schedule in infants and children aged 6 weeks to less than 2 years	
Two-dose primary series followed by a booster dose	The recommended immunization regimen consists of 3 doses of VAXNEUVANCE, each of 0.5 mL. The first dose is given as early as 6 weeks of age, with a second dose administered 8 weeks later. The third (booster) dose is recommended between 11 through 15 months of age.
Three-dose primary series followed by a booster dose	An immunization regimen consisting of 4 doses of VAXNEUVANCE, each of 0.5 mL, may be given. This primary series consists of 3 doses, with the first dose given as early as 6 weeks of age, with an interval of 4 to 8 weeks between doses in the primary series. The fourth (booster) dose is recommended between 11 through 15 months of age and at least 2 months after the third dose.
Preterm infants (<37 weeks gestation at birth)	The recommended immunization regimen consists of a three dose primary series of VAXNEUVANCE followed by a fourth (booster) dose, each of 0.5 mL, as per three-dose primary series followed by a booster dose posology
Prior vaccination with another pneumococcal conjugate vaccine	Infants and children who have begun immunization with another pneumococcal conjugate vaccine may switch to VAXNEUVANCE at any point in the schedule

Catch-up vaccination schedule for children 7 months to less than 18 years of age	
Unvaccinated infants 7 to less than 12 months of age	3 doses, each of 0.5 mL, with the first two doses given at least 4 weeks apart. A third (booster) dose is recommended after 12 months of age, separated from the second dose by at least 2 months.
Unvaccinated children 12 months to less than 2 years of age	2 doses, each of 0.5 mL, with an interval of 2 months between doses.
Unvaccinated or not fully vaccinated children and adolescents 2 to less than 18 years of age	1 dose (0.5 mL). If a previous pneumococcal conjugate vaccine was administered, at least 2 months should elapse before administering VAXNEUVANCE.
Vaccination schedule for individuals 18 years of age and older	
Individuals 18 years of age and older	1 dose (0.5 mL). The need for revaccination with a subsequent dose of VAXNEUVANCE has not been established.

1.3 Route of Administration:

For intramuscular use only

1.4 Pharmacological Aspects:

Pharmacodynamic Properties

Mechanism of Action

VAXNEUVANCE contains 15 purified pneumococcal capsular polysaccharides from Streptococcus pneumoniae (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 23F, with the additional serotypes 22F and 33F), each conjugated to a carrier protein (CRM197). VAXNEUVANCE elicits a T-cell dependent immune response to induce antibodies that enhance opsonisation, phagocytosis, and killing of pneumococci to protect against pneumococcal disease. Immune responses following natural exposure to Streptococcus pneumoniae or following pneumococcal vaccination can be determined by measuring opsonophagocytic activity (OPA) and immunoglobulin G (IgG) responses. OPA represents functional antibodies and is considered an important immunologic surrogate measure of protection against pneumococcal disease in adults. In children, a serotype-specific IgG antibody level corresponding to ≥0.35 µg/mL using the WHO enzyme linked immunosorbent assay (ELISA) has been used as the threshold value for the clinical evaluation of pneumococcal conjugate vaccines.

Special populations

Nursing Mothers

It is not known whether this vaccine is excreted in human milk.

Pediatric Use

The safety and effectiveness of VAXNEUVANCE in children younger than 6 weeks of age have not been established.

2.0 SUMMARY REPORT
2.1 Quality
2.1.1 Active Substance

The active substance of Vaxneuvance is Monovalent Bulk Conjugates (MBC) of each serotype (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F, and 33F). This MBC is made of two intermediates i.e., purified bulk (powder) of Pneumococcal Polysaccharides [PnPs] of 15 serotypes and Cross Reactive Material 197 [CRM197] carrier protein) by conjugation process. The PnP of 15 serotypes are derived from *Streptococcus pneumoniae* (*S. pneumoniae*) bacterium. CRM197 is a nontoxic (enzymatically inactive) form of diphtheria toxin (DT) from *Corynebacterium diphtheriae* C7. The characterization and quality attributes of Master Cell Bank (MCB) and Working Cell Bank (WCB) of each PnP and CRM197 have been conducted and concluded as satisfactory.

Process validation of PnP (including inactivation by liquefied phenol), CRM197 and MBC (including conjugation via reductive amination) have been conducted and the results from at least three consecutive batches of respective intermediates and active substance demonstrated that all batches met the pre-defined validation criteria.

