News Release

Health Canada Approves KEYTRUDA® (pembrolizumab) as monotherapy for the adjuvant treatment of adults with renal cell carcinoma (RCC) at intermediate-high or high risk of recurrence following nephrectomy or following nephrectomy and resection of metastatic lesions

Approval Based on Data from the Phase 3 KEYNOTE-564 Trial

KIRKLAND, QC, [October 06, 2022] – Merck (NYSE: MRK), known as MSD outside the United States and Canada, announced that Health Canada has granted approval for KEYTRUDA® (pembrolizumab), Merck's anti-PD-1 therapy, as monotherapy for the adjuvant treatment of adults with renal cell carcinoma (RCC) at intermediate-high or high risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesions. This approval is based on the results from the Phase 3 KEYNOTE-564 trial, which demonstrated a statistically significant improvement in disease-free survival.[1]

"It is estimated that in 2022 over eight thousand Canadians will be diagnosed with kidney and renal pelvis cancer, of which renal cell carcinoma is the most common type,[2]" said Christine Collins, Executive Director, Kidney Cancer Canada. "For people who are impacted by RCC, having a new treatment option following surgery, can offer patients and their loved ones support in managing the disease."

RCC is the most common type of kidney cancer, making up for more than 90% of cases of kidney cancer.[3] It occurs most often in people over 50, and is more common in men than in women. Some of the risk factors include smoking, obesity, and high blood pressure.[4] Given the impact on patients, there is active research in understanding the molecular biology of the disease and improvements in prevention, diagnosis, and availability of treatment options.[5]

"We are proud to be bringing another innovation in the management of renal cell carcinoma to Canadians, because this is our mission – to help improve the lives of those impacted by cancer by providing additional treatment options," said Marwan Akar, President and Managing Director of Merck Canada. "This is another great example of how scientific research, coupled with a passionate team, can help improve patient journeys and we hope to build on this momentum to continue making progress in the fight against cancer."

About KEYNOTE-564 Trial

Health Canada's approval is based on findings from KEYNOTE-564, a Phase 3 randomized, double-blind clinical trial that enrolled 994 patients.[6] The eligibility criteria for this study were adult patients who have undergone nephrectomy and have intermediate-high or high risk of recurrence, or M1 no evidence of disease (M1 NED) renal cell carcinoma. Patients who had received prior systemic therapy for advanced RCC were excluded from the trial

The primary efficacy outcome measure was investigator-assessed disease-free survival (DFS). DFS was defined as the time from randomization to the first recurrence (local, regional, or distant metastasis), or death, whichever occurs first. The results of KEYNOTE-564 demonstrated a statistically significant improvement in DFS for patients randomized to receive KEYTRUDA® monotherapy compared with patients randomized to placebo.[7]

About Renal Cell Carcinoma

RCC is the most common type of kidney cancer, which starts in the lining of the tubules of the kidney.[8] Signs and symptoms often appear as the cancer grows into surrounding tissues and organs, making early detection challenging. Symptoms may include blood in the urine, pain in the back and side of the abdomen, swelling of the legs and ankles, high blood pressure, tiredness, night sweats, weight loss, reduced appetite, or fever.[9] It is one of the most fatal genitourinary malignancies, with a 71% five-year survival rate, and tends to be more common in people over 50, with a higher occurrence in men.[10]

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.[1] 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.[11]

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, esophageal cancer, triple-negative breast cancer, melanoma, and head and neck squamous cell carcinoma.[12]

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 YouTube and Twitter @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 products that the products 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 2020 Annual Report on Form 10-K 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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Please see the product monograph for KEYTRUDA® (pembrolizumab) at: https://www.merck.ca/static/pdf/KEYTRUDA-PM_E.pdf

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