NEWS RELEASE

Systematic Review of 15 Studies Focused on Epidemiology and Antimicrobial Resistance of Pneumococcal Serotypes Covered by CAPVAXIVE® (Pneumococcal 21-valent Conjugate Vaccine) in U.S. Adults

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Findings presented at IDWeek 2025 underscore the importance of considering serotypes that disproportionately impact adults in the U.S. and show greater resistance to commonly prescribed antibiotics

RAHWAY, N.J.--(BUSINESS WIRE)-- Merck (NYSE: MRK), known as MSD outside of the United States and Canada, today announced the presentation of findings from a systematic literature review of studies on the epidemiology and antimicrobial resistance (AMR) of pneumococcal serotypes covered by CAPVAXIVE® (Pneumococcal 21-valent Conjugate Vaccine) in U.S. adults. The evaluation examined 15 studies published between 2015 and 2025 to assess the serotype-specific burden of pneumococcal disease (PD) associated with serotypes covered by CAPVAXIVE but not PCV20 (pneumococcal 20-valent conjugate vaccine) (CAPVAXIVE-unique serotypes: 9N, 15A, 15C, 16F, 17F, 20A, 23A, 23B, 24F, 31, 35B) compared to serotypes covered by PCV20 but not CAPVAXIVE (PCV20-unique serotypes: 1, 4, 5, 6B, 9V, 14, 18C, 19F, 23F). Findings were presented at IDWeek 2025 in Atlanta, GA.

A total of 15 full-text publications from the U.S., in addition to CDC Active Bacterial Core (ABC) Surveillance reports, were included in the analysis. Of these 15, 13 reported prevalence, five reported incidence, two reported mortality, two reported AMR, one reported health resource utilization (HRU) and PD complications. Results of this systematic literature review showed that CAPVAXIVE-unique serotypes are more prevalent in U.S. adults with PD than PCV20-unique serotypes. Based on two of the publications, PD caused by CAPVAXIVE-unique serotypes have higher rates of resistance to commonly prescribed antibiotics used to treat non-invasive PD. Specific findings from the systematic review of the studies

include:

- As of 2023, the ABC data indicated that in older adults (≥65 years), the prevalence of invasive PD attributed to CAPVAXIVE-unique serotypes was more than triple (34.8%) that of PCV20-unique serotypes (8.5%). Among adults 50-64 years old, the prevalence of CAPVAXIVE-unique serotypes was ~30%, vs ~15% for PCV20-unique serotypes;
- Among hospitalized adults (≥18 years) from 2009-2017, AMR was reported for seven of the CAPVAXIVE-unique serotypes and one of the PCV20-unique serotypes;
- Among hospitalized adults (≥18 years) in studies where AMR was reported, penicillin and erythromycin resistance were higher for serotypes 35B (96% and 89%) and 23A (72% and 46%). Multidrug resistance rates were highest for serotypes 19F (42%) and 23A (27%). Serotype 19F is covered by PCV20; serotypes 35B and 23A are covered by CAPVAXIVE.

CAPVAXIVE is indicated in the U.S. for:

- Active immunization for the prevention of invasive disease and pneumonia 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 should not be administered 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.

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.

“To help address the burden of pneumococcal disease, it is important to understand the prevalence and antimicrobial resistance among pneumococcal serotypes,” said Dr. Paula Annunziato, senior vice president, infectious diseases and vaccines, Global Clinical Development, Merck Research Laboratories. “By covering the serotypes responsible for the majority of invasive pneumococcal disease cases in U.S. adults, based on 2018-2022 national-level CDC data, CAPVAXIVE is specifically designed for adults."

CAPVAXIVE is currently approved in the U.S., European Union, Japan and many other countries around the world. Specifically designed for adults, CAPVAXIVE helps provide coverage against the serotypes responsible for approximately

84% of invasive pneumococcal disease (IPD) cases in adults 50 years of age and older, compared to approximately 52% covered by PCV20, based on national-level CDC ABC surveillance data from 2018-2022, representing ~35 million persons and 10 states across the US. Regional variations may exist. 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. These values do not reflect the efficacy of the respective vaccines, and there are currently no studies comparing the efficacy of CAPVAXIVE and PCV20.

About CAPVAXIVE

CAPVAXIVE is Merck's 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.

Selected Safety Information for CAPVAXIVE in the U.S.

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.

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 225,000 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. 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, 2024 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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