



NEWS RELEASE

European Commission Expands Merck's VAXNEUVANCE™ (Pneumococcal 15-valent Conjugate Vaccine) Indication to Include Infants, Children and Adolescents

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RAHWAY, N.J.--(BUSINESS WIRE)-- Merck (NYSE: MRK), known as MSD outside of the United States and Canada, announced today that the European Commission (EC) has approved an expanded indication for VAXNEUVANCE™ (Pneumococcal 15-valent Conjugate Vaccine) to include active immunization for the prevention of invasive disease, pneumonia and acute otitis media caused by *Streptococcus pneumoniae* (*S. pneumoniae*) in infants, children and adolescents from 6 weeks to less than 18 years of age. The approval facilitates availability of VAXNEUVANCE for this population in all 27 European Union (EU) Member States plus Iceland, Norway and Lichtenstein. VAXNEUVANCE is also indicated in the EU for active immunization for the prevention of invasive disease and pneumonia caused by *S. pneumoniae* in individuals 18 years of age and older. The use of VAXNEUVANCE in the EU should be in accordance with official recommendations.

"VAXNEUVANCE was developed to maintain a strong immune response to serotypes included in currently available pneumococcal conjugate vaccines, or PCVs, while expanding coverage to disease-causing serotypes that can pose substantial risk to infants and children," said Dr. Eliav Barr, senior vice president, head of global clinical development and chief medical officer, Merck Research Laboratories. "With this approval, we are pleased to bring an important new PCV option to a vulnerable population in Europe, including infants less than one year of age, who typically experience the highest rates of disease."

The EC's decision follows a positive opinion from the European Medicines Agency's Committee for Medicinal



Products for Human Use (CHMP), who reviewed data from eight randomized, double-blind clinical studies that enrolled approximately 8,400 individuals, including 5,400 who received VAXNEUVANCE. The studies evaluated the use of VAXNEUVANCE in various pediatric populations at risk for pneumococcal disease, including healthy infants, children and adolescents, pre-term infants and children living with HIV infection or sickle cell disease. The use of VAXNEUVANCE was also evaluated across a variety of clinical circumstances, such as interchangeable use following initiation of an infant vaccination schedule with the currently licensed 13-valent pneumococcal conjugate vaccine (PCV13) or in a catch-up setting for older children who are either pneumococcal vaccine-naïve or who previously received an incomplete series of another PCV.

The data supporting the approval included findings from the pivotal PNEU-PED-EU-1 study which evaluated the safety, tolerability and immunogenicity of a two-dose infant series followed by a toddler dose of VAXNEUVANCE in healthy infants (n=1,184). Results showed that immune responses for VAXNEUVANCE were noninferior to PCV13 for the 13 serotypes shared between the two vaccines and superior for the two additional serotypes in VAXNEUVANCE, 22F and 33F, as assessed by serotype-specific anti-pneumococcal polysaccharide immunoglobulin G (IgG) response rates and geometric mean concentrations (GMCs) at 30 days post-toddler dose.

Pneumococcal disease is an infection caused by the bacterium *S. pneumoniae*, or pneumococcus. While there are more than 100 different types of *S. pneumoniae*, called serotypes, a selected number of serotypes are responsible for the majority of pneumococcal infections. Invasive pneumococcal disease (IPD) can cause serious and potentially life-threatening infections such as bacteremia (infection in the bloodstream); bacteremic pneumonia (pneumonia with bacteremia); and meningitis (infection of the linings of the brain and spinal cord).

In July 2021, VAXNEUVANCE received approval from the U.S. Food and Drug Administration (FDA) for active immunization for the prevention of invasive disease caused by *S. pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F and 33F in adults 18 years of age and older, and in June 2022, the FDA approved an expanded indication for VAXNEUVANCE to include individuals 6 weeks through 17 years of age.