The proposed 10-year shelf life of PnP and CRM197 are justified based on the presented long-term stability data conducted at condition ≤ –60 °C/ambient humidity. For MBC, all data for studies at the long-term condition (≤–60°C) met the commercial acceptance criteria through all tested 10-year intervals.

The PnP Powders is manufactured at Merck Sharp & Dohme, West Point, Pennsylvania, USA (inspected by National Health Surveillance Agency (ANVISA), Brazil) while CRM197 is manufactured at Boehringer Ingelheim RCV, GmbH & Co KG (BI-RCV), Vienna, Austria (inspected by Federal Office for Safety in Health Care (BASG), Austria) and the MBC is manufactured at MSD International GmbH T/A, MSD Ireland (Brinny), Brinny, Innishannon, Co. Cork, Ireland (inspected by Health Products Regulatory Authority (HPRA), Ireland).

2.1.2 Finished Product

VAXNEUVANCE finished product manufacturing process consists of four main steps: (1) Buffer and intermediate preparations; (2) Thawing and transfer of monovalent bulk conjugates (MBCs); (3) Formulation; (4) Filling, visual inspection and storage. The process validation results of the three batches provide documented evidence establishing that the manufacturing process for Vaxneuvance consistently produces product meeting predetermined quality attributes.

The proposed shelf life for drug product as 24 months is justified based on the current real time data tested to 24 months and supportive data from the Phase 3 Clinical batch WL00068290 tested through 30 months when stored under the recommended storage condition of 5°C (2 to 8°C)/ambient humidity.

The product has passed the evaluation on analytical protocol and method validation in accordance with the ICH Q2 (R1) guidelines.

VAXNEUVANCE is manufactured by MSD International GmbH T/A MSD Ireland (Carlow) Dublin Road, Carlow, Co. Carlow, Ireland (inspected by Health and Youth Care Inspectorate, Netherlands).

2.2 Non-Clinical Study

Three pharmacology in-vivo immunogenicity studies (Study NZWR-14, Study NZWR-16 & Study NZWR-17) were performed in New Zealand White (NZW) rabbits to evaluate immunogenicity of VAXNEUVANCE formulations using a compressed vaccination regimen where rabbits received either one-half or one-fifth of a human dose of vaccine. Another 2 pharmacology in-vivo immunogenicity studies (Study IRM-6 & Study IRM-9) were conducted in infant rhesus monkeys to compare the immune responses induced by VAXNEUVANCE and Prevnar 13™, and to test formulations of VAXNEUVANCE. Under toxicology, three repeat-dose toxicity studies (TT #08-1077, TT #16-1044 & Report TT #18-1028) and three developmental and reproductive toxicology (DART) studies (TT #19-7090, TT #19-7170 & TT #19-7190) have been conducted using rats. All toxicology studies have been conducted at the GLP certified facilities and according to OECD principles.

Nonclinical immunogenicity studies have demonstrated that VAXNEUVANCE is immunogenic in both New Zealand white rabbits and infant rhesus monkeys. The totality of the data from the repeat-dose toxicity studies were also evaluated the effects of an immune response to Vaxneuvance in age-appropriate populations and support the pediatric development program. From the DART studies, no Vaxneuvance-related maternal or developmental toxicity was observed at a dose providing 200-fold multiples over the current proposed marketed Vaxneuvance dose and formulation for adults on a µg/kg basis (32 µg of polysaccharide conjugated to CRM197 with 125 µg APA).
In conclusion, the non-clinical immunogenicity and toxicity profiles of VAXNEUVANCE have been thoroughly evaluated and concluded as satisfactory.

2.3 Clinical Study

2.3.1 Immunogenicity

The major pivotal studies were provided to support the indications:

Table 1: Summary of pivotal clinical studies conducted (Pediatrics and Adults)

