

Health Canada Approves CAPVAXIVE[®], (Pneumococcal 21-valent Conjugate Vaccine) for Prevention of Invasive Pneumococcal Disease in Adults

KIRKLAND, QC, July 16, 2024 – Merck (NYSE: MRK), known as MSD outside of the United States and Canada, announced today that Health Canada has approved CAPVAXIVE[®] (Pneumococcal 21-valent Conjugate Vaccine) for:

- Active immunization for the prevention of invasive pneumococcal disease (including sepsis, meningitis, bacteremic pneumonia, pleural empyema and bacteremia) caused by *Streptococcus pneumoniae* serotypes (3, 6A, 6C, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15B, 15C, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F, and 35B) in individuals 18 years of age and older;

The approval follows Health Canada’s Priority Review of Merck’s application.

“Invasive pneumococcal disease (IPD) can cause serious illness, especially in older and immunocompromised adults. The approval of this vaccine by Health Canada expands pneumococcal disease prevention options for Canadians and underscores Merck’s unrelenting focus on developing new options to help with important public health issues.” Said Marwan Akar, Managing Director of Merck Canada.

Based on 2020 surveillance data from the Public Health Agency of Canada, the serotypes covered by this Pneumococcal 21-valent conjugate vaccine were responsible for:

- 76% of IPD cases reported in adults 50 to 64 years of age.
- 81% of IPD cases reported in adult 65 years of age and older.

These values were based on surveillance data and do not reflect the efficacy of CAPVAXIVE[®].

Clinical Data Supporting Health Canada Approval

Four Phase 3, clinical studies (Protocol 003, Protocol 004, Protocol 005, and Protocol 006) conducted across the Americas, Europe, and Asia Pacific evaluated the immunogenicity of CAPVAXIVE[®] in approximately 6,500 adults 18 years of age and older, approximately 4,500 of whom received this Pneumococcal 21-valent conjugate vaccine. Of these adults enrolled, approximately 1,000 had received other prior pneumococcal vaccines. Approximately 34% of enrolled adults had chronic medical conditions (e.g., diabetes, renal disorders, chronic heart disease, chronic liver disease, chronic lung disease including asthma, smoking, alcoholism) known to increase the risk of pneumococcal disease.

In each study, immunogenicity was assessed by serotype specific opsonophagocytic activity (OPA) and immunoglobulin G (IgG) responses at 1-month postvaccination. The primary immunogenicity endpoints included OPA geometric mean titers (GMTs) and the proportion of individuals who achieved a ≥ 4 -fold rise in OPA responses from prevaccination to 1-month postvaccination.

For complete information, please refer to the CAPVAXIVE[®] product monograph.

About Pneumococcal Disease

Pneumococcal disease is an infection caused by a bacteria called *Streptococcus pneumoniae*. There are about 100 different types (referred to as serotypes) of pneumococcal bacteria, which can affect adults differently than children. Pneumococcal disease can be invasive or non-invasive. Non-invasive

pneumococcal illnesses include pneumonia (when pneumococcal disease is confined to the lungs), whereas invasive pneumococcal illnesses include pneumococcal bacteremia (infection in the bloodstream), bacteremic pneumococcal pneumonia (pneumonia with bacteremia) and pneumococcal meningitis (infection of the coverings of the brain and spinal cord). Pneumococcal pneumonia is a type of bacterial pneumonia, which is the most common clinical presentation of pneumococcal disease in adults.

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 about our operations in Canada, visit www.merck.ca and connect with us on [LinkedIn](#) and [X @MerckCanada](#).

Forward-Looking Statement of Merck & Co. Inc., Rahway, NJ, 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 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, 2023 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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