Category

Best Biotechnology Product

General Information

Company Name *

Merck & Co Inc.

Product/Solution Name *

CAPVAXIVE™ (Pneumococcal 21-valent Conjugate Vaccine)

Compound/Tech Name*

V116

Trade Name *

CAPVAXIVE™

Corporate Name *

CAPVAXIVE™

Date of Approval *

2024-06-17

Indications *

In the US, CAPVAXIVE™ is a vaccine indicated for:

- active immunization for the prevention of invasive disease caused by Streptococcus pneumoniae serotypes 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15B, 15C, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F, and 35B in individuals 18 years of age and older.

- active immunization for the prevention of pneumonia caused by S. pneumoniae serotypes 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15C, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F, and 35B in individuals 18 years of age and older.

- The indication for the prevention of pneumonia caused by S. pneumoniae serotypes 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15C, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F, and 35B is approved under accelerated approval based on immune responses as measured by opsonophagocytic activity (OPA). Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

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Therapeutic Areas *

Vaccine for pneumococcal disease

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Background information and need for drug / device
(please be as specific as possible in your description; limit 500 words)

Streptococcus pneumoniae (S. pneumoniae) remains a major cause of vaccine-preventable disease worldwide, and pneumococcal disease (PD) remains an unmet medical need despite the significant public health impact of currently available pneumococcal vaccines. It is associated with significant morbidity and mortality among children and adults worldwide, with disease incidence varying by age, region, and race. More than 100 distinct serotypes of this gram-positive bacterium have been identified; a subset of which cause the majority of disease.

S. pneumoniae is a leading cause of lower respiratory tract infection and is estimated to cause around 10-30% of community-acquired pneumonia. The case fatality rate of invasive pneumococcal disease is approximately 11-22% in adults older than 50 years with a higher number of deaths observed in adults older than 85 years. Among adults, the incidence rates of invasive PD (IPD) are 2- to 8-fold higher in persons with chronic illnesses (e.g., alcoholism, chronic heart disease, chronic lung disease, diabetes, cancer, and HIV) than in healthy individuals, and rates increase with the number of conditions present. The risk of IPD is increased further in individuals considered high risk such as those individuals who are immunocompromised.

PCV vaccination is a global health priority and is the primary and most cost-effective medical intervention for the prevention of PD. The mechanism of action of all licensed pneumococcal vaccines is the induction of protective, serotype-specific, anti-capsular antibodies. Over 140 regions/countries have introduced a routine infant PCV immunization program, which has significantly reduced the PD burden in children, with more modest reductions observed in adults due to indirect protection. The PD burden in adults is now higher than it is in children, with approximately 7 cases per 100,000 in children younger than 5 years, and approximately 24 cases per 100,000 in adults 65 years of age and older based on data from 2019 in the US. Increases in IPD cases due to certain serotypes not included in currently available vaccines have been observed in various countries worldwide, especially in adult populations and are associated with a high degree of invasiveness and antimicrobial resistance. Additionally, while the disease incidence decreased during the COVID-19 pandemic, recent data indicate that it is now returning to pre-pandemic levels.

Despite surveillance data showing the differing serotype distribution and frequency between children and adults, the current approach in the field of PCV vaccinology has been the development of PCVs for use in both adult and pediatric populations. There remains an unmet need for a population specific approach that provides the potential to prevent a substantial proportion of the remaining

pneumococcal disease burden in adults. CAPVAXIVE was developed as the first population-specific PCV for adults.

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History of the development of the solution/product *
(please be as specific as possible in your description; 500 words)

CAPVAXIVE, (V116) a 21-valent pneumococcal conjugate vaccine (PCV) was designed to provide broader disease coverage in adults. This approach is centered on optimizing the public health impact by focusing on distinct, yet complementary approaches for pediatric and adult populations. This approach recognizes the importance of maintaining protection in children against serotypes afforded by PCV7 and PCV13, and also recognizes that there is a burden of residual disease in adults due to serotypes not included in alternate licensed options.

CAPVAXIVE was developed as the first adult-specific PCV; serotypes were selected for inclusion based, in part, on surveillance data from regions with established pediatric pneumococcal vaccination programs. This approach broadens the disease coverage against pneumococcal disease with a substantial incremental benefit compared to currently licensed pneumococcal vaccines. CAPVAXIVE includes 21 serotypes that are the largest contributors to adult residual disease, with serotypes that are common to PCV13, PCV15, and PCV20, as well as unique serotypes not included in any licensed vaccine.

CAPVAXIVE
The Phase 3 clinical program included multiple Phase 3 studies that randomized over 6,600 adults across 282 clinical study sites in 21 countries. Over 4,500 adults received CAPVAXIVE in these studies, including those with and without prior pneumococcal vaccination. The targeted enrollment of diverse populations of adults ≥18 years of age across different races and ethnicities who may benefit from prevention of pneumococcal disease through vaccination. Approximately one-third of participants were ≥65 years of age, and approximately one-third of those had ≥1 chronic medical condition associated with an increased risk of pneumococcal disease.

Based on results from the Phase 3 studies, CAPVAXIVE elicits an immune response to all 21 serotypes contained in the vaccine in adults ≥18 years of age when administered as a single dose, and is well tolerated in adults ≥18 years of age, including pneumococcal vaccine-naïve and pneumococcal vaccine-experienced individuals, with a safety profile that is comparable to currently licensed pneumococcal vaccines.

CAPVAXIVE was approved by the US FDA for use in adults for the prevention of invasive disease and prevention of pneumonia caused by certain serotypes of Streptococcus pneumoniae on 17-June-2024.