Study Type & Design (N)	Objective of the Study	Results
Paediatrics (2+1 doses) 6 wks to less than 2 yrs old		
Study V114-025 (PNEU-PED-EU-1) *Martinon-Torres, F. et.al*: A Phase III, multicenter, randomized, double-blind, active comparator controlled study to evaluate the safety, tolerability, and immunogenicity of V114 compared with PCV13 in healthy infants (PNEU-PED-EU-1). *Vaccine 41 (2023) 3387–3398* 1:1 N= 591 [Vaxneuvance (V114)] N= 593 (Prevenar 13) Dose given at 2, 4, and 11 - 15 months (full term) or 2, 3, 4 and 11 to 15 months (preterm) (Co-administration with Infranrix Hexa and Rotarix)	To evaluate the safety, tolerability, and immunogenicity of a **3-dose** regimen of V114 in healthy infants (approximately 2 months of age (42 to 90 days inclusive) without prior administration of any pneumococcal vaccine)	**Primary Immunogenicity Results** **<u>Non- Inferiority: Immunogenicity at 30 days Post Toddler Dose (PTD):</u>** **<u>Shared Serotypes & Additional Serotypes</u>** V114 met non inferiority criteria for the 13 shared serotypes as assessed by the proportions of participants meeting the IgG threshold value of ≥0.35 µg/mL (response rates) for each serotype. The lower bound of the 2-sided 95% CI for the difference in the response rates [V114 minus Prevenar 13™] was greater than -10 percentage points for each serotype. V114 also met non-inferiority criteria for all 13 shared serotypes, as assessed by serotype-specific IgG GMCs at Day 30 PTD. For the two additional serotypes in V114 (22F and 33F), the lower bound of the two-sided 95% CI for the difference in the response rates (V114 - PCV13) was greater than -10 percentage points for each serotype and the lower bound of the two-sided 95% CI for the serotype-specific IgG GMC ratio (V114/PCV13) was greater than 2.0 for each serotype, meeting criteria for superiority. Figure 1: Forest plot of the proportions of participants with serotype-specific anti-PnP IgG response rates at 30 days PTD

(includes 5.4% of preterm infant)		

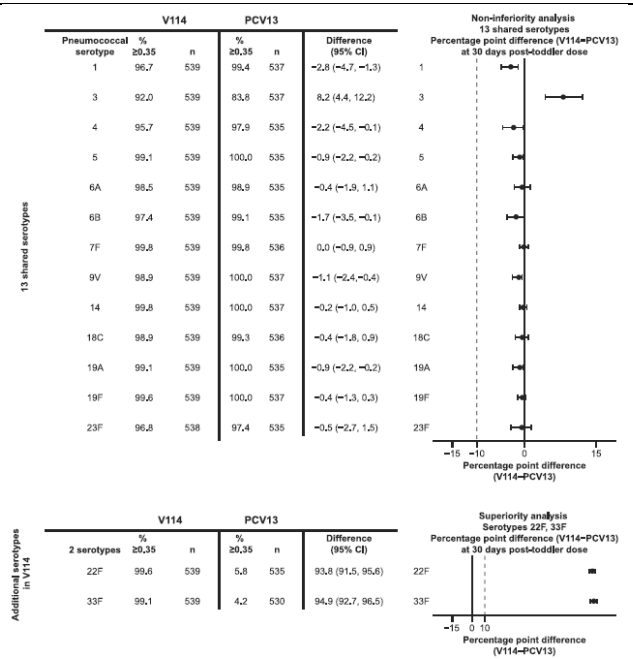
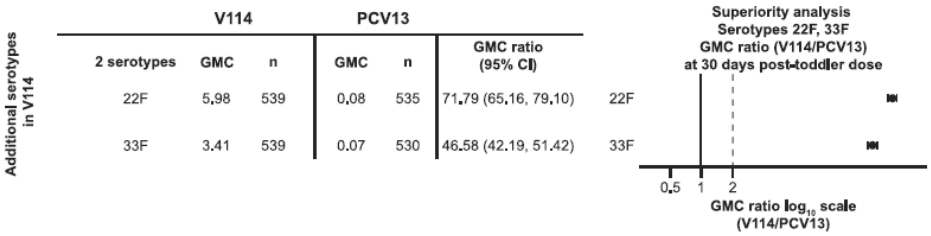


Figure 2: Forest plot of the proportions of participants with serotype-specific anti-PnP IgG GMCs at 30 days PTD



<u>Conclusion:</u>

After a 2 + 1 schedule (two-dose primary series followed by a toddler booster dose), V114 elicits non-inferior immune responses to the 13 shared serotypes and superior responses to the two additional serotypes (22F and 33F) compared to PCV13.

