Merck Announces Results from Phase 2 Trial of Investigational 15-valent Pneumococcal Conjugate Vaccine (V114) in Infants

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V114 Met Primary Endpoint by Demonstrating Noninferiority to PCV13 for all Shared Serotypes, and an Immune Response for Two Additional Serotypes

Data Support Continued Progression of Phase 3 Studies with V114

KENILWORTH, N.J.--(BUSINESS WIRE)--Merck (NYSE: MRK), known as MSD outside of the United States and Canada, today announced results from a Phase 2 trial (NCT02982972) evaluating the safety, tolerability and immunogenicity of V114, the company's investigational 15-valent pneumococcal conjugate vaccine, as compared to the currently available 13-valent pneumococcal conjugate vaccine (PCV13) in healthy infants 6-12 weeks of age. In the study, designated V114-008, V114 met its primary endpoint by demonstrating noninferiority for the 13 serotypes contained in both vaccines. V114 also induced an immune response in infants for two additional disease-causing serotypes, 22F and 33F, which are not contained in PCV13.

In January 2019, V114 received a Breakthrough Therapy Designation from the U.S. Food and Drug Administration (FDA) for the prevention of invasive pneumococcal disease (IPD) caused by the vaccine serotypes in pediatric patients 6 weeks to 18 years of age. The FDA's decision was informed in part by immunogenicity data from this Phase 2 study, V114-008, and the Phase 1/2 V114-005 study in healthy adults and infants. Results of the V114-008 study were presented during an oral session at the 37th Annual Meeting of the European Society for Paediatric Infectious Diseases (ESPID) in Ljubljana, Slovenia, and reinforce continued progression of Phase 3 clinical studies with V114.

“Children under the age of two are at increased risk for pneumococcal infection, which in some cases may lead to serious illnesses like pneumococcal pneumonia,” said Dr. David Greenberg, study investigator and physician in the Pediatric Infectious Disease Unit of Soroka University Medical Center in Beer-Sheva, Israel. “These Phase 2 data evaluating V114 in infants are encouraging and mark important progress to helping expand protection against pneumococcal disease for this vulnerable patient population.”

V114-008, a double-blind, randomized, Phase 2 trial, compared the safety, tolerability, and immunogenicity of two different clinical lots of V114 (n=350 for lot 1; n=347 for lot 2) to PCV13 (n=347) in approximately 1,050 healthy infants at two, four, six and 12-15 months of age. In the study, the percentage of subjects who achieved the WHO-accepted threshold of immune response (IgG≥0.35 mcg/mL) with either lot of V114 was noninferior to the percentage seen with PCV13 for the 13 serotypes shared between the two vaccines. For serotype 3, the percentage of subjects who achieved this threshold of immune response was higher for V114 (96.0% for lot 1; 94.1% for lot 2) compared with PCV13 (71.8%). For the two serotypes not included in PCV13, serotype 22F and serotype 33F, the percentage of subjects who achieved the defined threshold of immune response with V114 was above 98% (98.0% for lot 1; 98.5% for lot 2) and above 87% (87.7% for lot 1; 90.1% for lot 2), respectively. Results were consistent between the two lots of V114 studied.

Safety profiles were evaluated after each dose and throughout the study. In the study, the adverse event profile for V114, including the number of serious adverse events (AEs), was found to be comparable to PCV13. The percentage of subjects who reported clinical AEs and serious AEs was similar in all treatment arms. The most commonly reported adverse events were injection site reactions, the majority of which were mild to moderate in severity and of short duration.

“These new data for our investigational pneumococcal disease vaccine V114 build on Merck’s century-long heritage in vaccines and our commitment to improving global health through protection from infectious diseases,” said Dr. Nicholas Kartsonis, senior vice president and head of vaccine and infectious diseases clinical research at Merck Research Laboratories. “We are deeply committed to advancing compounds such as V114 that have the potential to make a meaningful impact on the burden of pneumococcal disease.”

Merck has a broad clinical development program for V114 currently comprised of 11 Phase 3 clinical trials. These studies are investigating V114 in adults (NCT03480763, NCT03615482), in the pediatric population (NCT03692871, NCT03620162).
Additional Detail About V114-008 Study Design

In the V114-008 study, immunogenicity results were described as the percentage of subjects who reached an internationally accepted threshold of immune response considered to be protective (IgG≥0.35 mcg/mL). The primary immunogenicity endpoint was to demonstrate that V114 was noninferior to PCV13 based on the proportion of infants achieving serotype-specific IgG≥0.35 mcg/mL for all 13 serotypes in common with PCV13 at one-month following the completion of the three-dose primary series. Additionally, serotype-specific IgG geometric mean concentrations (GMCs) were measured at one month following the completion of the primary series, immediately prior to the toddler dose and one month after the toddler dose.

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 IPD worldwide.

About Pneumococcal Disease

Pneumococcal disease is an infection caused by bacteria called Streptococcus pneumoniae. Pneumococcal disease includes non-invasive illnesses such as pneumonia (when it is confined to the lungs), sinusitis, and otitis media (middle ear infection); and invasive illnesses such as bacteremia (infection in the bloodstream), bactereemic pneumonia (pneumonia with bacteremia), and meningitis. While healthy adults and children are at risk for pneumococcal disease, certain populations, particularly vulnerable to infection include children under the age of 2, adults aged 65 and older, and people with immunosuppressive or 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 a century, Merck, a leading global biopharmaceutical company 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. Through our prescription medicines, vaccines, biologic therapies and animal health products, we work with customers and operate in more than 140 countries to deliver innovative health solutions. We also demonstrate our commitment to increasing access to health care through far-reaching policies, programs and partnerships. Today, Merck continues to be at the forefront of research to advance the prevention and treatment of diseases that threaten people and communities around the world - including cancer, cardio-metabolic diseases, emerging animal diseases, Alzheimer's disease and infectious diseases including HIV and Ebola. 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 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 2018 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).