Merck Announces V116, an Investigational, 21-valent Pneumococcal Conjugate Vaccine Specifically Designed for Adults, Met Key Immunogenicity and Safety Endpoints in Two Phase 3 Trials

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Topline results demonstrated V116 elicited positive immune responses in both vaccine-naïve and vaccine-experienced adult patient populations

The 21 serotypes covered by V116 are responsible for 85% of invasive pneumococcal disease in individuals 65 and older

RAHWAY, N.J.--(BUSINESS WIRE)-- Merck (NYSE: MRK), known as MSD outside of the United States and Canada, today announced positive topline results from two Phase 3 trials evaluating V116, the company's investigational 21-valent pneumococcal conjugate vaccine in vaccine-naïve and previously vaccinated individuals. If approved, V116 would be the first pneumococcal conjugate vaccine specifically designed for adults. Results from the STRIDE-3 trial demonstrated statistically significant immune responses compared to PCV20 (pneumococcal 20-valent conjugate vaccine) in vaccine-naïve adults for serotypes common to both vaccines as assessed by serotype-specific opsonophagocytic activity (OPA) 30 days post-vaccination. Positive immune responses were also observed for serotypes unique to V116. Additionally, results from STRIDE-6 demonstrated that V116 was immunogenic for all 21 pneumococcal serotypes in the vaccine among adults who previously received a pneumococcal vaccine at least one year prior to the study. In both studies, V116 had a safety profile comparable to the comparator in the studies. Results will be shared with the scientific community in the near future and will support global regulatory licensure applications.
According to pre-pandemic 2019 CDC data, the 21 serotypes covered by V116 are responsible for 85% of invasive pneumococcal disease in individuals 65 and older. V116 includes eight serotypes not currently covered by approved pneumococcal vaccines. Serotypes unique to V116 include 15A, 15C, 16F, 23A, 23B, 24F, 31 and 35B, which were responsible for approximately 30% of invasive pneumococcal disease in individuals 65 and older, based on pre-pandemic 2019 CDC data.

“Despite the availability of current pneumococcal conjugate vaccines, many adults remain vulnerable to pneumococcal disease, especially those who are older,” said Dr. Eliav Barr, senior vice president, head of global clinical development and chief medical officer, Merck Research Laboratories. “These results support the potential for V116 to become an important new preventative option for adults, regardless of prior pneumococcal vaccination status, by expanding coverage to include eight serotypes not currently included in any licensed vaccine. We are very grateful to the patients and investigators who contributed to these studies.”

About STRIDE-3

STRIDE-3 (NCT05425732) is a Phase 3, randomized, double-blind, active comparator-controlled study evaluating the safety, tolerability, and immunogenicity of V116 compared to PCV20 (pneumococcal 20-valent conjugate vaccine) in pneumococcal vaccine-naïve adults (n=2,600). Participants were randomized to receive a single dose of either V116 or PCV20. Primary endpoints included safety, serotype-specific opsonophagocytic activity (OPA) geometric mean titers (GMTs) 30 days post-vaccination and percentage of participants with ≥4-fold rise from baseline in serotype-specific OPAs.

About STRIDE-6

STRIDE-6 (NCT05420961) is a Phase 3, randomized, double-blind, active comparator-controlled study evaluating the safety, tolerability, and immunogenicity of V116 in adults 50 years of age or older (n=717) who previously received a pneumococcal vaccination at least one year before enrollment, including PPSV23 (pneumococcal vaccine, polyvalent [23-valent]), PCV13 (pneumococcal 13-valent conjugate vaccine), PCV15 (pneumococcal 15-valent conjugate vaccine) or PCV20 (pneumococcal 20-valent conjugate vaccine), PCV13+PPSV23, PCV15+PPSV23 or PPSV23+PCV13. Participants were randomized to receive one dose of either V116, PCV15, or PPSV23. The primary endpoints were safety and geometric mean titer (GMT) of serotype-specific opsonophagocytic activity (OPA) responses 30 days post-vaccination.

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 the serotypes that represent adult pneumococcal disease, including eight unique serotypes, 15A, 15C, 16F, 23A, 23B, 24F, 31 and 35B, which account for approximately 30% of adult disease, according to 2019 pre-pandemic CDC data. V116 has potential to expand disease coverage to help protect against invasive pneumococcal disease in more than 85% of individuals 65 and older, based on the same data.

Multiple Phase 3 trials of V116 were initiated within the last 12 months, including STRIDE-3 (NCT05425732), STRIDE-6 (NCT05420961), STRIDE-7 (NCT05393037), STRIDE-4 (NCT05464420), STRIDE-5 (NCT05526716), and STRIDE-8 (NCT05696080).

About Pneumococcal Disease

The global prevalence of pneumococcal disease, an infection caused by bacteria called Streptococcus pneumoniae, is evolving. There are more than 100 different types of pneumococcal bacteria, which can affect adults differently than children. Highly aggressive strains, or 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 adults 65 years of age and older and those with certain chronic or immunocompromising health conditions.

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 to address the specific needs of different populations, including infants and children, healthy adults and at-risk subgroups. 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 https://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 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 the global outbreak of novel coronavirus disease (COVID-19); 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, 2022 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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