<table>
<tr><th>Study Type & Design (N)</th><th>Objective of the Study</th><th>Results</th></tr>
<tr><td colspan="3">Paediatrics (3+1 doses) 6 wks to less than 2 yrs old</td></tr>
<tr><td>Study P029V114 (PNEU-PED)

Lupinacci, R. et.al: A Phase III, multicenter, randomized, double-blind, active comparator controlled study to evaluate the safety, tolerability, and immunogenicity of a 4-dose of V114, a 15-valent pneumococcal conjugate vaccine, in healthy infants. Vaccine 41 (2023) 1142-1152

1:1
N= 858 [Vaxneuvance (V114)]
N= 856 (Prevenar 13)

Dose given at 2, 4, 6 and 12-15 months
(Co-administration with Pentacel, Hiberix, MMR-II, Varivax, Vaqta

(includes 8.6% of preterm infant)</td><td>To evaluate the safety, tolerability, and immunogenicity of a 4-dose regimen of V114 in healthy infants (approximately 2 months of age (42 to 90 days inclusive) without prior administration of any pneumococcal vaccine)</td><td>Primary Immunogenicity Results

<u>Non- Inferiority: Immunogenicity (Response rate) at 30 days Post Dose 3 (PD3): Shared Serotypes & Additional Serotypes</u>

● V114 met non-inferiority criteria by IgG response rates for each of the 13 shared serotypes compared to PCV13.
● V114 also met statistical non-inferiority criteria to PCV13 for the 2 serotypes unique to V114 (serotypes 22F and 33F) by IgG response rates and IgG GMCs at 30 days PD3, as well as IgG GMCs at 30 days PD4.

