NEWS RELEASE

CAPVAXIVE® (Pneumococcal 21-valent Conjugate Vaccine) Demonstrates Positive Immune Responses in Children and Adolescents at Increased Risk of Pneumococcal Disease

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Results from the Phase 3 STRIDE-13 trial presented at the 6th ESCMID Conference on Vaccines

Merck to share STRIDE-13 results with global regulatory authorities

RAHWAY, N.J.--(BUSINESS WIRE)-- Merck (NYSE: MRK), known as MSD outside of the United States and Canada, today announced positive results from the Phase 3 STRIDE-13 trial evaluating CAPVAXIVE® (Pneumococcal 21-valent Conjugate Vaccine) at the 6th European Society of Clinical Microbiology and Infectious Diseases (ESCMID) Conference on Vaccines, taking place in Lisbon, Portugal. The trial evaluated the safety, tolerability and immunogenicity of CAPVAXIVE compared to PPSV23 (pneumococcal 23-valent polysaccharide vaccine) in children and adolescents aged 2 to <18 years who have completed a primary pediatric pneumococcal vaccination regimen and have one or more chronic medical conditions that put them at an increased risk of pneumococcal disease.

Key findings from the STRIDE-13 study include:

- CAPVAXIVE elicited immune responses to all 21 serotypes (or strains) as assessed by serotype-specific opsonophagocytic activity (OPA) geometric mean titers (GMTs) at 30 days post-vaccination (secondary immunogenicity endpoint);
- CAPVAXIVE was noninferior to PPSV23 for each of the 12 serotypes shared between the vaccines and superior to PPSV23 for each of the nine serotypes unique to CAPVAXIVE, as measured by serotype-specific OPA GMTs

at 30 days post-vaccination (primary immunogenicity endpoint);
- The proportions of participants with adverse events (AEs), including systemic and serious vaccine-related AEs, were generally comparable between groups (primary safety endpoint).

These results will be presented today (Abstract #00093) at the 6th Vaccines Conference organized by the ESCMID, in scientific collaboration with the European Society for Paediatric Infectious Diseases (ESPID), the European Association of Hospital Pharmacists (EAHP) and the European Medicines Agency (EMA).

“Children and adolescents living with chronic medical conditions are at increased risk of pneumococcal disease and offering them additional protection is essential,” said Dr. Rotem Lapidot, chief of Pediatric Infectious Diseases at Rambam Health Care Campus and investigator, STRIDE-13 trial. “Results from STRIDE-13 demonstrate the potential of CAPVAXIVE to deliver protection for these vulnerable populations, who may benefit from additional pneumococcal disease coverage by including serotypes not contained in other approved pneumococcal infant regimens.”

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 OPA. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

“While CAPVAXIVE was designed to specifically cover the serotypes that cause the majority of invasive pneumococcal disease (IPD) cases in adults, findings from STRIDE-13 underscore its added potential to help protect children and adolescents who are at an increased risk,” said Dr. Paula Annunziato, senior vice president, infectious diseases and vaccines, Global Clinical Development, Merck Research Laboratories. “We are encouraged by the safety and immunogenicity data presented at the 6th ESCMID Conference on Vaccines, which underpin our commitment to ensuring infants and adults have access to protection against invasive pneumococcal disease.”

CAPVAXIVE is specifically designed for adults and helps provide coverage against the serotypes responsible for approximately 84% of IPD cases in adults 50 years of age and older, compared to approximately 52% covered by PCV20 (pneumococcal 20-valent conjugate vaccine), based on national-level CDC data from 2018-2022. In children and adolescents ages 2 to <18 years of age who are at increased risk of IPD, CAPVAXIVE has the potential to provide additional protection by covering approximately 78% of IPD cases, with 11 unique serotypes that account for approximately 34% of IPD cases, based on national-level CDC data from 2019-2023 in individuals 2-17 years old.

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

These results from STRIDE-13 represent the final readout of the Phase 3 STRIDE clinical program and will be shared with global regulatory authorities. CAPVAXIVE is currently approved in the U.S., European Union, Japan and multiple other countries around the world, based on safety and immunogenicity data from the Phase 3 STRIDE clinical program.

STRIDE-13 Data (Abstract #00093)

STRIDE-13 (**NCT06177912**) is a Phase 3, randomized, double-blind, active comparator-controlled clinical study, evaluating the immunogenicity, safety and tolerability of CAPVAXIVE compared to PPSV23 in children and adolescents aged ≥2 to <18 years with increased risk for pneumococcal disease due to medical conditions (including diabetes mellitus, chronic compensated liver disease, chronic lung disease, chronic heart disease or chronic kidney disease). The study enrolled 882 participants who were randomized 3:2 to receive a single dose of CAPVAXIVE or PPSV23, following completion of a primary pediatric pneumococcal vaccine regimen, including PCV7 (pneumococcal 7-valent conjugate vaccine), PCV10 (pneumococcal 10-valent conjugate vaccine) or PCV13 (pneumococcal 13-valent conjugate vaccine).

Immunogenicity of CAPVAXIVE serotypes was assessed 30 days post-vaccination by measuring serotype-specific OPA GMTs. Safety was evaluated as the proportion of participants with AEs. Results demonstrated that:

- CAPVAXIVE was immunogenic for all 21 serotypes as assessed by serotype-specific OPA GMTs at 30 days post-vaccination;
- Immune responses elicited by CAPVAXIVE were noninferior to PPSV23 for each of the 12 serotypes shared between the vaccines (lower bound of the two-sided 95% confidence interval for the serotype-specific OPA GMT ratio >0.5), as measured by the pre-specific statistical criteria;
- CAPVAXIVE demonstrated superiority to PPSV23 for each of the nine serotypes included in CAPVAXIVE but not PPSV23 (lower bound of the two-sided 95% confidence interval for the serotype-specific OPA GMT ratio >2.0),

as measured by serotype-specific OPA GMTs at 30 days post-vaccination;
- The proportions of participants with solicited systemic AEs and serious vaccine-related AEs were generally comparable between groups, and solicited injection-site AEs were higher in the CAPVAXIVE group (72.3%) compared to the PPSV23 group (58.2%).

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 approved 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. 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, 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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