



NEWS RELEASE

U.S. FDA Approves CAPVAXIVE™ (Pneumococcal 21-valent Conjugate Vaccine) for Prevention of Invasive Pneumococcal Disease and Pneumococcal Pneumonia in Adults

6/17/2024

CAPVAXIVE (V116) is specifically designed for adults and covers serotypes responsible for approximately 84% of invasive pneumococcal disease in adults 50 years of age and older

Across four Phase 3 studies, CAPVAXIVE demonstrated robust immune responses in both vaccine-naïve and vaccine-experienced adult populations

RAHWAY, N.J.--(BUSINESS WIRE)-- Merck (NYSE: MRK), known as MSD outside of the United States and Canada, announced today that the U.S. Food and Drug Administration (FDA) has approved CAPVAXIVE™ (Pneumococcal 21-valent Conjugate Vaccine) 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.

CAPVAXIVE is specifically designed to help protect adults against the serotypes that cause the majority of invasive pneumococcal disease (IPD) cases. The approval follows the FDA's Priority Review of Merck's application. Do not

administer CAPVAXIVE to individuals with a history of a severe allergic reaction (e.g., anaphylaxis) to any component of CAPVAXIVE or to diphtheria toxoid; see additional Select Safety Information below.

This 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.

The U.S. Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices is expected to meet later this month to discuss and make recommendations for the use of CAPVAXIVE in adults.

"Complications from invasive pneumococcal disease can lead to hospitalization, organ damage and even death. Many cases of adult disease are caused by serotypes not included in other approved pneumococcal conjugate vaccines," said Dr. Walter Orenstein, professor emeritus of medicine, epidemiology, global health and pediatrics at Emory University and member of Merck's Scientific Advisory Committee. "CAPVAXIVE is designed to include the serotypes that cause the majority of invasive pneumococcal disease in adults, helping to protect adults against invasive pneumococcal disease and pneumococcal pneumonia."

Based on CDC data from 2018-2021, the serotypes covered by CAPVAXIVE are responsible for more cases of IPD in adults compared to PCV20 (pneumococcal 20-valent conjugate vaccine).

- In adults 50 years of age and older, CAPVAXIVE covers the serotypes responsible for approximately 84% of IPD cases, compared to approximately 52% covered by PCV20.
- In adults 65 years of age and older, CAPVAXIVE covers the serotypes responsible for approximately 85% of IPD cases, compared to approximately 51% covered by PCV20.

These values are based on CDC epidemiologic data and do not reflect the efficacy of the respective vaccines. There are currently no studies comparing the efficacy of CAPVAXIVE and PCV20.

CAPVAXIVE includes eight unique serotypes not covered by other currently approved pneumococcal vaccines; those serotypes were responsible for approximately 27% of IPD cases in adults 50 years of age and older and approximately 30% in adults 65 years of age and older, based on the same CDC data.

"Today's approval is a testament to our population-specific strategy behind CAPVAXIVE, which demonstrated robust immunogenicity in a range of adult populations and is driven by a deep understanding of pneumococcal disease," said Dr. Dean Y. Li, president, Merck Research Laboratories. "We are proud to provide CAPVAXIVE as a new option specifically designed to help protect against the majority of invasive pneumococcal disease-causing serotypes in

adults.”

Among the clinical data supporting the approval are results from the pivotal Phase 3 STRIDE-3 trial (NCT05425732), which evaluated CAPVAXIVE compared to PCV20 in adults 18 years of age and older who had not previously received a pneumococcal vaccine. The approval is also supported by results from the Phase 3 STRIDE-5 (NCT05526716) and STRIDE-6 (NCT05420961) trials evaluating CAPVAXIVE in vaccine-naïve and vaccine-experienced adults (see “Clinical Data Supporting FDA Approval,” below, for additional details).

About CAPVAXIVE

CAPVAXIVE is Merck’s approved 21-valent pneumococcal conjugate vaccine indicated for active immunization for the prevention of invasive disease and pneumonia in adults 18 years of age and older. CAPVAXIVE is specifically designed to help address *Streptococcus pneumoniae* serotypes predominantly responsible for adult invasive pneumococcal disease (IPD), including eight unique serotypes, 15A, 15C, 16F, 23A, 23B, 24F, 31 and 35B compared to other pneumococcal vaccines. CAPVAXIVE is administered as a single dose.