Table 1: V114 non-inferiority assessment by IgG response rates for the 13 shared serotypes at 30 days PD3.

<table>
<tr><th rowspan="2">Shared serotypes</th><th colspan="2">Observed response percentage (%)</th><th colspan="2">Difference (V114- PCV13)</th></tr>
<tr><th>V114</th><th>PCV13</th><th>Estimate (95% CI)</th><th>p value</th></tr>
<tr><td>1</td><td>95.7</td><td>99.1</td><td>-3.4 (-5.2, -1.8)</td><td><0.001</td></tr>
<tr><td>3</td><td>94.7</td><td>79.2</td><td>15.6 (12.1, 19.2)</td><td><0.001</td></tr>
<tr><td>4</td><td>96.4</td><td>98.6</td><td>-2.2 (-4.0, -0.6)</td><td><0.001</td></tr>
<tr><td>5</td><td>95.3</td><td>97.4</td><td>-2.1 (-4.2, -0.2)</td><td><0.001</td></tr>
<tr><td>6A</td><td>93.7</td><td>98.6</td><td>-4.9 (-7.1, -3.0)</td><td><0.001</td></tr>
<tr><td>6B</td><td>88.6</td><td>92.0</td><td>-3.4 (-6.6, -.03)</td><td><0.001</td></tr>
</table>
</td></tr>
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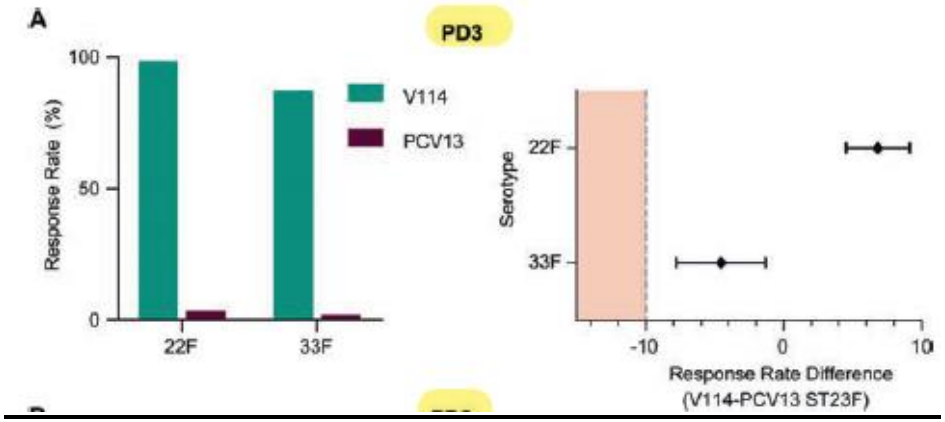
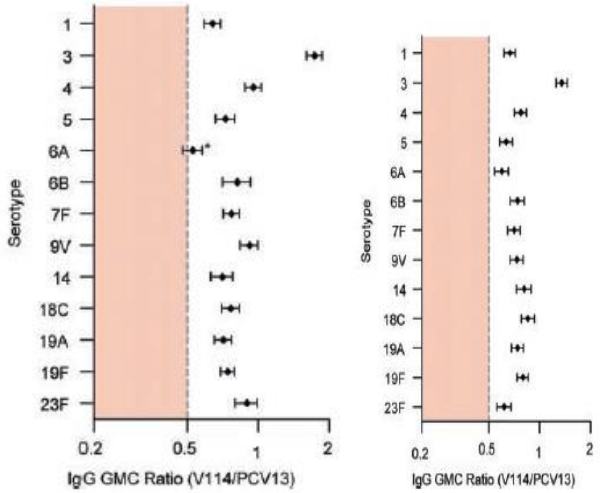
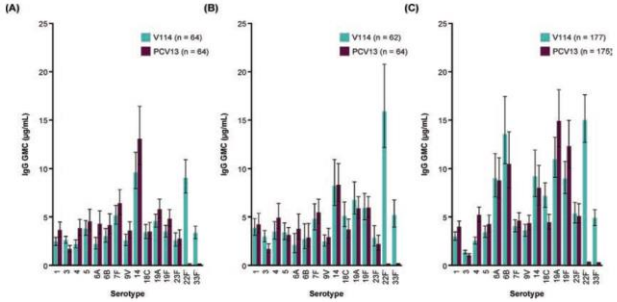
7F	99.0	99.8	-0.8 (-1.9, -.01)	<0.001
9V	97.1	98.2	-1.0 (-2.8, 0.6)	<0.001
14	97.9	97.9	0.0 (-1.6, 1.6)	<0.001
18C	97.4	98.3	-0.9 (-2.6, 0.7)	<0.001
19A	97.9	99.7	-1.8 (-3.2, -0.8)	<0.001
19F	99.0	100	-1.0 (-2.1, -0.4)	<0.001
23F	91.5	91.8	-0.3 (-3.2, 2.7)	<0.001

