NEWS RELEASE

Merck Announces Positive Topline Results from PNEU-DIRECTION (V114-027) and PNEU-PLAN (V114-024) Phase 3 Pediatric Studies for V114, Merck's Investigational 15-valent Pneumococcal Conjugate Vaccine

5/20/2021

V114 Met Primary Immunogenicity and Safety Endpoints in Both Trials

KENILWORTH, N.J.--(BUSINESS WIRE)-- Merck (NYSE: MRK), known as MSD outside the United States and Canada, today announced V114, the company's investigational 15-valent pneumococcal conjugate vaccine, met its primary immunogenicity and safety endpoints in two trials of the V114 Phase 3 pediatric clinical program. These data support the potential use of V114 in healthy infants who may have previously started a pneumococcal vaccination series with the currently available 13-valent pneumococcal conjugate vaccine (PCV13) (PNEU-DIRECTION), and in a catch-up setting for healthy children who were either pneumococcal vaccine-naïve or who previously received a full or partial regimen with lower valency pediatric pneumococcal conjugate vaccines (PCV) (PNEU-PLAN).

In the PNEU-DIRECTION (V114-027) interchangeability study in healthy infants 42-90 days of age, immune responses in those who received a four-dose series of PCV13, and those who received a mixed dose schedule of PCV13 followed by V114, were generally comparable for the 13 serotypes, or strains of pneumococcal disease, targeted by both vaccines. In the PNEU-PLAN (V114-024) catch-up study, immune responses were generally comparable to PCV13 for the 13 shared serotypes when V114 was used as a catch-up regimen in healthy children 7 months to 17 years of age who were either pneumococcal vaccine-naïve or who previously received a partial or full regimen of a licensed pediatric PCV. For serotypes 22F and 33F, two serotypes included in V114 but not PCV13,

immunogenicity in PNEU-PLAN was higher in the V114 group than in the PCV13 group. In each study, V114 was generally well-tolerated, with a safety profile comparable to PCV13.

“Pneumococcal disease continues to cause serious illness and death worldwide in children under the age of 5, despite the positive impact of pneumococcal conjugate vaccination on pediatric case numbers,” said Dr. Roy Baynes, senior vice president and head of global clinical development, chief medical officer, Merck Research Laboratories. “At Merck, our goal is to expand coverage to new serotypes not targeted by currently available pediatric pneumococcal conjugate vaccines, while maintaining a strong immune response to current vaccine serotypes so as to help sustain progress achieved to date. Results from these studies support the potential of V114 to confer immunogenicity for PCV13 serotypes in infants who have previously received one or multiple doses of PCV13, and for the 15 serotypes in V114 in children in a catch-up setting.”

There are 100 different types of pneumococcal bacteria, which can affect children differently than adults. Children under the age of 2 are particularly vulnerable to pneumococcal infection and invasive pneumococcal disease incidence remains highest in the first year of life. Certain pneumococcal serotypes continue to put children at risk, including serotypes 22F and 33F which represent 16 percent of all cases of invasive pneumococcal disease in children under the age of 5.

Full results from PNEU-DIRECTION and PNEU-PLAN will be presented at a future scientific congress. 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**. Plans are on track for submission of a supplemental regulatory licensure application to the U.S. Food and Drug Administration (FDA) for use in children before the end of the year, pending action on the adult Biologics Licensure Application currently under FDA review. Merck is involved in litigation challenging the validity of several Pfizer Inc. patents that relate to pneumococcal vaccine technology in the United States and several foreign jurisdictions.

About PNEU-DIRECTION

PNEU-DIRECTION is a Phase 3, multi-center, randomized, double-blind study evaluating the interchangeability of V114 and PCV13 with respect to safety, tolerability, and immunogenicity in healthy infants 42-90 days of age (n=900).

Participants were randomized to one of five vaccination groups receiving a complete 4-dose schedule with PCV13, one of three mixed 4-dose schedules with PCV13 followed by V114, or a complete 4-dose schedule with V114. Immune responses for the 13 shared serotypes contained in V114 and PCV13 were measured at 30 days post-dose

four (PD4) and compared between the groups receiving mixed PCV13/V114 schedules and the group receiving a complete PCV13 schedule. Immune responses were assessed based on anti-pneumococcal polysaccharide (PnPs) serotype-specific immunoglobulin G (IgG) geometric mean concentrations (GMCs). Results of the primary immunogenicity analyses demonstrated that the IgG GMCs for the 13 shared serotypes at 30 days PD4 were generally comparable between participants administered mixed dosing schedules with PCV13/V114 and participants administered a complete dosing schedule with PCV13.

Safety analyses were performed on the All-Participants-As-Treated (APaT) population, defined as all randomized participants who received at least one dose of study vaccination, and showed comparable safety profiles across the five vaccination groups.

About PNEU-PLAN

PNEU-PLAN is a Phase 3, multicenter, randomized, double-blind, active comparator-controlled, descriptive study to evaluate the safety, tolerability, and immunogenicity of catch-up vaccination regimens of V114 in healthy infants, children, and adolescents 7 months to 17 years of age (n=606).

Participants who were either pneumococcal vaccine-naïve or who previously received a partial or full regimen of licensed pediatric PCV were randomized to receive either V114 or PCV13. Participants received a three, two or one dose regimen of V114 depending on their age cohort at randomization. The three age cohorts were children 7 to 11 months of age (three dose regimen), 12 to 23 months of age (two dose regimen) and 2 to 17 years of age (one dose regimen). Immune responses for the 13 shared serotypes contained in V114 and PCV13 and the two serotypes unique to V114 were measured at 30 days post final vaccination. Immunogenicity comparisons were assessed based on anti-PNPs serotype specific IgG GMCs. Results of the primary immunogenicity analyses demonstrated that the IgG GMCs for the 13 shared serotypes 30 days post final vaccine were generally comparable between groups for each of the three cohorts, and higher in V114 groups for serotypes 22F and 33F, the two serotypes included in V114 but not PCV13.

Results of the safety analyses demonstrated that V114 was generally well-tolerated with a safety profile comparable to PCV13.

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 children and 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, continue to put people at risk for 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). Serotypes 22F, 33F and 3 represent a sizeable portion of invasive pneumococcal disease cases in adults and children. This supports the need for robust immune suppression of current vaccine serotypes while also expanding serotype coverage. While healthy adults and children can suffer from invasive 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 130 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 2020 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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Source: Merck & Co., Inc.