



News Release

Health Canada Approves KEYTRUDA SC™, a subcutaneous formulation of pembrolizumab across multiple cancer indications

KIRKLAND, Quebec, Feb. 17, 2026 — Merck (NYSE: MRK), known as MSD outside of the United States and Canada, announced today that Health Canada has approved KEYTRUDA SC™ (pembrolizumab injection), a new subcutaneous formulation of pembrolizumab, Merck's anti-PD-1 therapy.

This Health Canada approval marks an important milestone for Merck in Canada. "We remain committed to bringing meaningful solutions to Canadian patients," said David D. Jones, Managing Director, Merck Canada. "By providing KEYTRUDA SC™, we aim to offer the flexibility of an additional administration option for eligible patients and help healthcare providers to deliver care in the way that best meets patient needs."

The approval is based on results from pivotal trial 3475A-D77, which compared pembrolizumab administered subcutaneously with pembrolizumab administered intravenously, both in combination with chemotherapy, in patients with treatment-naïve metastatic squamous or non-squamous non-small cell lung cancer (NSCLC) with no EGFR, ALK or ROS1 genomic tumor aberrations.

The primary endpoints of the trial demonstrated that the subcutaneous (SC) formulation produced noninferior levels of pembrolizumab in the blood compared to the intravenous (IV) formulation based on pharmacokinetic exposure measures (C_{trough} : minimum concentration in the blood; $AUC_{0-6\text{weeks}}$: area under the curve from time zero to dosing interval).

This decision authorizes the marketing of the subcutaneous formulation of pembrolizumab in Canada. Timing for commercial availability will depend on multiple factors, including provincial and territorial reimbursement processes.

Clinical Data Supporting Health Canada's Approval

Use of KEYTRUDA SC™ for its authorized indications is supported by evidence from adequate and well-controlled studies conducted with intravenous KEYTRUDA®, across tumour types, and additional pharmacokinetic, efficacy, and safety data from Study MK-3475A-D77.

Study 3475A-D77 demonstrated that pembrolizumab 790 mg administered subcutaneously every six weeks in combination with platinum doublet chemotherapy was pharmacokinetically noninferior to pembrolizumab 400 mg administered intravenously every six weeks in combination with platinum doublet chemotherapy.

For the dual primary outcome measures of Cycle 1 $AUC_{0-6weeks}$ and Cycle 3 (steady-state) C_{trough} , the geometric mean ratios were 1.14 (96% CI: 1.06–1.22) and 1.67 (94% CI: 1.52–1.84), respectively. Additionally, the trial showed similar secondary efficacy outcomes, including objective response rate (ORR) and progression free survival (PFS), between the SC and IV treatment arms.

Study MK-3475A-D77 was a randomized, multicenter, open-label, active-controlled trial conducted to compare KEYTRUDA SC™ with intravenous KEYTRUDA®, both in combination with platinum doublet chemotherapy, in patients with metastatic, squamous or non-squamous NSCLC who had not received prior systemic treatment for metastatic NSCLC and in whom there were no EGFR, ALK or ROS1 genomic tumour aberrations.

Study MK-3475A-D77 was designed to evaluate the non-inferiority of pembrolizumab Cycle 1 $AUC_{0-6weeks}$ and Steady State (Cycle 3) C_{trough} of KEYTRUDA SC™ compared with intravenous KEYTRUDA® (primary endpoint). Secondary endpoints included objective response rate (ORR) and progression free survival (PFS) as assessed by Blinded Independent Central Review (BICR), and overall survival (OS).

A total of 377 patients were randomized (2:1) to receive either KEYTRUDA SC™ 790 mg subcutaneously every 6 weeks with platinum doublet chemotherapy (n=251) or intravenous KEYTRUDA® 400 mg intravenously every 6 weeks with platinum doublet chemotherapy (n=126).

Additionally, the trial showed similar secondary efficacy outcomes (ORR and PFS) between the SC and IV treatment arms. The safety profile of KEYTRUDA SC™ in combination with platinum doublet chemotherapy was overall consistent with the known safety profile of intravenous KEYTRUDA® in combination with platinum doublet chemotherapy, with the addition of injection site reactions, which occurred in 2.4% (6/251) of patients receiving KEYTRUDA SC™, all Grade 1.

For complete information, refer to the KEYTRUDA SC™ (pembrolizumab injection) product monograph: https://www.merck.ca/en/wp-content/uploads/sites/20/2026/02/KEYTRUDA-SC_PM_E.pdf

About KEYTRUDA SC™ (pembrolizumab injection)

KEYTRUDA SC™ solution contains the active substance pembrolizumab, which provides the therapeutic effect of this medicinal product, and berahyaluronidase alfa.

Pembrolizumab is an anti-programmed death receptor-1 (PD-1) therapy that works by increasing the ability of the body's immune system to help detect and fight tumor cells. Pembrolizumab is a humanized monoclonal antibody that blocks the interaction between PD-1 and its ligands, PD-L1 and PD-L2, thereby activating T lymphocytes, which may affect both tumor cells and healthy cells.

Berahyaluronidase alfa is a variant of human hyaluronidase PH20, an enzyme that temporarily and locally breaks down hyaluronan, a polysaccharide found in the extracellular matrix of subcutaneous tissue. Its activity results in enhanced dispersion

and permeation, facilitating delivery of medicinal products that are co-administered subcutaneously.

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](#).

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 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, 2024 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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