News Release

Health Canada Approves KEYTRUDA® for the treatment of adult patients with unresectable locally advanced or metastatic urothelial cancer (mUC) with no prior systemic therapy for mUC, in combination with enfortumab vedotin

Approval is based on the Phase 3 KEYNOTE-A39 Trial

KIRKLAND, QC, August 22, 2024 - Merck (NYSE: MRK), known as MSD outside the United States and Canada, announced that Health Canada has granted approval of KEYTRUDA® (pembrolizumab), Merck's anti-PD-1 therapy, in combination with enfortumab vedotin, an antibody-drug conjugate, for the treatment of adult patients with unresectable locally advanced or metastatic urothelial cancer (mUC) with no prior systemic therapy for mUC. This approval is based on the results from the Phase 3 KEYNOTE-A39 trial (also known as EV-302), which demonstrated statistically significant improvements in overall survival (OS) and progression-free survival (PFS) versus platinum-based chemotherapy.

"Bladder cancer is an important cause of cancer-related death. The approval of this new combination of an immunotherapy and an antibody drug conjugate represents a significant step forward for patients with advanced bladder cancer," says Dr. Srikala Sridhar, Professor in the Department of Medicine at the University of Toronto and a Genitourinary Medical Oncologist at the Princess Margaret Cancer Centre. "The availability of this new treatment means more options to help patients affected by this disease."

"This combination therapy offers patients a new alternative which is important for individuals living with advanced bladder cancer," commented André Galarneau, PhD, Executive Director & Vice President, Oncology Business Unit at Merck Canada. "This approval further underscores our dedication to helping advance cancer care in Canada, diversifying the available treatment options for patients."

"Bladder cancer affects over 12 thousand Canadians each year," stated Michelle Colero, Executive Director, Bladder Cancer Canada."This approval helps expand the range of therapeutic options, which can lead to a greater ability to customize treatment plans for individual patients with advanced bladder cancer."

About KEYNOTE-A39

KEYNOTE-A39 (also known as EV-302), which was conducted in a research collaboration with Pfizer (previously Seagen and Astellas), was an open-label, multicentre, randomized, active-controlled Phase 3 trial (ClinicalTrials.gov NCT04223856), evaluating pembrolizumab in combination with enfortumab vedotin (P+EV) compared to gemcitabine and platinum-based chemotherapy for the treatment of unresectable locally advanced or metastatic urothelial cancer in adult patients who received no prior systemic therapy for unresectable locally advanced or metastatic disease. The primary efficacy outcome measures were overall survival (OS) and progression-free survival (PFS), with an additional outcome measure being objective response rate (ORR), as assessed by BICR according to RECIST v1.1.

The trial demonstrated a 53% reduction in the risk of death with P+EV (HR=0.47 [95% CI, 0.38-0.58]; p<0.0001) versus platinum-based chemotherapy; the median OS was 31.5 months (95% CI, 25.4, NR) for the P+EV combination versus 16.1 months (95% CI, 13.9, 18.3) for platinum-based chemotherapy. There was also a statistically significant improvement in PFS and ORR in patients randomized to pembrolizumab in combination with enfortumab vedotin compared to the control arm.

The most common adverse events (reported in at least 10% of patients) were fatigue, pruritus, rash, decreased appetite and hypothyroidism.

For complete information, refer to the KEYTRUDA® product monograph.

About Bladder and Urothelial Cancer

Urothelial cancer, making up 90% of all bladder cancers, begins in the urothelial cells, which line the inside of the bladder. Urothelial carcinoma can be found in more than one place in the urinary tract such as the renal pelvis, ureters and urethra. In Canada, it is estimated that approximately 12,300 individuals are diagnosed with bladder cancer each year, representing the fifth most common cancer type in the country and the ninth leading cause of cancer-related deaths. The risk of developing bladder cancer increases with age. It usually occurs in people older than 65 years of age. Bladder cancer is most common in Caucasians, and men develop this disease more often than women.

About the Pfizer, Astellas and Merck Collaboration

Seagen, aquired by Pfizer in December of 2023, and Astellas entered a clinical collaboration agreement with Merck to evaluate the combination of Seagen's and Astellas' PADCEV® (enfortumab vedotin) and Merck's KEYTRUDA® (pembrolizumab) in patients with previously untreated metastatic urothelial cancer.

About KEYTRUDA®

KEYTRUDA® is an anti-programmed death receptor-1 (PD-1) therapy that works by helping increase 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 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, cervical cancer, esophageal cancer, triple-negative breast cancer, melanoma, and head and neck squamous cell carcinoma.

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 LinkedIn and X @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 candidates that the candidates 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 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 Annual Report on Form 10-K for the year ended December 31, 2023 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 **Merck.ca.**
