**CAPVAXIVE™**

**Company Name:**

Merck & Co., Inc.

**Product Name:**

CAPVAXIVE

**Compound Technical Name:**

Pneumococcal 21-valent Conjugate Vaccine

**Date of FDA Approval:**

17-June-2024

**Therapeutic Categories**

Vaccine for *pneumococcal disease*

**Indication**

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.

**Drug Innovation Description**

*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 pneumococcal vaccines.  *Streptococcus pneumoniae* infection 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.

PCV vaccination is a global health priority and is the primary and most cost-effective medical intervention to prevent PD. Over 140 regions/countries have introduced a routine infant PCV immunization program, which has significantly reduced the PD burden in children. The PD burden in adults is now higher than it is in children, and invasive PD cases due to certain serotypes not included in currently available vaccines have been observed in various countries worldwide.

There remains an unmet need in adults where pneumococcal disease is a major health threat. Despite surveillance data showing the differing serotype distribution and frequency between children and adults, until recently PCVs have been developed 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 is the first population-specific PCV for adults.

CAPVAXIVE was developed as the first adult-specific PCV; serotypes were selected for inclusion based, in part, on surveillance data in 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 currently licensed vaccines, as well as unique serotypes.

In summary, 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 and as such represents a significant advancement over other vaccines currently licensed for the prevention of invasive disease and pneumonia due to *S. pneumoniae* in adults.