Fig 1: V114 non-inferiority assessment for serotypes 22F and 33F. IgG response rates at 30 days PD3.



		<u>Non- Inferiority: Immunogenicity (IgG GMCs ratio) at 30 days Post Dose 3 (PD3) and Post Dose 4 (PD4): Shared Serotypes & Additional Serotypes</u> ● V114 met noninferiority criteria compared to PCV13 for all 13 shared serotypes at PD4 and for 12 out of 13 shared serotypes at PD3, narrowly missing for serotype 6A (the lower bound of the confidence interval for V114/PCV13 GMC ratio for serotype 6A was 0.48 with a non-inferiority cutoff of > 0.50, p = 0.17). Fig 3: V114 non-inferiority assessment for the 13 shared serotypes by IgG GMCs.  <u>Conclusion:</u> V114 was immunogenic for all 15 serotypes included in the vaccine. For the immunogenicity analyses, non-inferiority of V114 was demonstrated

		for all 15 serotypes based on response rates at PD3 and IgG GMCs at PD4.

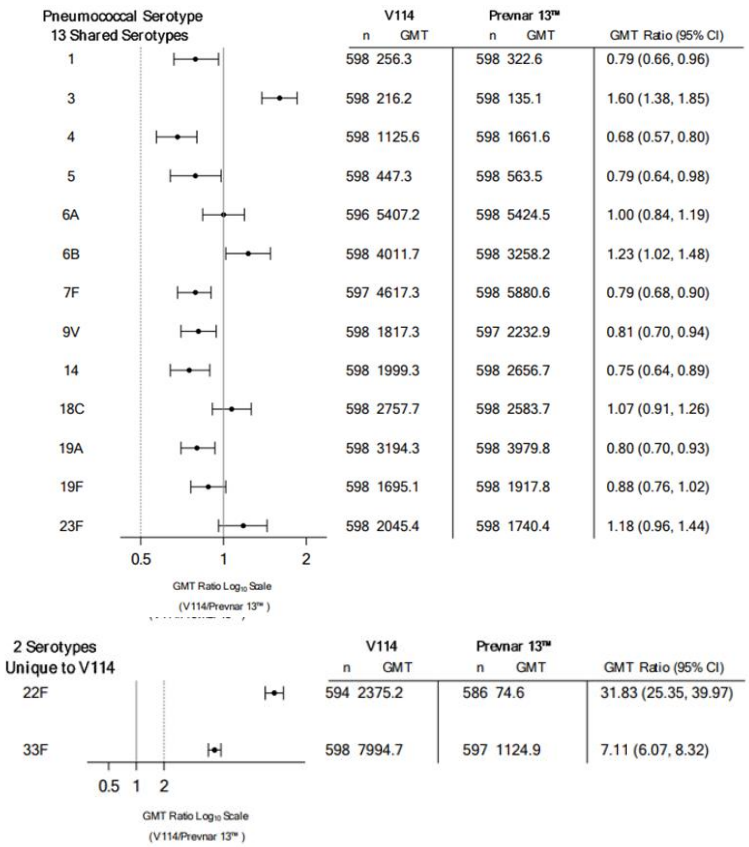
Study Type & Design (N)	Objective of the Study	Results
Paediatrics (Catch up) 7 months till less than 18 years old		
Study V114-024 (PNEU-PLAN) Banniettis N. et.al: A phase III, multicenter, randomized, double-blind, active comparator controlled study to evaluate the safety, tolerability, and immunogenicity of catch-up vaccination regimens of V114, a 15-valent pneumococcal conjugate vaccine, in healthy infants, children, and adolescents (PNEU-PLAN). *Vaccine 40* (2022) 6315–6325 1:1 N= 303 [Vaxneuvance (V114)] N= 303 (Prevenar 13) **Schedule A** 7 to 11 months of age (PCV-naïve): 3 doses Dose 1: at randomization Dose 2: 4 to 8 weeks after Dose 1	To assess the safety and immunogenicity of V114 when given as catch-up vaccination using recommended age-appropriate catch-up vaccination schedules (7 months to 17 years old)	**Primary Immunogenicity Endpoint - Serotype-specific IgG GMCs at 30 Days Following the Last Dose of Study Intervention** ● Anti-PnP serotype-specific IgG GMCs at 30 days post-final dose were generally comparable between the vaccination groups for the 13 shared serotypes in V114 and PCV13 for participants 7–11 months of age, 12–23 months of age, and 2–17 years of age. ● Anti-PnP IgG GMCs for the two serotypes (22F and 33F) unique to V114 at 30 days post final dose were higher in the V114 group than in the PCV13 group.  Fig. 3: Estimated serotype-specific anti PnP IgG GMCs 30 days after final vaccination with PCV for participants (A) 7-11 months, (B) 12-23 months, (C) 2-17 years old <u>Conclusion:</u> Overall, catch-up vaccination with V114 elicited serotype specific anti-pneumococcal IgG responses to all 15 serotypes in healthy children 7 months–17 years of age.

Dose 3: 8 to 12 weeks after Dose 2 and ≥12 months of age **Schedule B** 12 to 23 months of age (PCV-naïve): 2 doses Dose 1: at randomization Dose 2: 8 to 12 weeks after Dose 1 **Schedule C** 2 to 17 years of age (PCV-naïve or PCV-experienced): Single dose administered at randomization and at least 8 weeks after previous dose of PCV for participants who were PCV-experienced		

Study Type & Design (N)	Objective of the Study	Results
Adults (18 to 49 years old)		
Study V114-017 (PNEU-DAY) Phase 3, Multicenter, Randomized, Double-blind, Active Comparator-controlled Study to Evaluate the Safety, Tolerability, and Immunogenicity of V114 Followed by Administration of	To evaluate the safety, tolerability, and immunogenicity of V114 in pneumococcal vaccine-naïve, immunocompetent adults 18 to 49 years of age with or without risk factors for pneumococcal disease.	**Primary Immunogenicity Results- Serotype-specific Opsonophagocytic activity (OPA) responses at Day 30 (Following vaccination with V114)** ● V114 was immunogenic in pneumococcal vaccine-naïve, immunocompetent adults 18 to 49 years of age with or without risk factors for pneumococcal disease as assessed by OPA GMTs at 30 days postvaccination (Day 30) for all 15 serotypes contained in the vaccine.

