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**Health Canada Approves KEYTRUDA® in combination with trastuzumab and chemotherapy, as a first-line treatment for patients with locally advanced unresectable or metastatic HER2-positive gastric or gastroesophageal junction adenocarcinoma whose tumours express PD-L1 (CPS ≥ 1)**

**Approval is based on the Phase 3 KEYNOTE-811 Trial**

KIRKLAND, QC, February 6, 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 trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy, for the first-line treatment of adult patients with locally advanced unresectable or metastatic HER2 positive gastric or gastroesophageal junction (GEJ) adenocarcinoma whose tumours express PD-L1 (Combined Positive Score [CPS] ≥ 1) as determined by a validated test. This approval is based on the results from the Phase 3 KEYNOTE-811 trial, which demonstrated a statistically significant improvement in progression-free survival (PFS) compared to placebo in combination with trastuzumab and chemotherapy in the intention-to-treat (ITT) study population.

"The approval granted by Health Canada represents a significant milestone for patients with advanced gastric and GEJ adenocarcinoma - cancer types in which patients have faced limited treatment options," says André Galarneau, PhD, Executive Director & Vice President, Oncology Business Unit at Merck Canada. "Our commitment to delivering more options to patients and their families is underscored by the results observed in this Phase 3 trial, representing a step forward in our mission to bring more hope to Canadians impacted by this challenging disease."

**About KEYNOTE-811**

KEYNOTE-811 was a randomized, double-blind Phase 3 trial (ClinicalTrials.gov, NCT03615326) evaluating pembrolizumab in combination with trastuzumab and chemotherapy for the first-line treatment of locally advanced unresectable or metastatic HER2-positive gastric or GEJ adenocarcinoma. The dual primary endpoints were PFS per RECIST v1.1 as assessed by blinded independent central review and overall survival (OS). Secondary endpoints included objective response rate (ORR), duration of response (DOR) and safety. The trial enrolled 698 patients who were randomized to receive pembrolizumab (200 mg every three weeks) in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy (investigator’s choice of 5-fluorouracil plus cisplatin or capecitabine plus oxaliplatin), or placebo in combination with trastuzumab and chemotherapy. Among the 698 patients randomized in KEYNOTE-811, 594 (85%) had tumors that expressed PD-L1 with a CPS ≥1.

At the first interim analysis conducted on the first 264 patients randomized in the overall population (133 patients in the pembrolizumab arm and 131 in the placebo arm), a statistically significant improvement was observed in the ORR (74.4% vs 51.9%, representing a 22.7% difference; 95% CI (11.2, 33.7); p-Value 0.00006).

At the second interim analysis in the overall population, a statistically significant improvement in PFS (HR 0.72; 95% CI 0.60, 0.87; p-Value 0.0002) was demonstrated in patients randomized to pembrolizumab in combination with trastuzumab and chemotherapy compared with placebo in combination with trastuzumab and chemotherapy. At the time of this analysis in the overall population, there was no statistically significant difference with respect to OS.

The most frequently reported treatment-related adverse events (≥20% incidence) for pembrolizumab in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy group were diarrhea, nausea, anemia, neutrophil count decreased, decreased appetite, platelet count decreased, vomiting, peripheral sensory neuropathy, and palmar-plantar erythrodysesthesia syndrome.

For complete information, refer to the product monograph: <https://www.merck.ca/en/keytruda-pm_e>.

**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. In 20-25% of patients with GEJ/gastric adenocarcinoma, there is tumour over-expression of the HER2 protein. 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](http://www.merck.ca/) and connect with us on [LinkedIn](https://www.linkedin.com/company/merck-canada/) and [X](https://twitter.com/merckcanada) @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 the global outbreak of novel coronavirus disease (COVID-19); 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, 2022 and the company’s other filings with the Securities and Exchange Commission (SEC) available at the SEC’s Internet site ([www.sec.gov](http://www.sec.gov)).

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Please see the product monograph for KEYTRUDA® (pembrolizumab) at: [**https://www.merck.ca/en/wp-content/uploads/sites/20/2021/04/KEYTRUDA-PM\_E.pdf**](https://www.merck.ca/en/wp-content/uploads/sites/20/2021/04/KEYTRUDA-PM_E.pdf).

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