Select Safety Information for CAPVAXIVE

Do not administer CAPVAXIVE to individuals with a history of a severe allergic reaction (eg, anaphylaxis) to any component of CAPVAXIVE or to diphtheria toxoid.

Individuals with altered immunocompetence, including those receiving immunosuppressive therapy, may have a reduced immune response to CAPVAXIVE.

The most commonly reported (>10%) solicited adverse reactions in individuals 18 through 49 years of age who received CAPVAXIVE were: injection-site pain (73.1%), fatigue (36.0%), headache (27.5%), myalgia (16.4%), injection-site erythema (13.8%), and injection-site swelling (13.3%).

The most commonly reported (>10%) solicited adverse reactions in individuals 50 years of age and older who received CAPVAXIVE were: injection-site pain (41.2%), fatigue (19.7%), and headache (11.0%).

Vaccination with CAPVAXIVE may not protect all vaccine recipients.

Clinical Data Supporting FDA Approval

CAPVAXIVE was approved based on data that included Phase 3 clinical studies designed to evaluate its safety and immunogenicity in a variety of adult populations. These included studies of:

- Vaccine-naïve adults : STRIDE-3 (NCT05425732) is a double-blind, Phase 3 study which evaluated CAPVAXIVE compared to PCV20 in individuals 18 years of age and older who had not previously received a pneumococcal conjugate vaccine. Participants 50 years of age and older were enrolled in cohort 1 (n=2,362), and participants 18 through 49 years of age were enrolled in cohort 2 (n=300). Participants were randomized to receive a single dose of either CAPVAXIVE or PCV20. Results from the study include:
 - In adults 50 years of age and older (cohort 1), CAPVAXIVE was non-inferior to PCV20 for the 10 serotype polysaccharides shared with both vaccines (3, 6A, 7F, 8, 10A, 11A, 12F, 19A, 22F, 33F), as assessed by serotype-specific OPA geometric mean titers (GMTs) at 1 month postvaccination;
 - CAPVAXIVE was superior to PCV20 for 10 of 11 serotype polysaccharides included in CAPVAXIVE but not in PCV20 (9N, 15A, 16F, 17F, 20A, 23A, 23B, 24F, 31, 35B), as assessed by serotype-specific OPA GMTs 1 month postvaccination and the proportions of patients with a greater than or equal to four-fold increase in OPA from prevaccination to 1 month postvaccination;
 - Immune responses were observed for serotype 15C in participants receiving CAPVAXIVE but did not meet criteria for statistical significance.
 - In individuals 18 through 49 years of age (cohort 2), CAPVAXIVE elicited non-inferior immune responses (immunobridged) compared to individuals 50 through 64 years of age, as assessed by serotype-specific OPA GMTs 1 month postvaccination;
 - Across both cohorts, CAPVAXIVE had a safety profile comparable to PCV20.
- Co-administration of CAPVAXIVE with quadrivalent influenza vaccine (QIV) : STRIDE-5 (NCT05526716) is a randomized, double-blind, Phase 3 study which evaluated CAPVAXIVE when administered concomitantly or sequentially (30 days later) with QIV in adults 50 years of age and older (n=1,080). Results from the study include:
 - For the primary immunogenicity endpoints, CAPVAXIVE administered concomitantly with QIV was non-inferior to CAPVAXIVE administered sequentially with QIV for 20 of 21 serotypes in CAPVAXIVE (as assessed by OPA GMTs at 1 month postvaccination), as well as for three of four influenza strains in QIV (as assessed by hemagglutination inhibition (HAI) GMTs at 1 month postvaccination);
 - The rates and severity of solicited systemic adverse reactions and solicited local adverse reactions at the CAPVAXIVE injection site were similar when CAPVAXIVE was administered with or without inactivated QIV.
- Vaccine-experienced adults : STRIDE-6 (NCT05420961) is a randomized descriptive Phase 3 study which evaluated CAPVAXIVE in individuals 50 years of age and older who had previously received a pneumococcal vaccine at least one year before enrollment. Participants were enrolled into one of three cohorts based on their previous pneumococcal vaccination history (cohort 1: PPSV23 [pneumococcal 23-valent polysaccharide vaccine], cohort 2: PCV13 [pneumococcal 13-valent conjugate vaccine], or cohort 3: PPSV23 followed by or