PNEUMOVAX™23 Six Months Later in Immunocompetent Adults Between 18 and 49 Years of Age at Increased Risk for Pneumococcal Disease N= 1515 [Vaxneuvance (V114)] N= 380 (Prevenar 13) 1 dose V114 or Prevenar 13 given (Day 1 1 dose Pneumovax 23 (Month 6)		**Primary Immunogenicity Results- Serotype-specific Opsonophagocytic activity (OPA) responses at Day 30 (Following vaccination with PPV23)** ● V114 or Prevnar 13 followed by PPV23 was immunogenic for all 15 serotypes as assessed by serotype-specific OPA GMTs and IgG GMCs at 30 days postvaccination with PPV23. PPV23 elicited an immune response for serotypes 22F and 33F at 30 days postvaccination with PPV23 in the Prevnar 13 group. <u>Conclusion:</u> V114 induces immune responses for all 15 pneumococcal serotypes as assessed by OPA GMTs and IgG GMCs at 30 days postvaccination with V114. V114 can be followed by PPV23 at 6 months as immune response is maintained for shared serotypes and the sequential administration is well tolerated.

Study Type & Design (N)	**Objective of the Study**	**Results**
Adults (≥50 years old)		
Study V114-019 (PNEU-AGE) A Phase 3, Multicenter, Randomized, Double-blind, Active Comparator-controlled Study to Evaluate the Safety, Tolerability, and Immunogenicity of V114 in	To evaluate the safety, tolerability, and immunogenicity of a of V114 in healthy adults 50 years of age or older without a history of invasive pneumococcal disease or prior administration of any pneumococcal vaccine	**Primary Immunogenicity Results- Serotype-specific OPA Responses at 30 Days Post Vaccination** ● V114 met non inferiority criteria for the 13 shared serotypes as assessed by serotype-specific OPA GMTs at 30 days post vaccination. The lower bound of the 95% CI of the estimated OPA GMT ratio (V114/Prevnar 13) was >0.5 for all shared serotypes ● V114 met superiority criteria for the 2 serotypes unique to V114 as assessed by serotype specific OPA GMTs at 30 days post vaccination. The lower bound of the 95% CI of the estimated OPA GMT ratio (V114/Prevnar 13) was >2.0 for both unique serotypes

Healthy Adults 50 Years of Age or Older 1:1 N= 600 [Vaxneuvance (V114)] N= 600 (Prevenar 13)		Figure 11-1 Forest Plot of OPA GMT Ratios at Day 30 (Per-Protocol Population)  <u>Conclusion:</u> In pneumococcal vaccine-naïve adults ≥50 years of age, V114 elicits an immune response that is comparable to Prevnar 13 for the shared serotypes, and higher than Prevnar 13 for serotypes 3, 22F, and 33F.

2.3.2 Safety

Paediatric

- V114 is well tolerated in infants (healthy or preterm receiving 3 or 4 doses) and children 6 weeks through 17 years of age with a safety profile that is comparable to that of Prevenar 13.
- The safety profile of a catch-up vaccination schedule in healthy infants and children from 7 months through 23 months of age is consistent with the safety profile of a routine vaccination schedule initiated from 6 to 12 weeks of age.
- Post vaccination AEs were generally mild and the most frequently reported AEs after each dose of V114 were the solicited AEs of irritability, somnolence, injection-site pain, injection-site erythema, decreased appetite, injection-site swelling, and injection-site induration.
- V114 is also well tolerated when used concomitantly with other routine paediatric vaccines as part of recommended paediatric vaccination schedules.

Adult

- V114 is well tolerated when administered as a single dose to adults ≥18 years of age with and without prior pneumococcal vaccination, with a safety profile that is generally comparable with Prevnar 13.
- The most frequently reported adverse events were solicited injection site and systemic events which were injection-site pain, fatigue and myalgia and were comparable across the intervention groups. Of the participants with solicited AEs, the majority had events of short duration (≤3 days).

3.0 CONCLUSION:

Drug Control Authority (DCA) on the 391th meeting on 7 December 2023 has decided to approve the registration of this product with the following indication:

VAXNEUVANCE is indicated for active immunisation 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 in infants, children and adolescents from 6 weeks to less than 18 years of age.

VAXNEUVANCE is indicated for active immunisation 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 in individuals 18 years of age and older.

VAXNEUVANCE may not prevent disease caused by S. pneumoniae serotypes that are not contained in the vaccine.

The use of this vaccine should be in accordance with official recommendations.