NEWS RELEASE

U.S. FDA Approves an Additional Indication for CAPVAXIVE® (Pneumococcal 21-valent Conjugate Vaccine) in Children and Adolescents Aged 2 through 17 at Increased Risk for Pneumococcal Disease

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CAPVAXIVE is the only Pneumococcal Conjugate Vaccine (PCV) specifically indicated and studied in the U.S. for use in this population

CAPVAXIVE, when added to existing primary pediatric pneumococcal vaccination series, helps deliver additional protection by including serotypes not contained in approved primary pediatric PCV series

RAHWAY, N.J.--(BUSINESS WIRE)-- Merck (NYSE: MRK), known as MSD outside of the United States and Canada, today announced that the U.S. Food and Drug Administration (FDA) has approved an expanded indication for CAPVAXIVE® (Pneumococcal 21-valent Conjugate Vaccine) to include children and adolescents aged 2 through 17 years who have completed a primary pediatric pneumococcal vaccination series and have one or more chronic medical conditions that put them at an increased risk for pneumococcal disease. With this approval, CAPVAXIVE is the only PCV specifically indicated and studied in the U.S. for use in this patient population.

CAPVAXIVE is indicated for:

- Active immunization for the prevention of invasive pneumococcal 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 and individuals 2 through 17 years of age who are at

increased risk for pneumococcal disease;
- 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.

“Children and adolescents with certain chronic conditions are at an increased risk for pneumococcal disease, including pneumonia, meningitis, and bloodstream infections,” said Dr. Rotem Lapidot, Chief of Pediatric Infectious Diseases at Rambam Health Care Campus, investigator, STRIDE-13 trial. “This approval recognizes the potential of CAPVAXIVE to deliver additional protection by including serotypes not contained in approved primary pediatric PCV series, and represents a new approach to helping protect children and adolescents at increased risk for pneumococcal disease.”

The approval is based on data from the Phase 3 STRIDE-13 trial, which evaluated CAPVAXIVE compared to PPSV23 (pneumococcal 23-valent polysaccharide vaccine) in children and adolescents aged 2 through 17 years who completed a primary pediatric pneumococcal vaccination series and have one or more chronic medical conditions that put them at an increased risk of pneumococcal disease. See “STRIDE-13 Clinical Data Supporting Approval” below for additional details.

“While CAPVAXIVE was specifically designed for adults, it may also offer additional disease protection for this specific population of children and adolescents, when given after the primary pediatric pneumococcal vaccination series,” said Dr. Paula Annunziato, senior vice president, infectious diseases and vaccines, global clinical development, Merck Research Laboratories. “The approval of CAPVAXIVE for children and adolescents at increased risk for pneumococcal disease demonstrates our commitment to addressing this disease in people of all ages, not only addressing an unmet need, but also reinforcing Merck’s longstanding commitment to public health and infectious diseases.”

The expanded indication for CAPVAXIVE complements existing primary pediatric pneumococcal vaccination series for children and adolescents at increased risk for pneumococcal disease. According to a 2025 study of 2015-2019 CDC ABC surveillance data, including three groups, one of which consisted of children <18 years old (age range 31

to 109 months; n=219) with at least one risk condition for invasive pneumococcal disease (IPD) such as chronic heart disease, chronic lung disease, diabetes, and chronic kidney disease, CAPVAXIVE covers the serotypes responsible for ~79% of IPD cases. In this risk group, the 11 unique serotypes covered by CAPVAXIVE account for ~40% of IPD cases. These values are based on CDC epidemiologic data and do not reflect the efficacy of CAPVAXIVE. There are currently no studies evaluating the efficacy of CAPVAXIVE.

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 and for the prevention of invasive disease in children and adolescents aged 2 through 17 years who have one or more chronic medical conditions that put them at an increased risk of pneumococcal disease. CAPVAXIVE was specifically designed to help address the Streptococcus pneumoniae serotypes predominantly responsible for IPD in adults, including eight unique serotypes, 15A, 15C, 16F, 23A, 23B, 24F, 31 and 35B compared to other approved pneumococcal vaccines. CAPVAXIVE is administered as a single dose.

CAPVAXIVE helps provide coverage against the serotypes responsible for approximately 82% of IPD cases in adults 50 years of age and older, compared to ~54% by PCV20, based on national-level CDC data from 2019-2023. 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.

With this approval, CAPVAXIVE is also indicated for the prevention of invasive disease in children and adolescents aged 2 through 17 years who have one or more chronic medical conditions that put them at an increased risk for pneumococcal disease.

Select Safety Information for CAPVAXIVE in Children and Adolescents at Increased Risk for Pneumococcal Disease in the U.S.

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.

Syncope may occur with administration of injectable vaccines.

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%).

The most commonly reported (>10%) solicited adverse reactions in individuals 2 through 17 years of age who are at increased risk for pneumococcal disease were: injection-site pain (67.7%), injection-site erythema (24.3%), fatigue (20.1%), injection-site swelling (18.8%), headache (17.1%), malaise (13.3%), and irritability (11.6%).

Vaccination with CAPVAXIVE may not protect all vaccine recipients.

STRIDE-13 Clinical Data Supporting Approval

STRIDE-13 (**NCT06177912**) is a randomized, double-blind, active comparator-controlled Phase 3 study that evaluated individuals 2 through 17 years of age with one or more prespecified medical conditions (diabetes mellitus, chronic heart disease, chronic kidney disease, chronic liver disease, chronic lung disease) known to increase the risk of pneumococcal disease and who have previously completed a primary pneumococcal vaccination regimen at least 8 weeks prior to enrollment (n=874). Participants were randomized 3:2 to receive a single dose of CAPVAXIVE (n=527) or PPSV23 (n=347). Results from the study include:

- CAPVAXIVE was noninferior to PPSV23 for the 12 shared serotypes and induced statistically significantly greater OPA GMTs compared to PPSV23 for the 9 serotypes unique to CAPVAXIVE;
- CAPVAXIVE also elicited immune responses to serotype 15B (cross-reactive to serotype 15C). In a post hoc analysis utilizing the same prespecified noninferiority criterion that was used for the shared serotypes, CAPVAXIVE was noninferior to PPSV23 for serotype 15B;
- The safety profile of CAPVAXIVE was generally comparable to PPSV23. Solicited adverse reactions following administration of CAPVAXIVE lasted a median of 2 days with most reactions lasting ≤3 days;
- The proportion of individuals reporting 1 or more serious adverse events (SAE) within 6 months postvaccination was 5.5% (n=29) in individuals vaccinated with CAPVAXIVE and 7.2% (n=25) in individuals vaccinated with PPSV23. There were no notable patterns or imbalances between vaccine groups for SAEs. One individual (0.2%) who received CAPVAXIVE had an SAE considered related to vaccination. This SAE was syncope (Grade 2, required hospitalization) and occurred approximately 3 minutes postvaccination.

About Pneumococcal Disease

Pneumococcal disease is an infection caused by 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).

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, 2025 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 the Prescribing Information for CAPVAXIVE (Pneumococcal 21-valent Conjugate Vaccine) at **https://www.merck.com/product/usa/pi_circulars/c/capvaxive/capvaxive_pi.pdf** and the Patient Information/Medication Guide for CAPVAXIVE at **https://www.merck.com/product/usa/pi_circulars/c/capvaxive/capvaxive_ppi.pdf** .

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