Merck Announces Positive Data for V116, an Investigational, 21-Valent Pneumococcal Conjugate Vaccine Specifically Designed for Adults

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Late-breaker Phase 3 STRIDE-10 trial presented as an oral presentation at European Society of Clinical Microbiology and Infectious Diseases

Results build on the data supporting the clinical profile of V116 for adults

RAHWAY, N.J.--(BUSINESS WIRE)-- Merck (NYSE: MRK), known as MSD outside of the United States and Canada, today announced results from STRIDE-10, a Phase 3 trial evaluating V116, the company’s investigational, adult-specific 21-valent pneumococcal conjugate vaccine, at the 34th European Society of Clinical Microbiology and Infectious Diseases (ESCMID Global) in Barcelona, Spain. The trial evaluated the immunogenicity, tolerability and safety of V116 compared to PPSV23 (pneumococcal vaccine, polyvalent [23-valent]) in adults 50 years of age and older who had not previously received a pneumococcal vaccine.

Key results from the study include:

- V116 elicited immune responses that were noninferior compared to PPSV23 for the 12 serotypes (or strains) common to both vaccines, as measured by serotype-specific opsonophagocytic activity (OPA) geometric mean titers (GMTs) at Day 30.
- Immune responses elicited by V116 were superior for the nine serotypes included in V116 but not PPSV23, as measured by OPA GMT ratios at Day 30, and superior for eight of nine serotypes unique to V116 compared to PPSV23, as measured by the proportions of participants with ≥4-fold rise in immune responses.
• V116 had a safety profile comparable to PPSV23.

These data build upon Phase 3 trial results that were presented at this year’s Meeting of the International Society of Pneumonia and Pneumococcal Diseases and the 2023 World Vaccine Congress West Coast.

“Invasive pneumococcal disease and pneumococcal pneumonia represent significant public health challenges, particularly among older adult populations and those with risk conditions,” said Dr. Walter Orenstein, professor emeritus of medicine, epidemiology, global health and pediatrics at Emory University and member of Merck’s Scientific Advisory Committee. “These positive results show that V116 has the potential to help prevent invasive pneumococcal disease among adult populations.”

“Even with the availability of current pneumococcal conjugate vaccines for adults, gaps in serotype coverage for invasive pneumococcal disease persist,” said Dr. Eliav Barr, senior vice president, head of global clinical development and chief medical officer, Merck Research Laboratories. “These data add to the evidence supporting the potential for V116 to become an important new preventative option for adults, with results showing V116 elicited immune responses to the serotypes responsible for the majority of adult invasive pneumococcal disease.”

In addition to the clinical data on V116, Merck also presented findings that suggest V116 may help to reduce the health and economic burden associated with invasive pneumococcal disease and non-bacteremic pneumococcal pneumonia among adults in France, Sweden, Spain, and the Netherlands.

V116 is currently under review by the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA). The FDA granted V116 priority review with a Prescription Drug User Fee Act (PDUFA), or target action date, of June 17, 2024. V116 is specifically designed to help protect adults from invasive pneumococcal disease; the serotypes in V116 account for approximately 83% of adult invasive pneumococcal disease in individuals 65 and older, according to U.S. Centers for Disease Control and Prevention data from 2018-2021. An overview of the V116 late-stage development program is available here.

Summary of Findings from Select Studies Presented at ESCMID

Data from STRIDE-10 (Abstract #353)

STRIDE-10 (NCT05569954) is a Phase 3, randomized, double-blind, active comparator-controlled study evaluating the immunogenicity, tolerability and safety of V116 compared to PPSV23 in adults 50 years of age and older who had not previously received pneumococcal vaccine (n=1,484). Participants were randomized to receive a single dose of either V116 or PPSV23.

The primary objectives included serotype-specific OPA GMTs 30 days post-vaccination and percentage of
participants with greater than or equal to four-fold rise from baseline in serotype-specific OPAs. Serotype-specific OPA responses were measured at baseline and 30 days post-vaccination. Safety was evaluated as the proportion of participants with adverse events (AEs). Results demonstrated that:

- V116 elicited noninferior immune responses for the 12 serotypes (or strains) shared with PPSV23 (3, 7F, 8, 9N, 10A, 11A, 12F, 17F, 19A, 20A, 22F, 33F), as measured by serotype-specific OPA GMTs 30 days post-vaccination;
- V116 elicited superior immune responses for the nine serotypes only covered by V116 and not PPSV23 (6A, 15A, 15C, 16F, 23A, 23B, 24F, 31, 35B), as assessed by serotype-specific OPA GMT ratios 30 days post-vaccination;
- The proportion of patients with ≥4-fold rise in OPA GMT ratios from Day 1 to Day 30 for serotype-specific OPA for V116 was superior to PPSV23 for eight out of nine serotypes unique to V116 compared to PPSV23;
- V116 had a comparable safety profile to PPSV23.

Data from Health and Economic Burden of Disease Studies (Abstract #7201, Abstract #2784, Abstract #2738, and Abstract #2843)

Four studies were conducted to quantify the health and economic burden of invasive pneumococcal disease and non-bacteremic pneumococcal pneumonia attributable to V116 and PCV20 (pneumococcal 20-valent conjugate vaccine) serotypes among adults in France, Sweden, Spain, and the Netherlands. Across the studies, results showed that when compared with PCV20, V116 serotypes were associated with considerably higher health and economic burden in France, Sweden, Spain, and the Netherlands—the difference is driven largely by the eight unique V116 serotypes not in any currently approved pneumococcal vaccine, suggesting V116 may help reduce the health and economic burden associated with invasive pneumococcal disease and non-bacteremic pneumococcal pneumonia among adults in these countries.