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Why this drug or device is innovative, the broad implications for future research, and/or how it will improve the human condition *

CAPVAXIVE is the first PCV specifically developed to provide significantly broader pneumococcal disease coverage in adults compared with alternate licensed pneumococcal vaccines. CAPVAXIVE targets residual disease in adults with the inclusion of key serotypes common to licensed vaccines and 8 unique serotypes not contained in any other licensed vaccine. In 2019 in the US, the serotypes included in CAPVAXIVE were responsible for approximately 82% of IPD in adults 18 to 64 years of age and approximately 85% of IPD in adults ≥65 years, with the serotypes unique to CAPVAXIVE accounting for approximately 30% of IPD. The most recent data shared by CDC in Feb 2024 compares CAPVAXIVE to PCV20 based on data from 2018-2022, and estimates that the serotypes in CAPVAXIVE accounted for ~85% of IPD cases in adults 65+, and the 11 serotypes in CAPVAXIVE but not in PCV20 account for ~38% of IPD cases in adults 65+.

CAPVAXIVE represents a substantial improvement and provides a meaningful advantage over existing PD prevention strategies for adults ≥18 years of age. Clinical data show that CAPVAXIVE is immunogenic in all populations studied. It is anticipated that CAPVAXIVE-induced functional antibody responses will confer protection against pneumococcal disease caused by these serotypes, and that this will translate into effectiveness in a real-world setting. CAPVAXIVE has the potential to reduce morbidity and mortality of pneumococcal disease in adults due to protection attributed to the serotypes covered by the vaccine. Additionally, a recent study reported that, compared to currently recommended pneumococcal vaccines, CAPVAXIVE would be clinically and economically favorable in older adults. The model estimated >90,000 and >127,000 quality-adjusted life years gained in Black and non-Black adults, respectively.

Overall, CAPVAXIVE represents a significant and meaningful improvement over vaccines currently licensed for the prevention of invasive disease and pneumonia due to S. pneumoniae in adults.

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Please provide appropriate references (PubMed, Abstract, Website) *

1. Platt H, Omole T, Cardona J, et al. Safety, tolerability, and immunogenicity of a 21-valent pneumococcal conjugate vaccine, V116, in healthy adults: phase 1/2, randomised, double-blind, active comparator-controlled, multicentre, US-based trial. Lancet Infect Dis. 2023;23(2):233-246. doi:10.1016/S1473-3099(22)00526-6

2. Haranaka M, Yono M, Kishino H, et al. Safety, tolerability, and immunogenicity of a 21-valent pneumococcal conjugate vaccine, V116, in Japanese healthy adults: A Phase I study. Hum Vaccin Immunother. 2023;19(2):2228162. doi:10.1080/21645515.2023.2228162

3. Li J, Bruno C, Fernsler D, Morgan L, Waleed M, Platt H. Immunogenicity of V116, an Investigational Adult-Specific Pneumococcal Conjugate Vaccine, in Pneumococcal Vaccine-Naïve Adults 50-64, 65-74,

and ≥75 Years of Age: Subgroup Analysis of a Randomized Phase 3 Trial (STRIDE-3). Presented at International Society of Pneumonia & Pneumococcal Diseases, Cape Town, South Africa, March 2024.

4. Scott P, Haranaka M, Yang Y-C, Choi JH, Stacey H, Dionne M, Greenberg D, Grijalva CG, Orenstein WA, Fernsler D, Gallagher N, Zeng T, Li J, Platt H, for the STRIDE-6 study group. A Phase 3 Clinical Study to Evaluate the Safety and Immunogenicity of V116, an Investigational Adult-specific Pneumococcal Conjugate Vaccine, in Pneumococcal Vaccine–experienced Adults 50 Years of Age or Older (STRIDE-6). Presented at International Society of Pneumonia & Pneumococcal Diseases, Cape Town, South Africa, March 2024.

5. Fernsler D, Scott P, Gallagher N, Li J, Zeng T, Platt H. Immunogenicity of V116, an Investigational Adult-Specific Pneumococcal Conjugate Vaccine, in Adults ≥50 Years of Age by Time Since Prior Pneumococcal Vaccination: Subgroup Analysis of a Phase 3 Trial (STRIDE-6). Presented at International Society of Pneumonia &umoc Pneoccal Diseases, Cape Town, South Africa, March 2024.

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7. Omole T, Weinberg AS, Fernandez B, Azizad M, Pragalos AA, Greenberg D, Grijalva CG, Orenstein WA, Euler D, Fernsler D, Park J, Li J, Platt H, for the STRIDE-5 study group. A Phase 3 Randomized Study to Evaluate Safety, Tolerability, and Immunogenicity of V116, an Investigational Adult-Specific Pneumococcal Conjugate Vaccine, Administered Concomitantly With Influenza Vaccine in Adult ≥50 Years (STRIDE-5). Presented at International Society of Pneumonia & Pneumococcal Diseases, Cape Town, South Africa, March 2024.

8. Pathirana J, Ramgopal M, Martin C, Lombaard J, Shahin C, Launay O, Ratanasuwan W, Greenberg D, Grijalva CG, Orenstein WA, Hall L, Fernsler D, Kim Y, Li J, Platt HL. A Phase 3 Study to Evaluate the Safety, Tolerability, and Immunogenicity of V116, an Investigational Adult-Specific Pneumococcal Conjugate Vaccine, in Adults Living with HIV (STRIDE-7: Part A). Presented at International Society of Pneumonia & Pneumococcal Diseases, Cape Town, South Africa, March 2024.

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Attached Files:

- 2024 CAPVAXIVE Abstract Page.docx