Health Canada Approves KEYTRUDA® for the treatment of adult patients with muscle invasive bladder cancer who are ineligible for cisplatin containing chemotherapy, in combination with enfortumab vedotin, as neoadjuvant treatment and then continued after radical cystectomy as adjuvant treatment

Kirkland, Quebec – Merck (NYSE: MRK), known as MSD outside of the United States and Canada, announced that KEYTRUDA® (pembrolizumab for injection), Merck's anti-PD-1 therapy, in combination with enfortumab vedotin, an antibody-drug conjugate (ADC), is approved by Health Canada as neoadjuvant treatment and then continued after radical cystectomy (RC) as adjuvant treatment, for adults with muscle-invasive bladder cancer (MIBC) who are ineligible for cisplatin-containing chemotherapy.

This approval is based on results from the pivotal Phase 3 KEYNOTE-905 trial (also known as EV-303), which was conducted in collaboration with Pfizer and Astellas. The trial demonstrated a statistically significant improvement in EFS and OS in patients treated with neoadjuvant and adjuvant KEYTRUDA in combination with enfortumab vedotin compared with RC and PLND alone. It also demonstrated a statistically significant difference in pCR rate.

"Muscle-invasive bladder cancer can have a significant impact on patients and their families, particularly for those who are not candidates for cisplatin-based chemotherapy," said Michelle Colero, Executive Director at Bladder Cancer Canada. "The availability of an additional treatment option for eligible patients is welcome news for the bladder cancer community and highlights the importance of continued research in this area of unmet need."

About bladder cancer

Bladder cancer is the fifth most commonly diagnosed cancer in Canada, and 13,400 individuals are diagnosed each year with the disease, according to Bladder Cancer Canada. Around one-quarter (25%) of these newly diagnosed cases involve muscle-invasive bladder cancer (MIBC), where the cancer grows through the lining of the bladder into or through the muscle layer of the bladder wall .

For patients with MIBC, cisplatin-based neoadjuvant chemotherapy followed by surgery (radical cystectomy) is a standard treatment approach in Canada. Cisplatin ineligibility is common in this population and may be related to factors such as age or certain medical

conditions. For patients who are not eligible for cisplatin-containing chemotherapy, treatment decisions have traditionally centered on proceeding to radical cystectomy alone.

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 @MerckCanada.

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. 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, 2025 and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site (www.sec.gov).