



NEWS RELEASE

Merck Receives Breakthrough Therapy Designation from FDA for V114, the Company's Investigational 15-Valent Conjugate Vaccine for the Prevention of Invasive Pneumococcal Disease, in Infants, Children, and Adolescents

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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 V114, the company's investigational 15-valent pneumococcal conjugate vaccine, has received 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. V114 is also under development for the prevention of IPD in adults. Both indications are currently being studied in Phase 3 clinical trials.

The Breakthrough Therapy Designation is an FDA program designed to expedite the development and review of drugs intended for serious or life-threatening conditions. To qualify for this designation, preliminary clinical evidence must demonstrate that the drug may provide substantial improvement over currently available therapy on at least one clinically significant endpoint. The benefits of this Breakthrough Therapy Designation include more intensive guidance from FDA on an efficient drug development program, access to a scientific liaison to help accelerate review time and eligibility for Accelerated Approval and Priority Review if relevant criteria are met.

The FDA's decision was informed in part by immunogenicity data from two studies. Study 005 was a Phase 1/2, multicentre, randomized, double-blind study to evaluate the safety, tolerability and immunogenicity profiles of 4 different lots of a new formulation of V114 in healthy adults and infants. Study 008 was a proof of concept, Phase 2,

pediatric trial to confirm the results from Study 005 in a larger population of infants. In both studies, V114 induced an immune response in infants for two disease-causing serotypes (22F and 33F) not contained in the currently available 13-valent pneumococcal conjugate vaccine, while demonstrating non-inferiority for the serotypes contained in both vaccines.

“We are pleased with the data on V114 compiled to date, and we look forward to working closely with the FDA on the subsequent development of this investigational vaccine,” said Dr. Nicholas Kartsonis, senior vice president and head of vaccine and infectious diseases clinical research at Merck Research Laboratories. “The goal of our program in pediatric patients remains focused on providing additional serotype coverage versus currently available vaccines, while at the same time maintaining a strong immune response across all serotypes in the 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).

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