Merck Announces First Phase Three Studies for PCV-15 (V114) Its Investigational Pneumococcal Disease Vaccine

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KENILWORTH, N.J.--(BUSINESS WIRE)--Merck (NYSE:MRK), known as MSD outside of the United States and Canada, today announced that the company is beginning two Phase 3 studies of PCV-15 (V114), its investigational polyvalent conjugate vaccine for the prevention of pneumococcal disease. The first study (ClinicalTrials.gov, NCT03480763) will evaluate the safety, tolerability and immunogenicity of PCV-15 followed by Pneumococcal Vaccine Polyvalent one year later in healthy adult subjects 50 years of age or older. The second Phase 3 study (ClinicalTrials.gov, NCT03480802) will evaluate the safety, tolerability and immunogenicity of PCV-15 followed by Pneumococcal Vaccine Polyvalent administered eight weeks later in adults infected with human immunodeficiency virus (HIV).

The decision to move PCV-15 to Phase 3 is based on the findings of Phase 1 and Phase 2 studies, the results of which are being presented at the upcoming International Society on Pneumococci and Pneumococcal Diseases (ISPPD), which begins on Sunday, April 15.

“Merck has been a pioneer in pneumococcal and infectious disease prevention. We are building on this heritage with the development program for PCV-15,” said Eliav Barr, M.D. senior vice president, Merck Research Laboratories. “Based on our Phase 1 and 2 studies of PCV-15 findings, we are initiating a comprehensive Phase 3 program to further evaluate this investigational vaccine.”

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 2017 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).