News Release

Health Canada Approves KEYTRUDA® Plus Pemetrexed and Platinum Chemotherapy as First-Line Treatment for Adult Patients with Unresectable Advanced or Metastatic Malignant Pleural Mesothelioma (MPM)

Approval is based on the results from the Phase 3 CCTG IND.227/KEYNOTE-483 trial

KIRKLAND, QC., April 22, 2025 – Merck (NYSE: MRK), known as MSD outside of the United States and Canada, announced today that Health Canada has approved KEYTRUDA® (pembrolizumab), Merck's anti-PD-1 therapy, in combination with pemetrexed and platinum chemotherapy, for the first-line treatment of adult patients with unresectable advanced or metastatic malignant pleural mesothelioma (MPM). The approval is based on data from the pivotal Phase 3 IND.227/KEYNOTE-483 trial, which demonstrated a statistically significant improvement in overall survival (OS), progression-free survival (PFS) and overall response rate (ORR) in patients randomized to KEYTRUDA® in combination with chemotherapy compared with patients randomized to chemotherapy alone. This pivotal trial was led by the Canadian Cancer Trials Group (CCTG) in collaboration with the National Cancer Institute of Naples (NCIN) and the Intergroupe Francophone de Cancérologie Thoracique (IFCT).

"This approval marks the first combination treatment of KEYTRUDA® and chemotherapy in Canada for patients with malignant pleural mesothelioma," says Dr. Quincy Chu, Medical Oncologist at the Cross Cancer Institute and Associate Professor at the University of Alberta. "This combination provides a new therapeutic option for this patient group, which has limited options available and may help improve health outcomes."

"We're pleased to announce this first-line treatment option for adults with advanced or metastatic malignant pleural mesothelioma, a condition that often has a challenging prognosis," says André Galarneau, PhD, Executive Director & Vice President, Oncology Business Unit at Merck Canada. "This is an important step for us within the mesothelioma space. It demonstrates the CCTG's leadership in advancing patient care and underscores our commitment to research for patients with difficult-to-treat cancers.

About IND.227/KEYNOTE-483

IND.227/KEYNOTE-483 is a multicenter, randomized, open-label, active-controlled Phase 2/3 trial (ClinicalTrials.gov, NCT02784171). Merck provided pembrolizumab and support for the trial, which was also supported by grants to CCTG from the Canadian Cancer Society. The trial investigated the efficacy and safety of pembrolizumab in combination with pemetrexed and platinum chemotherapy versus pemetrexed and platinum chemotherapy for the treatment of patients with unresectable advanced or metastatic MPM and no prior systemic therapy for advanced/metastatic disease.

The Phase 3 component of the trial enrolled 440 patients, regardless of tumour PD-L1 expression. Patients with autoimmune disease that required systemic therapy within three years of treatment or a medical condition that required immunosuppression were ineligible. Patients were randomized (1:1) to one of the following treatment arms; all study medications were administered via intravenous infusion:

- Pembrolizumab 200 mg with pemetrexed 500 mg/m^2 and cisplatin 75 mg/m^2 or carboplatin AUC 5-6 mg/mL/min on Day 1 of each 21-day cycle for up to 6 cycles, followed by pembrolizumab 200 mg every three weeks. Pembrolizumab was administered prior to chemotherapy on Day 1.

- Pemetrexed 500 mg/m^2 and cisplatin 75 mg/m^2 or carboplatin AUC 5-6 mg/mL/min on Day 1 of each 21-day cycle for up to 6 cycles.

Treatment with pembrolizumab continued until disease progression as determined by the investigator according to modified RECIST 1.1 for mesothelioma (mRECIST), unacceptable toxicity, or a maximum of 24 months. Assessment of tumour status was performed every 6 weeks for 18 weeks, followed by every 12 weeks thereafter. The primary efficacy outcome measure was overall survival (OS). Additional efficacy outcome measures were progression free survival (PFS), objective response rate (ORR), and duration of response (DoR), as assessed by BICR using mRECIST.

Pembrolizumab plus chemotherapy demonstrated a statistically significant improvement in OS, reducing the risk of death by 21% (Hazard Ratio (HR) =0.79 [95% CI, 0.64-0.98]; p=0.0162) compared to chemotherapy alone at the trial's pre-specified final analysis. Median OS was 17.3 months (95% CI, 14.4-21.3) for pembrolizumab plus chemotherapy versus 16.1 months (95% CI, 13.1-18.2) for chemotherapy alone. Pembrolizumab plus chemotherapy also demonstrated a statistically significant improvement in progression-free survival (PFS) versus chemotherapy alone (HR=0.80 [95% CI, 0.65-0.99], p=0.0194. Median PFS was 7.1 months [95% CI, 6.9-8.1] for pembrolizumab plus chemotherapy versus 7.1 months [95% CI, 6.8-7.7] for chemotherapy alone. Based on an interim analysis, the overall response rate (ORR) was significantly higher for pembrolizumab plus chemotherapy versus chemotherapy alone (52% [95% CI, 45.5-59.0] versus 29% [95% CI, 23.0-35.4], respectively; p<0.00001).

The most frequently reported adverse events (≥ 20% incidence) for pembrolizumab in combination with pemetrexed and platinum chemotherapy were fatigue, nausea, diarrhea, vomiting and stomatitis.

For complete information, refer to the KEYTRUDA® product monograph.

About malignant mesothelioma

Malignant mesothelioma is a type of cancer that starts in the mesothelium, a lining that covers most internal organs, including the lungs, heart and stomach. The most recent incidence statistics from 2019 indicated that 460 Canadians were diagnosed with mesothelioma that year. The most recent mortality statistics from 2022 indicated that 472 Canadians died from

mesothelioma that year. Pleural mesothelioma, which develops in the lining of the lungs, is the most common form of malignant mesothelioma. The 5-year net survival for Canadians diagnosed with mesothelioma cancer is estimated to be 7%.

About KEYTRUDA®

KEYTRUDA® is an anti-programmed death receptor-1 (anti-PD-1) therapy that works by helping increase the ability of the body's immune system to help detect and fight tumour cells. KEYTRUDA® 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 tumour cells and healthy cells.

KEYTRUDA® was first approved in Canada in 2015 and currently has indications in several disease areas, including advanced renal cell carcinoma, bladder cancer, non-small cell lung carcinoma, primary mediastinal B-cell lymphoma, classical Hodgkin lymphoma, colorectal cancer, endometrial carcinoma, cervical cancer, esophageal cancer, triple-negative breast cancer, melanoma, and head and neck squamous cell carcinoma.

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. 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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