News Release

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Health Canada Approves KEYTRUDA® (pembrolizumab) for the treatment of adult patients with high-risk early-stage triple-negative breast cancer (TNBC) in combination with chemotherapy as neoadjuvant treatment, and then continued as monotherapy as adjuvant treatment after surgery

Approval Based on Data from Phase 3 KEYNOTE-522 Trial

KIRKLAND, QC, April 18, 2022 - Merck (NYSE: MRK), known as MSD outside the United States and Canada, today announced that Health Canada has granted approval for KEYTRUDA® (pembrolizumab), Merck's anti-PD-1 therapy, as a treatment for adult patients with high-risk early-stage triple-negative breast cancer (TNBC) in combination with chemotherapy as neoadjuvant treatment and then continued as monotherapy as adjuvant treatment after surgery.[1] This approval is based on the results from the Phase 3 KEYNOTE-522 trial, which demonstrated a statistically significant improvement in event-free survival (EFS) and pathological complete response (pCR) rate among patients.[1]

"I welcome this approval from Health Canada as an important milestone for patients with high-risk early-stage triple-negative breast cancer," said Dr. Jean-François Boileau, Professor of Surgery, McGill University and Surgical Oncologist, Montreal Jewish General Hospital. "Having a new therapeutic option for the treatment of this challenging subset of cancer is a valuable advancement in this disease area."

In 2021, over 28,000 Canadians were estimated to be diagnosed with breast cancer[2], one of the most common cancers among Canadian women.[2] TNBC is an aggressive subtype of breast cancer that tends to grow and spread quickly.[3] TNBC is also characterized by its high recurrence rate within the first five years after diagnosis.[3] Many breast cancers have receptors for common therapeutic targets such as estrogen, progesterone, or HER2 whereas triple-negative breast cancer tests negative for all three,[3] making this type of cancer difficult to treat as it has fewer treatment options.[4]

"We are proud that Keytruda is approved for this indication, for Canadian patients with triple-negative breast cancer," said Marwan Akar, President, and Managing Director, Merck Canada. "This is another step forward in reinforcing our unwavering commitment to research, science and innovation to support patients."

About KEYNOTE-522 Trial

Health Canada's approval is based on findings from KEYNOTE-522, a Phase 3 randomized, double-blind clinical trial that enrolled 1,174 patients.[1] The eligibility criteria for this study were newly diagnosed previously untreated high-risk early-stage TNBC (tumor size >1 cm but ≤2 cm

in diameter with nodal involvement or tumor size >2 cm in diameter regardless of nodal involvement), regardless of tumor PD-L1 expression.[1]

The major efficacy outcome measures were pathological complete response (pCR) rate and event-free survival (EFS). pCR was defined as the absence of invasive cancer in the breast and lymph nodes and was assessed by the blinded local pathologist at the time of definitive surgery. EFS was defined as the time from randomization to the first occurrence of any of the following events: progression of disease that precludes definitive surgery, local or distant recurrence, second primary malignancy, or death due to any cause.[1] The results of KEYNOTE-522 demonstrated a statistically significant improvement in pCR and EFS for patients randomized to receive KEYTRUDA® in combination with chemotherapy followed by adjuvant KEYTRUDA® as monotherapy compared with patients randomized to placebo in combination with chemotherapy followed by placebo alone.[1]

About Triple-Negative Breast Cancer
TNBC is an aggressive subtype of breast cancer that lacks estrogen receptors, progesterone receptors, and HER2 amplification, making it difficult to target therapeutically.[5] TNBC has the highest rates of metastatic disease and the poorest overall survival of all breast cancer subtypes.[5] It characteristically has a high recurrence rate within the first five years after diagnosis and tends to be more common in women under the age of 40.[3]

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.[1]

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.[1]

Our Focus on Cancer
Our goal is to translate progressive science into innovative oncology medicines to help people with cancer worldwide. At Merck Canada, helping people fight cancer is our passion and supporting accessibility to our cancer medicines is our commitment. Our focus is on pursuing research in oncology and we are accelerating every step in the journey — from lab to clinic — to potentially bring new hope to people with cancer.

About Merck
For more than 130 years, Merck, known as MSD outside of the United States and Canada, has been inventing for life, bringing forward medicines and vaccines for many of the world's most challenging diseases in pursuit of our mission to save and improve lives. We demonstrate our commitment to patients and population health by increasing access to health care through far-reaching policies, programs and partnerships. Today, Merck continues to be at the forefront of research to prevent and treat diseases that threaten people and animals – including cancer, infectious diseases such as HIV and Ebola, and emerging animal diseases – as we aspire to be the premier research-intensive biopharmaceutical company in the world. 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., Kenilworth, NJ, USA
This news release of Merck & Co., Inc., Kenilworth, 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 2021 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

References

[1]KEYTRUDA® Product Monograph. Merck & Co. Inc. Updated April 12, 2022.
[2] Canadian Cancer Society. *Breast cancer statistics.* Taken from: https://cancer.ca/en/cancer-information/cancer-types/breast/statistics. Accessed on February 23, 2022.
[3] Canadian Cancer Society. *Triple-negative and basal-like breast cancers.* Taken from: https://cancer.ca/en/cancer-information/cancer-types/breast/what-is-breast-cancer/cancerous-tumours/triple-negative-breast-cancer. Accessed on February 23, 2022.
[4] American Cancer Society. Triple-negative Breast Cancer. Taken from: https://www.cancer.org/cancer/breast-cancer/about/types-of-breast-cancer/triple-negative.html. Accessed on March 9, 2022.
[5] Lee A, Djamgoz MBA. Triple-negative breast cancer: Emerging therapeutic modalities and novel combination therapies. Cancer Treat Rev. 2018 Jan;62:110-122. doi: 10.1016/j.ctrv.2017.11.003. Epub 2017 Nov 13. PMID: 29202431.