



NEWS RELEASE

Merck Submits Applications for Licensure of V114, the Company's Investigational 15-valent Pneumococcal Conjugate Vaccine, for Use in Adults to the U.S. FDA and European Medicines Agency

11/23/2020

KENILWORTH, N.J.--(BUSINESS WIRE)-- Merck (NYSE: MRK), known as MSD outside the United States and Canada, today announced the company has submitted applications to the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) for licensure of V114, Merck's investigational 15-valent pneumococcal conjugate vaccine, for use in adults 18 years of age and older. The company awaits acceptance of the submissions by the U.S. and European regulatory authorities.

"For more than a century, Merck inventors have developed vaccines that help tackle some of society's biggest public health challenges, and that heritage is reflected today in our pneumococcal vaccine portfolio," said Dr. Roy Baynes, senior vice president and head of global clinical development, chief medical officer, Merck Research Laboratories. "These submissions for V114 help bring us closer to offering more options to help protect against pneumococcal disease."

The regulatory applications for licensure of V114 include results from Phase 2 and Phase 3 clinical studies in a variety of adult populations, including healthy adults and those at increased risk, such as adults with chronic medical conditions, adults with HIV, and those 65 years of age and older.

About V114

V114 is Merck's investigational 15-valent pneumococcal conjugate vaccine candidate 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 in older adults worldwide and are not contained in the pneumococcal conjugate vaccine currently licensed for use in adults. An overview of the late-stage development program for V114 is available [here](#).

V114 previously received Breakthrough Therapy Designation from the FDA for the prevention of invasive pneumococcal disease in pediatric patients 6 weeks to 18 years of age and adults 18 years of age and older.

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 125 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 2019 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.