NEWS RELEASE

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

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In PNEU-PATH (V114-016) and PNEU-DAY (V114-017), V114 Met Primary Immunogenicity Objectives and Elicited A Strong Immune Response for All 15 Serotypes Included in the Vaccine, Including 22F and 33F - Serotypes Unique to V114

KENILWORTH, N.J.--(BUSINESS WIRE)-- Merck (NYSE: MRK), known as MSD outside the United States and Canada, today announced findings from two additional Phase 3 studies evaluating the safety, tolerability and immunogenicity of V114, the company's investigational 15-valent pneumococcal conjugate vaccine. In the PNEU-PATH (V114-016) study, healthy adults 50 years of age or older received V114 or PCV13 followed by PNEUMOVAX® 23 one year later. Immune responses following vaccination with PNEUMOVAX 23 (month 13) were comparable in both vaccination groups for the 15 serotypes in V114. Results also showed that at 30 days post vaccination with either V114 or PCV13 (day 30), immune responses were comparable for both groups across the 13 serotypes shared by the conjugate vaccines and higher in the V114 group for serotypes 22F and 33F, the two serotypes not included in PCV13. In PNEU-DAY (V114-017), a Phase 3 study in immunocompetent adults 18 to 49 years of age with underlying medical conditions associated with increased risk for pneumococcal disease, V114 generated immune responses generally comparable to PCV13 for the 13 shared serotypes and higher immune responses for serotypes 22F and 33F at 30 days post-vaccination. Results from both studies are based on opsonophagocytic activity (OPA) responses – a measure of vaccine-induced functional antibodies. V114 was generally well tolerated in both studies, with a safety profile consistent with that observed for V114 in previously reported studies.

“Pneumococcal disease in adults is on the rise globally, in part driven by disease-causing serotypes not targeted by the currently available pneumococcal conjugate vaccine,” said Dr. Roy Baynes, senior vice president and head of global clinical development, chief medical officer, Merck Research Laboratories. “These data provide important information about the potential for V114 followed by PNEUMOVAX 23, a polysaccharide vaccine included in more than 90 percent of age-based adult pneumococcal immunization programs globally, to help protect healthy adults and adults who are at increased risk for pneumococcal disease.”

Findings from the V114 Phase 3 clinical program in adults, including PNEU-PATH and PNEU-DAY, will be presented at a future scientific congress. Plans for global regulatory licensure applications, beginning with the U.S. Food and Drug Administration before the end of the year, remain on track.

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 among the most common serotypes causing invasive pneumococcal disease in parts of the world, including the U.S., among adults 65 years of age or older. Invasive pneumococcal disease due to serotypes 22F and 33F has been linked to higher case fatality rates and prolonged hospitalization in adults. Overall, adults with certain medical conditions, such as heart disease, diabetes or chronic obstructive pulmonary disease (COPD), have a higher risk for pneumococcal disease compared to those without these conditions.

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-PATH

PNEU-PATH is a Phase 3, multi-center, randomized, double-blind, active comparator-controlled study evaluating the safety, tolerability and immunogenicity of V114 followed by administration of PNEUMOVAX 23 one year later in healthy adults 50 years of age or older (n=652). The primary endpoints included serotype specific OPA geometric mean titers (GMTs) at 30 days post-vaccination with PNEUMOVAX 23. The serotype specific OPA GMTs at 30 days post-vaccination with PNEUMOVAX 23 were comparable in the V114 and PCV13 groups for all 15 serotypes in V114.

Secondary endpoints included serotype specific OPA GMTs at 30 days post-vaccination with either V114 or PCV13. The OPA GMTs were comparable for the 13 shared serotypes between V114 and PCV13 at 30 days post-vaccination with either V114 or PCV13. The OPA GMTs were higher in the V114 group compared with the PCV13 group for the two serotypes unique to V114 (22F and 33F) at 30 days post-vaccination with either V114 or PCV13. Results of the

safety analyses demonstrated that V114 was generally well tolerated and can be followed by PNEUMOVAX 23.

About PNEU-DAY

PNEU-DAY is a Phase 3, multi-center, randomized, double-blind, active comparator-controlled study evaluating the safety, tolerability and immunogenicity of V114 followed by administration of PNEUMOVAX 23 six months later in adults between 18 and 49 years of age who are at increased risk for pneumococcal disease due to an underlying medical condition, behavioral habits, or living in an environment with increased risk of disease transmission (n=1,514). Participants were considered at increased risk for pneumococcal disease due to the presence of one or more risk factors, including chronic lung disease, smoking, diabetes mellitus, chronic liver disease, chronic heart disease and alcohol consumption.

The primary endpoints included serotype specific OPA GMTs at 30 days post-vaccination with either V114 or PCV13. The OPA GMTs were generally comparable for the 13 shared serotypes between V114 and PCV13 at 30 days post-vaccination. The OPA GMTs were higher in the V114 group compared with the PCV13 group for the two serotypes unique to V114 (22F and 33F) at 30 days post-vaccination.

Results of the safety analyses demonstrated that V114 was generally well tolerated with a safety profile generally 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.

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

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 fluid (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.

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**).

Please see Prescribing Information for PNEUMOVAX 23 at
http://www.merck.com/product/usa/pi_circulars/p/pneumovax_23/pneumovax_pi.pdf and
Patient Information for PNEUMOVAX 23 at
http://www.merck.com/product/usa/pi_circulars/p/pneumovax_23/pneumovax_ppi.pdf.

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