News Release

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Health Canada Approves KEYTRUDA® (pembrolizumab) as First-Line Treatment for Patients with Advanced Renal Cell Carcinoma (RCC)

Approval Based on Results of KEYNOTE-426, Where KEYTRUDA® in Combination with Axitinib Reduced the Risk of Death by Nearly Half Compared to Sunitinib

- Renal cell carcinoma (RCC) is the most common form of kidney cancer, representing 80 per cent of all cases[1]
- The five-year survival rate for advanced RCC is currently estimated to be 8 per cent[2]

KIRKLAND, QC – January 23, 2020 - Merck (NYSE: MRK), known as MSD outside the United States and Canada, today announced that Health Canada has approved KEYTRUDA® (pembrolizumab), Merck's anti-PD-1 therapy, in combination with Inlyta® (axitinib), a tyrosine kinase inhibitor, for first-line treatment of patients with advanced renal cell carcinoma (RCC). The approval is based on findings from the pivotal Phase 3 KEYNOTE-426 trial, which demonstrated significant improvements in overall survival (OS), progression-free survival (PFS) and objective response rate (ORR) for KEYTRUDA® in combination with axitinib (KEYTRUDA®-axitinib combination) compared to sunitinib.

For Canadians living with advanced renal cell carcinoma, the cancer has spread beyond the kidney to other areas of the body.[3] While the five-year survival rate for patients living with Stage 1 RCC is currently estimated to be 81 per cent, those living with advanced (Stage 4) RCC face an 8 per cent chance of survival.[4]

"It's important that Canadians living with renal cell carcinoma, an aggressive form of cancer, have access to new treatment options that are well tolerated and can improve survival outcomes," said Dr. Sebastien Hotte, medical oncologist at McMaster University. "The approval of pembrolizumab, or KEYTRUDA®, in combination with axitinib, is an important advancement in treatment that physicians can now consider in managing patients newly diagnosed with advanced RCC."

“For kidney cancer patients whose cancer has spread beyond the kidney and metastasized in other parts of the body, their disease is much more aggressive. For these patients, there is a need for additional treatment options,” Dr. Pierre Karakiewicz, medical oncologist at the Centre hospitalier de l’Université de Montréal (CHUM). “Health Canada’s approval of pembrolizumab in combination with axitinib represents an important advancement in the treatment of kidney cancer that helps extend survival outcomes for patients living with advanced renal cell carcinoma.”

In the Phase 3 KEYNOTE-426 trial, KEYTRUDA® in combination with axitinib demonstrated a statistically significant reduced risk of death by 47% compared to sunitinib (HR=0.53 [95% CI, 0.38-0.74]; p=0.00005). For progression-free survival (PFS), the KEYTRUDA®-axitinib combination showed a reduction in the risk of progression of disease or death of 31% compared to sunitinib (HR=0.69 [95% CI, 0.57-0.84]; p=0.00012). The objective response rate (ORR), an additional efficacy outcome measure, was 59% for patients who received the KEYTRUDA®-axitinib combination (95% CI, 54-64) and 36% for those who received sunitinib (95% CI, 31-40) (p<0.0001). The observed safety profiles of pembrolizumab plus axitinib were as expected on the basis of the known profiles of these drugs, although the incidence of grade 3 or 4 elevations in liver enzyme levels in the pembrolizumab-axitinib group was higher than previously observed when each agent was used as monotherapy.[5]

This is the first indication for KEYTRUDA® in advanced RCC, and the first anti-PD-1 therapy as part of a combination regimen that significantly improved OS, PFS and ORR versus sunitinib in patients with advanced RCC.

“We welcome Health Canada’s decision to offer a new evidence-based treatment option to patients living with advanced renal cell carcinoma,” said Stephen Andrew, Executive Director of Kidney Cancer Canada. “This immuno-oncology combination represents an important milestone in our community and offers new hope to patients and their caregivers.”

About Kidney Cancer

In most cases, kidney cancer starts in the cells that line the tubules, which are tiny tubes that collect the waste materials and chemicals from the blood moving through the kidneys.[6] This type of cancer is known as renal cell carcinoma (RCC), accounting for 80 per cent of all cases.[7] RCC is considered advanced when the cancer has metastasized, or spread, beyond the primary cancer site.[8] The five-year relative survival rate for patients suffering from advanced, metastatic (Stage 4) kidney cancer is estimated to be 8 per cent.[9]

In 2019, an estimated 7,200 Canadians were diagnosed with kidney cancer and 1,900 Canadians died from kidney cancer.[10] Known risk factors for kidney cancer include smoking, hypertension, obesity, and occupational exposure to some chemicals.[11]

About KEYTRUDA®

KEYTRUDA® is an anti-PD-1 therapy that works by increasing 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 14 indications in several disease areas, including advanced renal cell carcinoma (RCC), bladder cancer, non-small cell lung carcinoma (NSCLC), classical Hodgkin lymphoma and melanoma.

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 breakthrough 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 Canada

For over a century, Merck, a leading global biopharmaceutical company 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. Through our prescription medicines, vaccines, biologic therapies and animal health products, we work with customers and operate in more than 140

countries to deliver innovative health solutions. We also demonstrate our commitment to increasing access to health care through far-reaching policies, programs and partnerships.

Today, Merck continues to be at the forefront of research to advance the prevention and treatment of diseases that threaten people and communities around the world – including cancer, cardio-metabolic diseases, emerging animal diseases, Alzheimer's disease and infectious diseases including HIV and Ebola. 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. 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 2017 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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Rini KN-426, NEJM 2019;380:1116-27.

Please see the product monograph for KEYTRUDA® (pembrolizumab) at:

https://www.merck.ca/static/pdf/KEYTRUDA-PM_E.pdf

References

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