



NEWS RELEASE

U.S. FDA Accepts for Priority Review the Biologics License Application for V114, Merck's Investigational 15-valent Pneumococcal Conjugate Vaccine, for Use in Adults 18 Years of Age and Older

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KENILWORTH, N.J.--(BUSINESS WIRE)-- Merck (NYSE: MRK), known as MSD outside the United States and Canada, today announced the U.S. Food and Drug Administration (FDA) accepted for priority review a Biologics License Application (BLA) for V114, Merck's investigational 15-valent pneumococcal conjugate vaccine, for the prevention of invasive pneumococcal disease in adults 18 years of age and older. The FDA set a Prescription Drug User Fee Act (PDUFA), or target action date, of July 18, 2021. The European Medicines Agency is also reviewing an application for licensure of V114 in adults.

"Invasive pneumococcal disease in adults is on the rise in many countries, driven by highly-invasive serotypes including serotype 3, which is included in the currently licensed pneumococcal conjugate vaccine, as well as serotypes not included, such as serotypes 22F and 33F," said Dr. Roy Baynes, senior vice president and head of global clinical development, chief medical officer, Merck Research Laboratories. "Building on our nearly 40 years of experience with PNEUMOVAX® 23, Pneumococcal Vaccine Polyvalent, we have developed V114 as another potentially important option to help protect more adults from invasive pneumococcal disease, especially those who are at increased risk. We look forward to working with the FDA during the review of this application."

The BLA and priority review designation are supported by 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. Additional studies in the BLA support the

potential use of V114 in various real-world clinical settings, including in co-administration with the quadrivalent influenza vaccine and as part of a sequential administration with PNEUMOVAX 23, and demonstrate equivalent performance among consecutive lots of V114. The FDA grants priority review to medicines and vaccines that, if approved, would provide a significant improvement in the safety or effectiveness of the treatment or prevention of a serious condition.

About V114

V114 is Merck's investigational 15-valent pneumococcal conjugate vaccine candidate for the prevention of invasive pneumococcal disease in adults. 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. Merck is also developing V114 for use in children. 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.

Indication for PNEUMOVAX 23 (Pneumococcal Vaccine Polyvalent)

PNEUMOVAX 23 is a vaccine indicated for active immunization for the prevention of pneumococcal disease caused by the 23 serotypes contained in the vaccine (1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19F, 19A, 20, 22F, 23F and 33F).

PNEUMOVAX 23 is approved for use in persons 50 years of age or older and persons aged ≥ 2 years who are at increased risk for pneumococcal disease.

PNEUMOVAX 23 will not prevent disease caused by capsular types of pneumococcus other than those contained in the vaccine.

Select Safety Information for PNEUMOVAX 23

Do not administer PNEUMOVAX 23 to individuals with a history of a hypersensitivity reaction to any component of the vaccine.

Defer vaccination with PNEUMOVAX 23 in persons with moderate or severe acute illness.

Use caution and appropriate care in administering PNEUMOVAX 23 to individuals with severely compromised

cardiovascular and/or pulmonary function in whom a systemic reaction would pose a significant risk.

Available human data from clinical trials of PNEUMOVAX 23 in pregnancy have not established the presence or absence of a vaccine-associated risk.

Since elderly individuals may not tolerate medical interventions as well as younger individuals, a higher frequency and/or a greater severity of reactions in some older individuals cannot be ruled out.

Persons who are immunocompromised, including persons receiving immunosuppressive therapy, may have a diminished immune response to PNEUMOVAX 23.

PNEUMOVAX 23 may not be effective in preventing pneumococcal meningitis in patients who have chronic cerebrospinal fluid (CSF) leakage resulting from congenital lesions, skull fractures or neurosurgical procedures.

The most common adverse reactions, reported in >10% of subjects vaccinated with PNEUMOVAX 23 for the first time in a clinical trial, were: injection-site pain/soreness/tenderness, injection-site swelling/induration, headache, injection-site erythema, asthenia and fatigue, and myalgia.

For subjects aged 65 years or older in a clinical study, systemic adverse reactions which were determined by the investigator to be vaccine-related were higher following revaccination than following initial vaccination.

Vaccination with PNEUMOVAX 23 may not offer 100% protection from pneumococcal infection.

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).

Please see Prescribing Information for PNEUMOVAX 23
at http://www.merck.com/product/usa/pi_circulars/p/pneumovax_23/pneumovax_pi.pdf
and Patient Information for PNEUMOVAX 23
at http://www.merck.com/product/usa/pi_circulars/p/pneumovax_23/pneumovax_ppi.pdf.

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