

6,550 Canadians will develop HNSCC in 2020 and 1,900 will die from it.⁹

“As a survivor of head and neck cancer, I welcome new treatment options like KEYTRUDA,” said John-Peter Bradford, HSNCC survivor and CEO of Life-Saving Therapies Network. “It’s significant for patients to have a treatment option to battle with this disease.”

About KEYNOTE-048 Trial

Health Canada’s approval for HNSCC is based on findings from the phase 3 study KEYNOTE-048, a randomized, multicenter, open-label, active-controlled trial conducted in 882 patients with metastatic or recurrent HNSCC who had not previously received systemic therapy for recurrent or metastatic disease and who were considered incurable by local therapies.¹⁰ Randomization was stratified by tumor PD-L1 expression (TPS \geq 50% or <50%), HPV status (positive or negative), and ECOG PS (0 vs. 1).¹¹

The results of KEYNOTE-048 showed treatment with KEYTRUDA[®] in combination with chemotherapy resulted in a median overall survival of 13.0 months compared to 10.7 months with standard treatment (cetuximab in combination with chemotherapy) (HR=0.72 [95% CI, 0.60-0.87]; p=0.00025).¹² In the monotherapy study arm, the median overall survival was 12.3 months with KEYTRUDA[®] compared to 10.3 months with standard treatment in the PD-L1 CPS \geq 1 population (HR=0.74 [95% CI, 0.61-0.90]; p=0.00133).¹³

“The approval of KEYTRUDA[®] for the first-line treatment of recurrent and metastatic HNSCC further reinforces Merck’s continued commitment to pursue research and development in immuno-oncology with the ultimate goal of improving patient lives,” says AnnA Van Acker, President, Merck Canada. “HNSCC can have a significant negative impact on patients, affecting a person’s appearance or their ability to eat or speak. We are proud that our work can help these patients and provide new treatment options for the first-line management of their disease”

About Head and Neck Cancer

Head and neck cancers can occur in the mouth (oral cavity), the middle part of the throat near the mouth (oropharynx), the space inside and around the nose (nasal cavity and paranasal sinuses), the upper part of the throat near the nasal cavity (nasopharynx), the voice box (larynx), the lower part of the throat near the larynx (hypopharynx), or the salivary glands.¹⁴ Depending on the location, HNSCC can cause abnormal patches or open sores (ulcers) in the mouth and throat, unusual bleeding or pain in the mouth, sinus congestion, sore throat, earache, pain when swallowing or difficulty swallowing, a

hoarse voice, difficulty breathing, or enlarged lymph nodes.¹⁵ The primary risk factors associated with head and neck cancer are tobacco use and alcohol consumption. Other risk factors include human papillomavirus (HPV) infection (for oropharyngeal cancer), and Epstein-Barr virus (EBV) infection (for nasopharyngeal cancer).¹⁶

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.¹⁷ 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.¹⁸

KEYTRUDA® was first approved in Canada in 2015 and currently has 16 indications in several disease areas, including advanced renal cell carcinoma (RCC), bladder cancer, non-small cell lung carcinoma (NSCLC), classical Hodgkin lymphoma and melanoma.¹⁹

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

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

References

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