NEWS RELEASE

Merck Announces Positive Topline Results from Two Phase 3 Adult Studies Evaluating V114, Merck's Investigational 15-valent Pneumococcal Conjugate Vaccine, Including Pivotal Trial

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In PNEU-AGE (V114-019), V114 Demonstrated Non-inferiority to the Currently Available 13-valent Pneumococcal Conjugate Vaccine for Shared Serotypes and Met Study-Defined Superiority Criteria for Unique Serotypes 22F and 33F and Shared Serotype 3

Application for V114 Licensure in Adults to Be Submitted by Year-End

KENILWORTH, N.J.--(BUSINESS WIRE)-- Merck (NYSE: MRK), known as MSD outside the United States and Canada, today announced that two Phase 3 studies evaluating the safety, tolerability and immunogenicity of V114, the company's investigational 15-valent pneumococcal conjugate vaccine, met their primary immunogenicity objectives. The pivotal PNEU-AGE (V114-019) study in healthy adults 50 years of age or older demonstrated that V114 is non-inferior to the currently available 13-valent pneumococcal conjugate vaccine (PCV13) for the 13 serotypes targeted by both vaccines and superior for serotypes 22F and 33F, the two serotypes targeted by V114 but not PCV13. These results are based on opsonophagocytic activity (OPA) responses – a measure of vaccine-induced functional antibodies. The PNEU-AGE study also met the key secondary immunogenicity objective, demonstrating superiority of V114 compared to PCV13 for serotype 3, a leading cause of invasive pneumococcal disease globally. In another Phase 3 study, PNEU-TRUE (V114-020), in healthy adults 50 years of age or older, V114 met its primary immunogenicity objective demonstrating equivalent immune response across all 15 serotypes for three different lots of V114. In both studies, V114 was generally well tolerated, with a safety profile comparable to PCV13 and

consistent with that observed for V114 in previously reported studies. These findings, and additional Phase 3 data from Merck's clinical program, will be presented at a scientific congress in the future and will form the basis of global regulatory licensure applications, beginning with the U.S. Food and Drug Administration, before the end of the year.

"Diseases caused by serotypes not covered by the currently available pneumococcal conjugate vaccine are increasing worldwide and can vary by country or region. Additionally, we continue to see pneumococcal disease caused by serotypes included in the existing pneumococcal vaccines," said Dr. Roy Baynes, senior vice president and head of global clinical development, chief medical officer, Merck Research Laboratories. "Continued scientific innovation in pneumococcal disease prevention is needed to target the serotypes that pose the greatest risk to specific populations while maintaining immune response as new serotypes are added. These Phase 3 data demonstrated that V114 generated a robust immune response to all 15 serotypes included in the vaccine and reinforce the potential for this investigational vaccine to help protect adults against pneumococcal disease."

There are more than 90 different types of pneumococcal bacteria, which can affect adults differently than children. Pneumococcal serotypes not in the currently licensed conjugate vaccine, such as 22F and 33F, are commonly associated with invasive pneumococcal disease worldwide. Serotypes 22F and 33F currently cause 13 percent of the invasive pneumococcal disease seen among adults aged 65 and older in the U.S., and seven to 12 percent of the adult cases seen across Europe. Additionally, serotype 3 remains one of the top causes of invasive pneumococcal disease in adults and children despite being included in the currently available pneumococcal vaccines. In the U.S., 15 percent of invasive pneumococcal disease among adults aged 65 and older continues to be caused by serotype 3; this ranges from 12 to 18 percent of cases in adults across European countries.

The V114 Phase 3 clinical development program is comprised of 16 trials investigating the safety, tolerability and immunogenicity of V114 in a variety of populations who are at increased risk for pneumococcal disease including healthy older adults and children, as well as people who are immunocompromised or have certain chronic medical conditions. An overview of the late-stage development program is available **here**.

