News Release

Health Canada Approves KEYTRUDA® as a first-line treatment for adult patients with locally advanced unresectable or metastatic HER2-negative gastric or gastroesophageal junction (GEJ) adenocarcinoma in combination with fluoropyrimidine- and platinum-containing chemotherapy

Approval is based on the Phase 3 KEYNOTE-859 Trial

KIRKLAND, QC, April 19, 2024 - Merck (NYSE: MRK), known as MSD outside the United States and Canada, announced that Health Canada has granted approval of KEYTRUDA® (pembrolizumab), Merck's anti-PD-1 therapy, in combination with fluoropyrimidine- and platinum-containing-chemotherapy, for the first-line treatment of adult patients with locally advanced unresectable or metastatic HER2-negative gastric or gastroesophageal junction (GEJ) adenocarcinoma. This approval is based on the results from the Phase 3 KEYNOTE-859 trial, which demonstrated a statistically significant improvement in overall survival (OS), progression-free survival (PFS) and objective response rate (ORR) compared to placebo in combination with chemotherapy in the intention-to-treat (ITT) study population.

"We are proud of the recent expansion of KEYTRUDA®'s indications in gastric cancers, which often go undetected until an advanced stage, at which point patients face a poor prognosis," says André Galarneau, PhD, Executive Director & Vice President, Oncology Business Unit at Merck Canada. "This milestone underscores our commitment to helping improve the lives of patients by offering treatment options that can lead to better health outcomes."

About KEYNOTE-859

KEYNOTE-859 was a multicenter, randomized, double-blind, placebo-controlled Phase 3 trial (ClinicalTrials.gov NCT03675737) evaluating pembrolizumab in combination with fluoropyrimidine- and platinum-containing chemotherapy for the first-line treatment of locally advanced unresectable or metastatic HER2-negative gastric or GEJ adenocarcinoma. The primary endpoint was overall survival (OS) with progression-free survival (PFS) and objective response rate (ORR) included as secondary endpoints as assessed by blinded independent central review (BICR) using RECIST v1.1 modified to follow a maximum of 10 target lesions and a maximum of 5 target lesions per organ.

The trial enrolled 1579 patients who had not previously received systemic therapy for metastatic disease and were randomized 1:1 to receive pembrolizumab (200 mg every three weeks) in combination with fluoropyrimidine- and platinum-containing chemotherapy (n=790), or placebo in combination with chemotherapy (n=789). All patients received investigator's choice of chemotherapy (5-fluorouracil plus cisplatin [FP] or capecitabine plus oxaliplatin [CAPOX]). All study medications, except oral capecitabine, were administered as an intravenous infusion for every 3-week cycle. Platinum agents could be administered for 6 or more cycles following local guidelines. Treatment continued until RECIST v1.1-defined progression of disease as determined by BICR, unacceptable toxicity, or a maximum of 24 months.

A statistically significant improvement in OS, PFS and ORR was demonstrated in patients randomized to pembrolizumab in combination with chemotherapy compared with placebo in combination with chemotherapy at the pre-specified interim analysis of OS. In the study, there was a 22% reduction in the risk of death with pembrolizumab plus chemotherapy (HR=0.78 [95% CI, 0.70-0.87]; p<0.0001) versus chemotherapy alone. The median OS for patients receiving pembrolizumab plus chemotherapy was 12.9 months (95% CI, 11.9-14.0) versus 11.5 months (95% CI, 10.6-12.1) for those receiving chemotherapy alone.

A positive association was observed between PD-L1 CPS score and the magnitude of the treatment benefit. The median duration of exposure to pembrolizumab was 6.2 months (range, 1 day to 33.7 months).

The most common treatment-related adverse events (≥20% incidence) for patients receiving pembrolizumab plus fluoropyrimidine- and platinum-containing chemotherapy were nausea, diarrhea, anemia, vomiting, platelet count decreased, neutrophil count decreased, palmar-plantar erythrodysesthesia syndrome, decreased appetite and fatigue.

For complete information, refer to the product monograph.

About Gastric Cancer

Gastric (stomach) cancer tends to develop slowly over many years and rarely causes symptoms in its early stages, resulting in nearly half of cases being diagnosed at an advanced stage. About 95% of gastric cancers are adenocarcinomas, which develop from cells in the innermost lining of the stomach, known as the mucosa. It was estimated that gastric cancer accounted for approximately 4,100 cases and 2,000 deaths in Canada in 2023, with the highest mortality rates in Newfoundland and Labrador. Based on statistics from the United States, the relative five-year survival for patients diagnosed with gastric cancer at an advanced stage (cancer that had spread to other parts of the body) is only 5%.

About KEYTRUDA®

KEYTRUDA® is an 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, 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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