News Release

Health Canada Approves KEYTRUDA® for the Treatment of Adult Patients with Primary Advanced or Recurrent Endometrial Carcinoma, in Combination with Carboplatin and Paclitaxel and then Continued as Monotherapy

Approval is based on the Phase 3 KEYNOTE-868/NRG-GY018 Trial

KIRKLAND, QC., March 19, 2025 – Merck (NYSE: MRK), known as MSD outside of the United States and Canada, announced today that Health Canada approved KEYTRUDA® (pembrolizumab), Merck's anti-PD-1 therapy, in combination with carboplatin and paclitaxel, followed by KEYTRUDA® as a single agent, for the treatment of adult patients with primary advanced or recurrent endometrial carcinoma. The approval is based on data from the Phase 3 KEYNOTE-868 trial, also known as NRG-GY018, which demonstrated statistically significant improvements in progression-free survival (PFS) for patients randomized to KEYTRUDA® in combination with chemotherapy compared to placebo in combination with chemotherapy in both the deficient mismatch repair (dMMR) and proficient mismatch repair (pMMR) populations.

"Today's approval represents an important step forward in the treatment landscape for advanced or recurrent endometrial cancer, a condition that affects many women across Canada," expressed Dr. Alon Altman, Gynecologic Oncologist and Professor, Department of Obstetrics, Gynecology and Reproductive Sciences, University of Manitoba. "The use of immunotherapies, such as KEYTRUDA® alongside chemotherapy offers a new approach that may help address the specific needs of patients facing this diagnosis."

"NRG-GY018 represents the largest first-line immunotherapy trial in advanced or recurrent endometrial cancer," says André Galarneau, PhD, Executive Director & Vice President, Oncology Business Unit at Merck Canada. "This exciting news means an additional option is now available to patients in need. Merck remains focused on supporting research and development that aims to provide meaningful contributions to patient care."

About KEYNOTE-868/NRG-GY018

KEYNOTE-868/ NRG-GY018 is a multicenter, randomized, double-blind, placebo-controlled Phase 3 trial (ClinicalTrials.gov, NCT03914612) evaluating pembrolizumab in combination with standard of care chemotherapy (paclitaxel and carboplatin) versus placebo plus standard of care chemotherapy for the treatment of advanced stage (measurable stage III or IVA), stage IVB and recurrent endometrial cancer.

Randomization was stratified according to mismatch repair (MMR) status, ECOG Performance Status (0 or 1 vs. 2), and prior adjuvant chemotherapy. A total of 810 patients were randomized (1:1) to one of the following treatment arms:

- Pembrolizumab 200 mg every 3 weeks, paclitaxel 175 mg/m^2 and carboplatin AUC 5 mg/mL/min for 6 cycles, followed by pembrolizumab 400 mg every 6 weeks for up to 14 cycles.
- Placebo every 3 weeks, paclitaxel 175 mg/m^2 and carboplatin AUC 5 mg/mL/min for 6 cycles, followed by placebo every 6 weeks for up to 14 cycles.

The primary endpoint was PFS as assessed by the investigator according to RECIST 1.1.[4] Secondary endpoints included overall survival (OS), objective response rate (ORR), duration of response (DoR) and safety. The trial demonstrated statistically significant improvements in PFS for patients randomized to pembrolizumab in combination with chemotherapy, compared to placebo in combination with chemotherapy, in both dMMR and pMMR populations.

Pembrolizumab plus carboplatin and paclitaxel followed by pembrolizumab demonstrated a reduced risk of disease progression or death by 43% (Hazard Ratio (HR)=0.57 [95% Confidence Interval (CI), 0.44-0.74]; p<0.0001) in patients whose cancer was pMMR and by 66% (HR=0.34 [95% CI, 0.22-0.53]; p<0.0001) in patients whose cancer was dMMR, compared to placebo with carboplatin and paclitaxel followed by placebo alone.

For patients whose cancer was pMMR, median PFS in the pembrolizumab plus carboplatin and paclitaxel arm was 13.1 months (95% CI, 10.6-19.5) versus 8.7 months (95% CI, 8.4-11.0) for the placebo plus carboplatin and paclitaxel arm; for patients whose cancer was dMMR, median PFS was not reached (95% CI, 30.7- not reached (NR)) in the pembrolizumab plus carboplatin and paclitaxel arm versus 8.3 months (95% CI, 6.5-12.3) for the placebo plus carboplatin and paclitaxel arm. At the time of PFS analysis, OS data were not mature with 12% deaths in the dMMR population and 17% of deaths in the pMMR population.

The most frequently reported adverse events ((≥ 20% incidence) for pembrolizumab in combination with paclitaxel and carboplatin were fatigue, anemia, alopecia, nausea, peripheral sensory neuropathy, constipation, diarrhea, neuropathy peripheral, white blood cell count decreased, platelet count decreased, neutrophil count decreased, and arthralgia.

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

About endometrial carcinoma

Endometrial carcinoma starts in the inner lining of the uterus, called the endometrium, and makes up 95% of all uterine cancer cases. In Canada, uterine cancer is the fourth most common cancer among women, with an estimated 8,600 patients diagnosed in 2024 and 1,600 deaths as a result of the disease.

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 and X @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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