News Release

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Health Canada Approves KEYTRUDA® (pembrolizumab) in Combination with Chemotherapy for the Treatment of Locally Recurrent Unresectable or Metastatic Triple-Negative Breast Cancer Whose Tumors Express PD-L1 (CPS ≥10)

Conditional Approval Based on Data from Phase 3 KEYNOTE-355 Trial; Introduces First Breast Cancer Indication for KEYTRUDA®

KIRKLAND, QC – November 23, 2021 - Merck (NYSE: MRK), known as MSD outside the United States and Canada, today announced that Health Canada has granted conditional approval for KEYTRUDA® (pembrolizumab), Merck's anti-PD-1 therapy, in combination with chemotherapy for the treatment of locally recurrent unresectable or metastatic triple-negative breast cancer (TNBC) in adults whose tumors express PD-L1 (Combined Positive Score [CPS] ≥10) and who have not received prior chemotherapy for metastatic disease.[1] This conditional approval is based on the results of the pivotal Phase 3 KEYNOTE-355 trial which demonstrated KEYTRUDA®'s ability to improve progression-free survival (PFS) in combination with chemotherapy (nab-paclitaxel, paclitaxel or gemcitabine/carboplatin), as compared to chemotherapy alone.[2]

"As a complex and challenging subtype of cancer to treat, this approval is a welcome development for Canadian patients with triple-negative breast cancer," said Dr. David Cescon, Clinician Scientist, Princess Margaret Cancer Centre. "About 10-20% of breast cancers are triple-negative breast cancers. Historically, chemotherapy has been the main treatment for this type of breast cancer, and there has been great interest in finding other therapies to help improve patient outcomes. This news means that there will be more options available and thus represents an important advance in the treatment of triple negative-breast cancer."

Breast cancer is one of the most common cancers among Canadian women and the second leading cause of death from cancer in Canadian women.[3] In 2021, over 27,000 Canadians were estimated to be diagnosed.[3] TNBC is an aggressive subtype of breast cancer which lacks estrogen receptors, progesterone receptors and HER2 amplification, making it difficult to target therapeutically.[4] While TNBC can have the same signs and symptoms as other common types of breast cancer,[5] it differs from other types of invasive breast cancer in that it grows and spreads quickly, is more likely to have spread at the time it's found and has fewer treatment options compared to other types of invasive breast cancer. [6]

"When we hear from people in the metastatic breast cancer community, they say they want more tools in the toolbox – more options to help them treat their disease. And while there have been some advances in targeted treatment in breast cancer, fewer of them have been intended for people with the triple-negative diagnosis," said MJ DeCoteau, Founder and Executive Director, Rethink Breast Cancer. "New treatment options have been anticipated by patients and physicians alike for some time."

“It can be devastating to receive a triple-negative breast cancer diagnosis,” said Cathy Ammendolea, Chair of the Board, Canadian Breast Cancer Network. “It can be worrying for patients to learn about the aggressive nature of the disease and the limited treatment options available to them, but this news can bring some hope to patients and their families who are on this journey.”

About KEYNOTE-355 Trial
Health Canada’s approval is based on findings from the Phase 3 study KEYNOTE-355, a randomized, double blind, multicenter, placebo-controlled study, which enrolled 847 patients.[7] The key eligibility criteria for this study were locally recurrent unresectable or metastatic TNBC, regardless of tumor PD-L1 expression, and which had not been previously treated with chemotherapy in the metastatic setting.[8]

The results of KEYNOTE-355 showed that KEYTRUDA® in combination with chemotherapy demonstrated a statistically significant improvement in progression free survival (PFS) compared to patients treated with placebo in combination with chemotherapy.[9]

“As the first indication in breast cancer for KEYTRUDA®, this approval reinforces our dedication to patients and our legacy in innovative oncology medicines,” said Marwan Akar, President and Managing Director, Merck Canada. “We are so proud to expand on our commitment to discover, develop and provide innovative therapeutic options to those who need it most.”

About Triple-Negative Breast Cancer
TNBC is an aggressive subtype of breast cancer which lacks estrogen receptors, progesterone receptors and HER2 amplification, making it difficult to target therapeutically.[4] TNBC has the highest rates of metastatic disease and the poorest overall survival of all breast cancer subtypes.[4] It characteristically has a high recurrence rate within the first five years after diagnosis,[6] and tends to be more common in women under the age of 40.[6]

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.[10] 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 20 indications in several disease areas, including advanced renal cell carcinoma (RCC), bladder cancer, non-small cell lung carcinoma (NSCLC), classical Hodgkin lymphoma (cHL), melanoma and head and neck squamous cell carcinoma (HNSCC).[12]

Merck’s Research Program
Merck has the industry’s largest immuno-oncology clinical research program. There are currently more than 750 trials studying pembrolizumab across a wide variety of cancers and treatment settings. This clinical program seeks to understand the role of pembrolizumab across cancers and the factors that may predict a patient’s likelihood of benefitting from treatment with this medication, including exploring several different biomarkers.

Our Focus on Cancer
Our goal is to translate progressive science into innovative oncology medicines to help people with cancer worldwide. At Merck Oncology, helping people fight cancer is our passion and supporting accessibility to our cancer medicines is our commitment. Our focus is on pursuing

research in immuno-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.

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 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.

References

[1] KEYTRUDA® Product Monograph. Merck & Co. Inc. Updated November 19, 2021.
[2] KEYTRUDA® Product Monograph. Merck & Co. Inc. Updated November 19, 2021.
[3] Canadian Cancer Society. *Breast Cancer Statistics*. Taken from: https://cancer.ca/en/cancer-information/cancer-types/breast/statistics. Accessed October 21, 2021.
[4] 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.
[5] 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 October 21, 2021.
[6] 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 October 21, 2021.
[7] KEYTRUDA® Product Monograph. Merck & Co. Inc. Updated November 19, 2021.
[8] KEYTRUDA® Product Monograph. Merck & Co. Inc. Updated November 19, 2021.
[9] KEYTRUDA® Product Monograph. Merck & Co. Inc. Updated November 19, 2021.
[10] KEYTRUDA® Product Monograph. Merck & Co. Inc. Updated November 19, 2021.
[11] KEYTRUDA® Product Monograph. Merck & Co. Inc. Updated November 19, 2021.
[12] KEYTRUDA® Product Monograph. Merck & Co. Inc. Updated November 19, 2021.

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