News Release

Health Canada Approves KEYTRUDA® as monotherapy for the treatment of adult and pediatric patients with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) solid tumours that have progressed following prior treatment and who have no satisfactory alternative treatment options

KIRKLAND, QC, September 12, 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, as a monotherapy for the treatment of adult and pediatric patients with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) solid tumours, as determined by a validated test, that have progressed following prior treatment and who have no satisfactory alternative treatment options. This approval is based on the results from KEYNOTE-158, KEYNOTE-164, and KEYNOTE-051 trials, and includes data from 504 patients across more than 30 cancer types.

"This news helps reinforce Merck's ongoing commitment to research and development in immuno-oncology," expressed André Galarneau, PhD, Executive Director & Vice President, Oncology Business Unit at Merck Canada. "This is a step forward in addressing an important unmet medical need for patients with unresectable or metastatic MSI-H/dMMR solid tumours."

About KEYNOTES-158, 164 and 051

The efficacy of pembrolizumab was investigated in 504 patients with MSI-H or dMMR cancer enrolled in three multicenter, nonrandomized, open-label, multi-cohort studies: KEYNOTE-164 (NCT02460198), KEYNOTE-158 (NCT02628067) and KEYNOTE-051 (NCT02332668).

- KEYNOTE-164 enrolled 124 patients with advanced MSI-H or dMMR colorectal cancer (CRC) that progressed following treatment with a fluoropyrimidine and either oxaliplatin or irinotecan +/- anti-VEGF/EGFR mAb-based therapy.
- KEYNOTE-158 enrolled 373 patients with advanced MSI-H or dMMR non-colorectal cancer (non-CRC) who had disease progression following prior therapy.
- KEYNOTE-051 enrolled 7 pediatric patients with MSI-H or dMMR cancers.

The major efficacy outcome measures were objective response rate (ORR) and duration of response (DoR) as assessed by BICR according to RECIST 1.1 and as assessed by the investigator according to RECIST 1.1 in KEYNOTE-051.

In a pooled analysis for adult patients, pembrolizumab demonstrated an ORR of 34% (95% CI, 30,38), including a complete response rate of 11% and partial response rate of 23%. The median follow-up time for 497 adult and 7 pediatric patients treated with pembrolizumab was 20.5 months and 5.2 months respectively. In the pooled adult patient population (n=497), 75% had responses lasting 36 months or longer with the median DOR of 63.2 months (range, 1.9+ to 63.9+ months).

The most common adverse events (reported in at least 10% of patients) were pruritus, fatigue, diarrhea, and arthralgia.

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

About Microsatellite Instability-High (MSI-H) and Deficient Mismatch Repair (dMMR) Cancers

In normal cells, a process called mismatch repair (MMR) fixes errors (such as mutations) that can happen when DNA divides and makes a copy of itself. If a cell's MMR system isn't working correctly, errors will build up and cause the DNA to become unstable. Certain cancer tumours are referred to as having an "MSI status," meaning they are described as either MSI (microsatellite instable) or MSS (microsatellite stable). MSI biomarkers indicate how stable the DNA is in a tumour. Microsatellite instability high (MSI-H) or mismatch repair deficient (dMMR) are abnormal test results that indicate a cancer tumour has microsatellite instability. Microsatellite instability is found most often in colorectal cancer, gastric cancer, and endometrial cancer, but it may also be found in many other types of cancer.

About KEYTRUDA®

KEYTRUDA® is an anti-programmed death receptor-1 (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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