News Release

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KEYTRUDA® (pembrolizumab) Plus LENVIMA® (lenvatinib) Receive Public Listing for Patients with Advanced Endometrial Carcinoma (EC) that is not MSI-H or dMMR

KIRKLAND, QC, and MISSISSAUGA, ON, December 21, 2023 – Merck (NYSE: MRK), known as MSD outside the United States and Canada, and Eisai announce that KEYTRUDA®, Merck's anti-PD-1 therapy, plus LENVIMA®, an orally available multiple receptor tyrosine kinase inhibitor discovered by Eisai, is now reimbursed with clinical criteria and conditions under the British Columbia, Alberta, Saskatchewan, Ontario, Quebec, Nova Scotia, New Brunswick, and Newfoundland drug plans, for adult patients with advanced endometrial carcinoma (EC) that is not microsatellite instability high (MSI-H) or mismatch repair deficient (dMMR), who have disease progression following prior platinum-based systemic therapy, and are not candidates for curative surgery or radiation.

This announcement follows the notice of compliance issuance from Health Canada in July 2023 based on the results from the Phase 3 Study 309/KEYNOTE-775 trial, which evaluated KEYTRUDA® plus LENVIMA® versus chemotherapy (treatment of physician's choice of doxorubicin or paclitaxel) in patients with advanced endometrial carcinoma who had been previously treated with at least one prior platinum-based chemotherapy regimen in any setting. KEYTRUDA® plus LENVIMA® demonstrated statistically significant improvements in the dual primary endpoints of overall survival (OS) and progression-free-survival (PFS) compared to chemotherapy.

"Each patient's journey is unique, and this particular indication addresses an important care gap as it targets individuals that are diagnosed in a late stage setting with limited treatment options," says Dr. Amit Oza, Head of the Division of Medical Oncology & Hematology, Professor of Medicine, University of Toronto, and Medical Director of the Cancer Clinical Research Unit at Princess Margaret Cancer Centre. "By having an additional therapeutic option in our toolbox, we are better able to tailor treatment plans according to individual needs, which can help improve health outcomes."

These most recent developments are a result of the strategic collaboration between Merck and Eisai, whose collective mission is to help bring greater access to innovative medicines for patients in need.

"Endometrial cancer is a serious and potentially life-threatening condition affecting many Canadians," says Patrick Forsythe, Country Manager, Eisai Canada. "We commend Health Canada and the health technology assessment organizations for supporting the approval and availability of KEYTRUDA® plus LENVIMA® to provide an additional treatment option in an area of oncology where cases are rising in this country."

"This achievement is a result of the relentless work of our researchers and physicians, as well as the commitment of the patients who enroll in these clinical trials," says André Galarneau, Executive Director

& Vice President, Oncology Business Unit at Merck Canada. “It is thanks to them that we can provide more treatment options to Canadians impacted by this disease.”

About STUDY 309/KEYNOTE-775

Study 309/KEYNOTE-775 is a Phase 3 multicenter, open-label, randomized, active-controlled trial that enrolled 827 patients with advanced EC previously treated with at least one prior platinum-based chemotherapy regimen in any setting, including in the neoadjuvant and adjuvant settings. The study excluded certain patients such as those with endometrial sarcoma, including carcinosarcoma, or patients who had active autoimmune disease or a medical condition that required immunosuppression. The primary efficacy outcome measures were OS and PFS as assessed by blinded independent central review (BICR) according to Response Evaluation Criteria in Solid Tumors Version (RECIST) v1.1. Secondary efficacy outcome measures included ORR as assessed by BICR.

There were 697 patients with advanced EC that was not MSI-H or dMMR that were randomized 1:1 to receive pembrolizumab (200 mg intravenously every three weeks) plus lenvatinib (20 mg orally once daily or n=346) or investigator’s choice, consisting of either doxorubicin (60 mg/m^2 every three weeks; n=254) or paclitaxel (80 mg/m^2 given weekly, three weeks on/one week off; n=97). Treatment with pembrolizumab plus lenvatinib continued until RECIST v1.1-defined progression of disease as verified by BICR, unacceptable toxicity, or for pembrolizumab, a maximum of 24 months or up to 35 administrations - whichever was longer. Administration of pembrolizumab plus lenvatinib was permitted beyond RECIST-defined disease progression if the treating investigator considered the patient to be deriving clinical benefit and the treatment was.

The most common adverse events (reported in at least 30% of patients) among these patients receiving pembrolizumab and lenvatinib were hypothyroidism, hypertension, fatigue, diarrhea, musculoskeletal disorders, nausea, decreased appetite, vomiting, stomatitis, abdominal pain, weight loss, and urinary tract infection.

About Endometrial Carcinoma

Endometrial carcinoma (endometrial cancer) begins in the inner lining of the uterus, and makes up more than 95% of all uterine cancer cases. In 2023, an estimated 8,500 Canadian women will be diagnosed with uterine cancer, with a greater tendency to develop in women over the age of 50. Symptoms of endometrial cancer can include abnormal vaginal bleeding, pain during intercourse, difficult or painful urination and pain in the pelvic area.

About KEYTRUDA® (pembrolizumab)

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. 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, esophageal cancer, triple-negative breast cancer, melanoma, and head and neck squamous cell

carcinoma.

About LENVIMA® (lenvatinib)
LENVIMA®, discovered and developed by Eisai, is an orally available multiple receptor tyrosine kinase inhibitor that selectively inhibits the kinase activities of vascular endothelial growth factor (VEGF) receptors VEGFR1 (FLT1), VEGFR2 (KDR), and VEGFR3 (FLT4). LENVIMA® inhibits other kinases that have been implicated in pathogenic angiogenesis, tumor growth, and cancer progression in addition to their normal cellular functions, including fibroblast growth factor (FGF) receptors FGFR1-4, the platelet derived growth factor receptor alpha (PDGFRα), KIT, and RET. In syngeneic mouse tumor models, LENVIMA® decreased tumor-associated macrophages, increased activated cytotoxic T cells, and demonstrated greater antitumor activity in combination with an anti-PD-1 monoclonal antibody compared to either treatment alone.

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.

About Eisai
Eisai's Corporate Concept is "to give first thought to patients and the people in the daily living domain, and to increase the benefits that healthcare provides." Under this Concept [also known as our *human health care* (*hhc*) Concept], we aim to effectively achieve social good in the form of relieving anxiety over health and reducing health disparities. With a global network of R&D facilities, manufacturing sites and marketing subsidiaries, we strive to create and deliver innovative products to target diseases with high unmet medical needs, with a particular focus in our strategic areas of Neurology and Oncology.

In addition, our continued commitment to the elimination of neglected tropical diseases (NTDs), which is a target (3.3) of the United Nations Sustainable Development Goals (SDGs), is demonstrated by our work on various activities together with global partners.

For more information about Eisai, please visit www.eisai.com (for global headquarters: Eisai Co., Ltd.), us.eisai.com (for U.S. headquarters: Eisai Inc.) or www.eisai.eu (for Europe, Middle East, Africa, Russia, Australia, and New Zealand headquarters: Eisai Europe Ltd.), and connect with us on X, formerly known as Twitter (for U.S. and global), and LinkedIn (for U.S. and EMEA).

Forward-Looking Statement of Merck & Co., Inc., Rahway, N.J., 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 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 Annual Report on Form 10-K for the year ended December 31, 2022 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

Please see the product monograph for LENVIMA® (lenvatinib) at: https://ca.eisai.com/-/media/Files/CanadaEisai/LENVIMA-Product-Monograph-EN.pdf?hash=f43eb602-ffb4-469b-910b-6253e91084bc

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