About VAXNEUVANCE (Pneumococcal 15-valent Conjugate Vaccine)

VAXNEUVANCE, Merck's 15-valent pneumococcal conjugate vaccine, consists of purified capsular polysaccharides from *S. pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F and 33F individually conjugated to CRM197 carrier protein.

VAXNEUVANCE is indicated in the EU for active immunization for the prevention of invasive disease, pneumonia and acute otitis media caused by *S. pneumoniae* in infants, children and adolescents from 6 weeks to less than 18 years of age, and for active immunization for the prevention of invasive disease and pneumonia caused by *S. pneumoniae* in individuals 18 years of age and older.

VAXNEUVANCE is indicated in the U.S. for active immunization of individuals 6 weeks of age and older for the prevention of invasive disease caused by the *S. pneumoniae* serotypes contained in the vaccine.

Select Safety Information for VAXNEUVANCE

Do not administer VAXNEUVANCE to individuals with a severe allergic reaction (e.g., anaphylaxis) to any component of VAXNEUVANCE or to diphtheria toxoid.

Some individuals with altered immunocompetence, including those receiving immunosuppressive therapy, may have a reduced immune response to VAXNEUVANCE.

Apnea following intramuscular vaccination has been observed in some infants born prematurely. Vaccination of premature infants should be based on the infant's medical status and the potential benefits and possible risks.

The most commonly reported solicited adverse reactions in children vaccinated with a four-dose series at 2, 4, 6, and 12 through 15 months of age, provided as a range across the series, were: irritability (57.3% to 63.4%), somnolence (24.2% to 47.5%), injection-site pain (25.9% to 40.3%), fever $\geq 38.0^{\circ}\text{C}$ (13.3% to 20.4%), decreased appetite (14.1% to 19.0%), injection-site induration (13.2% to 15.4%), injection-site erythema (13.7% to 21.4%) and injection-site swelling (11.3% to 13.4%).

The most commonly reported solicited adverse reactions in children and adolescents 2 through 17 years of age vaccinated with a single dose were: injection-site pain (54.8%), myalgia (23.7%), injection-site swelling (20.9%), injection-site erythema (19.2%), fatigue (15.8%), headache (11.9%) and injection-site induration (6.8%).

The most commonly reported solicited adverse reactions in adults 18 through 49 years of age were: injection-site pain (75.8%), fatigue (34.3%), myalgia (28.8%), headache (26.5%), injection-site swelling (21.7%), injection-site erythema (15.1%) and arthralgia (12.7%).

The most commonly reported solicited adverse reactions in adults 50 years of age and older were: injection-site pain (66.8%), myalgia (26.9%), fatigue (21.5%), headache (18.9%), injection-site swelling (15.4%), injection-site erythema (10.9%) and arthralgia (7.7%).

Vaccination with VAXNEUVANCE may not protect all vaccine recipients.

Merck's Commitment to Pneumococcal Disease Protection

Merck has been at the forefront of pneumococcal disease prevention through vaccination for more than four decades and remains committed to helping to protect people of all ages from this disease. Merck's ongoing pneumococcal vaccine development program is designed to provide tailored options to address the specific needs

of different populations, including infants and children, healthy adults and at-risk subgroups. This approach recognizes that disease burden in pediatric and adult populations is often driven by different bacterial strains, or serotypes, and aims to address unmet needs by offering vaccine options that target serotypes posing the greatest global risk to each population. To learn more about Merck's pneumococcal portfolio and pipeline, visit <https://www.merck.com>.

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., Rahway, N.J., USA

This news release of Merck & Co., Inc., Rahway, 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).

Please see U.S. Prescribing Information for VAXNEUVANCE (Pneumococcal 15-valent Conjugate Vaccine) at https://www.merck.com/product/usa/pi_circulars/v/vaxneuvance/vaxneuvance_pi.pdf and Patient Information/Medication Guide for VAXNEUVANCE at https://www.merck.com/product/usa/pi_circulars/v/vaxneuvance/vaxneuvance_ppi.pdf.

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