About PNEU-AGE

PNEU-AGE is a Phase 3, multi-center, randomized, double-blind, active comparator-controlled study evaluating the safety, tolerability, and immunogenicity of V114 in healthy adults 50 years of age or older (n=1,205). The study met its immunogenicity and safety objectives. Immune responses were measured at baseline and 30 days post-vaccination, and immunogenicity comparisons were assessed based on study-defined criteria. Results of the primary immunogenicity analyses demonstrated:

- Non-inferiority of V114 to the currently available 13-valent pneumococcal conjugate vaccine (PCV13) for the

13 shared serotypes and superiority to PCV13 for serotypes 22F and 33F, the two serotypes unique to V114, as assessed by the serotype-specific opsonophagocytic activity (OPA) Geometric Mean Titers (GMTs).
- Superiority of V114 compared to PCV13 for the two unique serotypes in V114 as assessed by the proportion of participants with a ≥4-fold rise in serotype-specific OPA responses (from pre-vaccination to 30 days post-vaccination).

Results of the key secondary immunogenicity analyses demonstrated:

- Superiority of V114 compared to PCV13 for serotype 3 as assessed by the OPA GMTs and the proportions of participants with a ≥4-fold rise in OPA responses.

Results of the safety analyses demonstrated that V114 was generally well tolerated with a safety profile comparable to PCV13 and consistent with that observed in previously reported studies.

About PNEU-TRUE

PNEU-TRUE is a Phase 3, multi-center, randomized, double-blind, active comparator-controlled, lot-to-lot consistency study evaluating the safety, tolerability, and immunogenicity of V114 in healthy adults 50 years of age or older (n=2,340). In the study, V114 met all primary immunogenicity objectives, demonstrating equivalent immune response as assessed by serotype specific OPA GMTs for all 15 serotypes in V114 across three different manufactured lots of V114 at 30 days post-vaccination. Results of the safety analyses demonstrated that all three lots of V114 were generally well tolerated with a safety profile comparable to PCV13 and consistent with that observed in previously reported studies.

About V114

V114 is Merck's investigational 15-valent pneumococcal conjugate vaccine in Phase 3 development for the prevention of pneumococcal disease in adults and children. V114 consists of pneumococcal polysaccharides from 15 serotypes conjugated to a CRM197 carrier protein and includes serotypes 22F and 33F, which are commonly associated with invasive pneumococcal disease worldwide and are not contained in the pneumococcal conjugate vaccine currently licensed for use in adults.

About Pneumococcal Disease

The global prevalence of pneumococcal disease, an infection caused by bacteria called Streptococcus pneumoniae, is evolving. Highly aggressive strains, or serotypes, threaten to put more people at risk for non-invasive pneumococcal illnesses such as pneumococcal pneumonia (when it is confined to the lungs), sinusitis, and otitis media (middle ear infection), and invasive pneumococcal illnesses such as pneumococcal bacteremia (infection in

the bloodstream), bacteremic pneumonia (pneumonia with bacteremia) and pneumococcal meningitis (infection of the coverings of the brain and spinal cord). While healthy adults and children can suffer from pneumococcal disease, patient populations particularly vulnerable to infection include children under the age of 2, older adults such as those 65 years of age and older, and people with immunosuppressive or certain chronic health conditions.

Merck's Commitment to Infectious Diseases

For more than 100 years, Merck has contributed to the discovery and development of novel medicines and vaccines to combat infectious diseases. In addition to a combined portfolio of vaccines and antibacterial, antiviral and antifungal medicines, Merck has multiple programs that span discovery through late-stage development. To learn more about Merck's infectious diseases pipeline, visit **www.merck.com**.

About Merck

For more than 125 years, Merck, known as MSD outside of the United States and Canada, has been inventing for life, bringing forward medicines and vaccines for many of the world's most challenging diseases in pursuit of our mission to save and improve lives. We demonstrate our commitment to patients and population health by increasing access to health care through far-reaching policies, programs and partnerships. Today, Merck continues to be at the forefront of research to prevent and treat diseases that threaten people and animals – including cancer, infectious diseases such as HIV and Ebola, and emerging animal diseases – as we aspire to be the premier research-intensive biopharmaceutical company in the world. 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., Kenilworth, N.J., USA

This news release of Merck & Co., Inc., Kenilworth, 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 products that the products 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 2019 Annual Report on Form 10-K 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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