preceded by PCV13, PPSV23 preceded by PCV15 [pneumococcal 15-valent conjugate vaccine], or PCV15 alone). Participants in cohort 1 were randomized to receive CAPVAXIVE (n=231) or PCV15 (n=119), participants in cohort 2 were randomized to receive CAPVAXIVE (n=176) or PPSV23 (n=85), and participants in cohort 3 were allocated to receive CAPVAXIVE (n=106). In each of the 3 cohorts, serotype-specific OPA GMTs and the proportion of individuals with ≥ 4 -fold rise in OPA responses from baseline to 1-month postvaccination were assessed. Results from the study include:

- In cohort 1, CAPVAXIVE elicited OPA responses that were comparable to PCV15 for the 6 common serotypes, and higher for the 15 unique serotypes and serotype 15B;
- In cohort 2, CAPVAXIVE elicited OPA responses comparable to PPSV23 for the 12 common serotypes and serotype 15B, and higher for the 9 unique serotypes;
- OPA responses to CAPVAXIVE were similar across the 3 cohorts of participants who previously received one or more pneumococcal vaccines;
- CAPVAXIVE had a safety profile comparable to both PCV15 and PPSV23.

About Pneumococcal Disease

Pneumococcal disease is an infection caused by a bacteria called *Streptococcus pneumoniae*. There are about 100 different types (referred to as serotypes) of pneumococcal bacteria, which can affect adults differently than children. Pneumococcal disease can be invasive or non-invasive. Non-invasive pneumococcal illnesses include pneumonia (when pneumococcal disease is confined to the lungs), whereas invasive pneumococcal illnesses include pneumococcal bacteremia (infection in the bloodstream), bacteremic pneumococcal pneumonia (pneumonia with bacteremia) and pneumococcal meningitis (infection of the coverings of the brain and spinal cord). Pneumococcal pneumonia is a type of bacterial pneumonia, which is the most common clinical presentation of pneumococcal disease in adults. It's estimated that over 150,000 adults are hospitalized from pneumococcal pneumonia each year in the U.S.

About Merck

At Merck, known as MSD outside of the United States and Canada, we are unified around our purpose: We use the power of leading-edge science to save and improve lives around the world. For more than 130 years, we have brought hope to humanity through the development of important medicines and vaccines. We aspire to be the premier research-intensive biopharmaceutical company in the world – and today, we are at the forefront of research to deliver innovative health solutions that advance the prevention and treatment of diseases in people and animals. We foster a diverse and inclusive global workforce and operate responsibly every day to enable a safe, sustainable and healthy future for all people and communities. For more information, visit www.merck.com and connect with us on **X (formerly Twitter)**, **Facebook**, **Instagram**, **YouTube** and **LinkedIn**.

Forward-Looking Statement of Merck & Co., Inc., Rahway, N.J., USA

This news release of Merck & Co., Inc., Rahway, N.J., USA (the “company”) includes “forward-looking statements” within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. These statements are based upon the current beliefs and expectations of the company’s management and are subject to significant risks and uncertainties. There can be no guarantees with respect to pipeline candidates that the candidates will receive the necessary regulatory approvals or that they will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; the company’s ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of the company’s patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

The company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in the company’s Annual Report on Form 10-K for the year ended December 31, 2023 and the company’s other filings with the Securities and Exchange Commission (SEC) available at the SEC’s Internet site (www.sec.gov).

Please see Prescribing Information for CAPVAXIVE (Pneumococcal 21-valent Conjugate Vaccine) at https://www.merck.com/product/usa/pi_circulars/c/capvaxive/capvaxive_pi.pdf and Patient Information/Medication Guide for CAPVAXIVE at https://www.merck.com/product/usa/pi_circulars/c/capvaxive/capvaxive_ppi.pdf.

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