NEWS RELEASE

Merck Announces U.S. FDA has Granted Breakthrough Therapy Designation for V116, the Company's Investigational 21-Valent Pneumococcal Conjugate Vaccine, for the Prevention of Invasive Pneumococcal Disease and Pneumococcal Pneumonia in Adults

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V116 Designed to Target Serotypes that Account for 85% of all Invasive Pneumococcal Disease in Individuals Aged 65 and Over in the United States as of 20191

Phase 3 Clinical Trials for V116 to be Initiated in 2022

KENILWORTH, N.J.--(BUSINESS WIRE)-- Merck (NYSE: MRK), known as MSD outside the United States and Canada, announced today that V116, the company's investigational 21-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) and pneumococcal pneumonia caused by Streptococcus pneumoniae serotypes 3, 6A/C, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15B/C, 16F, 17F, 19A, 20, 22F, 23A, 23B, 24F, 31, 33F, 35B in adults 18 years of age and older. Phase 3 clinical trials for V116 are to be initiated later this year.

The FDA's decision was informed by data from a two-part randomized, comparator-controlled, double-blind Phase 1/2 study, V116-001 (**NCT04168190**), that assessed the safety, tolerability, and immunogenicity of a single dose of V116 in pneumococcal vaccine-naïve adults 18-49 years of age (Phase 1) and 50 years of age and older (Phase 2). Full results from the V116-001 study are planned for presentation at the upcoming International Symposium on

Pneumococci and Pneumococcal Diseases (ISPPD) in June.

“V116 is specifically designed to address strains of disease-causing pneumococcal bacteria that are most prevalent in adults, reflecting our population-specific approach to developing pneumococcal conjugate vaccines. V116 targets serotypes that account for 85% of all invasive pneumococcal disease in individuals aged 65 and over in the United States as of 20191 and it includes 8 serotypes not covered by currently licensed vaccines,” said Dr. Eliav Barr, senior vice president, head of global clinical development and chief medical officer, Merck Research Laboratories. “We look forward to discussing the ongoing development of this investigational vaccine, including the approach for Phase 3 studies, with the FDA and other regulatory agencies.”

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

About Merck

At Merck, known as MSD outside of the United States and Canada, we are unified around our purpose: We use the power of leading-edge science to save and improve lives around the world. For more than 130 years, we have brought hope to humanity through the development of important medicines and vaccines. We aspire to be the premier research-intensive biopharmaceutical company in the world – and today, we are at the forefront of research to deliver innovative health solutions that advance the prevention and treatment of diseases in people and animals. We foster a diverse and inclusive global workforce and operate responsibly every day to enable a safe, sustainable and healthy future for all people and communities. 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 candidates that the candidates 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 Annual Report on Form 10-K for the year ended December 31, 2021 and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site (**www.sec.gov**).

1Centers for Disease Control and Prevention, IPD serotype data 2019, as compiled from data provided through Active Bacterial Core surveillance (ABCs).

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