Confidential

News Release

Health Canada Approves KEYTRUDA® (pembrolizumab) as Adjuvant Treatment for Adults and Children with Stage IIB or IIC Melanoma Following Complete Resection

Approval is based on the Phase 3 KEYNOTE-716 Trial

Melanoma is the most serious of all skin cancers, with over 5,000 Canadians diagnosed each year.[1,2]

KIRKLAND, QC, September 13, 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, for the adjuvant treatment of adult and pediatric (12 years and older) patients with stage IIB or IIC melanoma following complete resection.[3] This approval is based on the results from the Phase 3 KEYNOTE-716 trial, which demonstrated a statistically significant improvement in recurrence-free survival (RFS).[3]

In 2022, an estimated 9,000 Canadians will be diagnosed with melanoma,[4] a form of cancer that takes place when melanocytes, the cells responsible for melanin production, start to grow uncontrollably and develop into a tumour.[5] Although it is the least common of all skin cancers, melanoma is the most serious type and early diagnosis and treatment are critical.[1,5]

"We welcome the news of a new treatment option for Canadians living with this disease as the incidence of melanoma continues to rise across the country,"[6,8] said Kathy Barnard, Founder/President of Save Your Skin Foundation. "Having options available right after surgery can help take action against a disease that moves quickly if not caught."

"Melanoma can affect anyone, including children, for whom, although rare, this is the most common amongst pediatric skin cancer types,"[7] said Falyn Katz, Executive Director, Melanoma Canada. "Having options available, like this one, can help to make a difference for Canadians facing this particular type of skin cancer, helping them navigate the disease."

About KEYNOTE-716 Trial

Health Canada's approval is based on findings from KEYNOTE-716, a multicenter, randomized, double-blind, placebo-controlled clinical trial in patients (n=976) with completely resected stage IIB or IIC melanoma.[3] Only patients that had not been previously treated for melanoma beyond complete surgical resection for their melanoma prior to study entry were included in the trial.[3] Patients were randomized to KEYTRUDA® 200 mg or the pediatric (≥12 years old) dose of KEYTRUDA® 2 mg/kg intravenously (up to a maximum of 200 mg) every three weeks (n=487) or placebo (n=489) for up to one year until disease recurrence or unacceptable toxicity.[3] The primary efficacy outcome was investigator-assessed recurrence-free survival (RFS). RFS was defined as the time between the date of randomization and the date of first recurrence (local, regional, or distant metastasis) or death, whichever occurs first.[3]

The results of KEYNOTE-716 demonstrated a statistically significant improvement in RFS for patients randomized to receive KEYTRUDA® compared with patients randomized to placebo at the first pre-specified interim analysis.[3] At the time of median follow-up (14.3 months), 11% (n=54/487) of patients who received KEYTRUDA® had a recurrence or died compared to 17% (n=82/489) of patients who received placebo.

In the study, the safety profile of KEYTRUDA® was consistent with previously reported studies in patients with solid tumors. The most common treatment-related adverse events (reported in at least 15% of patients) were pruritis, fatigue, diarrhea, and rash. KEYTRUDA® was discontinued for treatment-related adverse events in 15% of patients in KEYNOTE-716. Refer to the product monograph for complete information.[3]

“This approval is important for people living with melanoma and for all of us at Merck,” said Marwan Akar, President, and Managing Director, Merck Canada. “With this new indication, KEYTRUDA® is the first checkpoint inhibitor approved in Canada in the adjuvant space in Stage IIB or IIC melanoma, meaning it can be considered for patients earlier in their journey. We are proud to continue to pursue our passion to save and improve lives as well as reinforce our commitment to finding innovative and effective options for more patients with melanoma.”

About Melanoma

Melanoma is a form of skin cancer that starts in the melanocyte cells of the skin.[5] Although less common than other forms of skin cancer, melanoma is the most serious type.[5] Incidences of melanoma are higher in men than in women, and the risk tends to increase with age.[8] Major causes include chronic exposure to ultraviolet radiation from sunlight or other artificial sources.[1]

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.[3] 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.[3]

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.[3]

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

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 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/en/wp-content/uploads/sites/20/2021/04/KEYTRUDA-PM_E.pdf

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