About V116

V116 is an investigational, 21-valent pneumococcal conjugate vaccine in Phase 3 development for the prevention of invasive pneumococcal disease and pneumococcal pneumonia in the adult population. V116 is specifically designed to address Streptococcus pneumoniae serotypes predominantly responsible for adult pneumococcal disease, including eight unique serotypes not in any currently approved pneumococcal vaccine (15A, 15C, 16F, 23A, 23B, 24F, 31 and 35B) which account for approximately 30% of adult invasive pneumococcal disease, according to CDC data from 2018-2021. The serotypes covered by V116 are responsible for approximately 83% of invasive pneumococcal disease in individuals 65 years of age and older, based on the same CDC data. V116 is designed to be administered as a single dose to help prevent invasive pneumococcal disease and pneumococcal pneumonia in adults.

The V116 Phase 3 program includes multiple studies, including STRIDE-3 (NCT05425732), STRIDE-4 (NCT05464420),
STRIDE-5 (NCT05526716), STRIDE-6 (NCT05420961), STRIDE-7 (NCT05393037), STRIDE-8 (NCT05696080), STRIDE-9 (NCT05633992) and STRIDE-10 (NCT05569954).

Indication for PNEUMOVAX 23 (Pneumococcal Vaccine Polyvalent)

PNEUMOVAX 23 is a vaccine indicated for active immunization for the prevention of pneumococcal disease caused by the 23 serotypes contained in the vaccine (1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19F, 19A, 20, 22F, 23F and 33F).

PNEUMOVAX 23 is approved for use in persons 50 years of age or older and persons aged ≥2 years who are at increased risk for pneumococcal disease.

PNEUMOVAX 23 will not prevent disease caused by capsular types of pneumococcus other than those contained in the vaccine.

Select Safety Information for PNEUMOVAX 23

PNEUMOVAX 23 is contraindicated in individuals with a history of a hypersensitivity reaction to any component of PNEUMOVAX 23.

Do not administer PNEUMOVAX 23 to individuals with a history of a hypersensitivity reaction to any component of the vaccine.

Defer vaccination with PNEUMOVAX 23 in persons with moderate or severe acute illness.

Use caution and appropriate care in administering PNEUMOVAX 23 to individuals with severely compromised cardiovascular and/or pulmonary function in whom a systemic reaction would pose a significant risk.

Available human data from clinical trials of PNEUMOVAX 23 in pregnancy have not established the presence or absence of a vaccine-associated risk.

Since elderly individuals may not tolerate medical interventions as well as younger individuals, a higher frequency and/or a greater severity of reactions in some older individuals cannot be ruled out.

Persons who are immunocompromised, including persons receiving immunosuppressive therapy, may have a diminished immune response to PNEUMOVAX 23.

PNEUMOVAX 23 may not be effective in preventing pneumococcal meningitis in patients who have chronic
cerebrospinal uid (CSF) leakage resulting from congenital lesions, skull fractures or neurosurgical procedures.

The most common adverse reactions, reported in >10% of subjects vaccinated with PNEUMOVAX 23 for the first time in a clinical trial, were: injection-site pain/soreness/tenderness, injection-site swelling/induration, headache, injection-site erythema, asthenia and fatigue, and myalgia.

For subjects aged 65 years or older in a clinical study, systemic adverse reactions which were determined by the investigator to be vaccine-related were higher following revaccination than following initial vaccination.

Vaccination with PNEUMOVAX 23 may not offer 100% protection from pneumococcal infection.

**About Pneumococcal Disease**

Pneumococcal disease is an infection caused by a bacteria called Streptococcus pneumoniae. There are more than 100 different types (referred to as serotypes) of pneumococcal bacteria, which can affect adults differently than children. Certain serotypes threaten to put more people at risk for invasive pneumococcal illnesses, such as bacteremia (infection in the bloodstream); bacteremic pneumonia (pneumonia with bacteremia); and meningitis (infection of the coverings of the brain and spinal cord), as well as non-invasive pneumonia (when pneumococcal disease is confined to the lungs).

While healthy adults can suffer from pneumococcal disease, patient populations particularly vulnerable to infection include older adults and those with certain chronic or immunocompromising health conditions (including diabetes, HIV, or heart, lung and liver diseases). Mortality from invasive pneumococcal disease is highest among adults 50 years of age and older.

**Merck's Commitment to Pneumococcal Disease Protection**

Merck has been at the forefront of pneumococcal disease prevention through vaccination for more than four decades and remains committed to helping to protect people of all ages from this disease. Merck's ongoing pneumococcal vaccine development program is designed to provide options that address the specific needs of different populations, including infants and children, healthy adults and at-risk sub-groups. This approach recognizes that disease burden in pediatric and adult populations is often driven by different bacterial strains, or serotypes, and aims to address unmet needs by offering vaccine options that target serotypes posing the greatest global risk to each population. To learn more about Merck's pipeline, visit [www.merck.com](http://www.merck.com).

**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).

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